GAPMS Decision Tree Checklist

If any item on the list is "yes" discuss with your manager for the potential to move towards a coverage determination (decision point) instead of a GAPMS report.

This checklist should be used for each GAPMS request received through the HealthServiceResearch@ahca.myflorida.com inbox.

GAPMS Topic:
Requestor Name:
Requestor Email Address:
Date of Initial Request:

Item	Yes/No	Additional Information
1. Does the item have FDA approval?		*If yes, provide a link to FDA's website for the approval.*
2. Does the device/service have a unique procedure code?		*If yes, list the code.* *If not, list the unlisted code.*
3. Is there a National Coverage Determination (NCD) from Medicare?		*If yes, provide a link to CMS's website for the NCD.*
4. Is there a Local Coverage Determination (LCD) from Medicare?		*If yes, provide a link to CMS's website for the LCD.*
5. Does any Medicaid state cover the service?		*If yes, provide the state programs and reimbursement rates. This includes the use of policy reporter, a google search, and perhaps an individual review of each state's service-specific coverage policy.*
6. Does any private insurance cover the service?		*If yes, provide the private insurance companies that cover the service and their reimbursement rates. This includes the use of policy reporter, a google search, and perhaps an individual review of each insurer's service-specific coverage policy.*
7. Does the Agency cover a similar device, service, or product?		*If yes, how does it relate to the ask?*
8. Are there NICE guidelines (or similar research determinations) made regarding the device as not experimental/investigational?		*If yes, which and what did they determine? Include links.*

Pl. Trial Ex. 238

RICK SCOTT
GOVERNOR

ELIZABETH DUDEK
SECRETARY

HORMONE SUPPRESSION THERAPY IN CHILDREN
GAPMS DETERMINATION REPORT WITH RECOMMENDATION

Date: {DATE}

To: Justin Senior, Deputy Secretary for Medicaid

From: Bureau of Medicaid Policy

Subject: **Reproductive Hormone Suppression Therapy in Children**

PURPOSE

In order for the use of Hormone suppression therapy in children to be covered under the Florida Medicaid program, must meet medical necessity criteria as defined in 59G-1.010, Florida Administrative Code. (F.A.C.), and be funded through the General Appropriations Act of Chapter 216, Florida Statutes (F.S.).

Pursuant to the criteria set forth in 59G-1.010, F.A.C., the use of hormone suppression therapy in children must be consistent with generally accepted professional medical standards (GAPMS) as determined by the Medicaid program, and not experimental or investigational.

In accordance with the determination process established in rule 59G-1.035, F.A.C., the Deputy Secretary for Medicaid will make the final determination as to whether the use of hormone suppression therapy in children is consistent with generally accepted professional medical standards and not experimental or investigational.

REPORT WITH RECOMMENDATION

This report with recommendation is presented as the summary assessment considering the factors identified in 59G-1.035 F.A.C. based on the collection of information from credible sources of reliable evidence-based information. The intent is to provide a brief analysis with justification in support of the final recommendation.

The analysis described in this report includes:

- A high level review of relevant disease processes
- An overview of the health service information
- Confirmation of clearance from the government regulatory body
- Evidence based clinical practice guidelines
- A review of the literature considered by the relevant medical community or practitioner specialty associations from credible scientific evidence-based literature published in peer reviewed journals, and consensus of coverage policy from commercial and other state Medicaid insurers.

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HEALTH SERVICE SUMMARY

Hormones

Hormones are important chemical messengers in the body that effectively transfer signals and instructions from one set of cells to another. Hormones are secreted into the bloodstream by a collection of glands inside the body referred to as the endocrine system. A gland is a group of cells that produces and secretes chemicals into the body. The major glands that make up the endocrine system include the hypothalamus, pituitary gland, thyroid and parathyroid, adrenals, pineal body, and the ovaries and testes.

In a laboratory setting hormones are produced synthetically and are prescribed by physicians to treat disease or hormone deficiencies. An instance where synthetic hormones may be needed is when an individual has their thyroid gland surgical removed, a practitioner may prescribe synthetic thyroid hormones to replace those that their body can no longer produce.

Over fifty different hormones have been identified in the human body, and more are still being discovered. Hormones influence and regulate practically every cell, tissue, organ, and function of the body, including growth, development, metabolism, homeostasis, and sexual and reproductive function.[16]

Reproductive Hormones

The hormones commonly considered as reproductive hormones in the body are testosterone, estrogen, and progesterone. Testosterone is often referred to as a male hormone, and estrogen and progesterone are often referred to as female hormones. However, there are no exclusively male or female hormones that have been identified. All hormones characterized to date are present in all people regardless of sex, as are the receptor mechanisms that respond to those hormones. The physical manifestations of gender result from differences in the amounts of individual hormones in the body and differences in their patterns of secretion, first in utero and then again during puberty. In other words, testosterone, estrogen, and progesterone are produced by men and women, but in differing amounts and in different patterns[16]

Reproductive Hormone Suppression Therapy

There are many disease processes in which increased levels of reproductive hormones are released. They include, but are not limited to, prostate cancer, breast cancer, severe endometriosis, and central precocious puberty. To address this over secretion of reproductive hormones several medications have been design to aide in limiting hormone levels. There are a number of medications used to suppress puberty, which all use the same mechanism of action, gonadotropin-releasing hormone (GnRH) agonists. Agonists by definition function to stop receptors from meeting up with the appropriate transmitter. For a hormone to perform it's primary function in the brain and body, it must find the correct receptor to transmit its response; the GnRH agonists prevent this natural cycle.[16]

Government Regulatory Body Approval

The Food and Drug Administration (FDA) has approved seven drugs for the purpose of hormone suppression, three (indicated by an "*") of which are approved for use under 18 years of age. They are Lupron, Zoladex, Trelstar, Vantas, Eligard, Synarel, and Supprelin. Each of these drugs has specific indications for use and dosing information. They are as follows:

- Lupron*:
  - Indications for use- palliative treatment of advanced prostatic cancer and central precocious puberty.
  - Pediatric use: LUPRON DEPOT formulations are not indicated for use in children. LUPRON DEPOT PED® is indicated for use in children with central precocious puberty.
  - Dosage: 7.5mg, 11.25mg or 15mg intramuscular once a month. 11.25mg or 30mg intramuscular every 3 months [38]
- Zoladex:
  - Indications for use-Prostate cancer, endometriosis, endometrial-thinning prior to endometrial ablation for dysfunctional uterine bleeding, palliative treatment for advanced breast cancer in pre and peri-menopausal women.
  - Pediatric use: No information available for use in Pediatric Patients.[43]
- Trelstar:
  - Indications for use- palliative treatment of advanced prostate cancer.
  - Pediatric use: Safety and effectiveness in pediatric patients have not been established.[39]
- Vantas:
  - Indications for use- palliative treatment of advanced prostate cancer.
  - Pediatric use: Vantas is not indicated for use in pediatric patients.[42]
- Eligard:
  - Indications for use- palliative treatment of advanced prostate cancer.
  - Pediatric use: Safety and effectiveness in pediatric patients have not been established.[37]
- Synarel*:
  - Indications for use- central precocious puberty (CPP) (gonadotropin-dependent precocious puberty) in children of both sexes and endometriosis.
  - Pediatric use: Safety and effectiveness of SYNAREL for endometriosis in patients younger than 18 years have not been established.[41]
- Supprelin*:
  - Indications for use- central precocious puberty in males and females
  - Dosage and administration- 50mg subcutaneous implant every 12 months. Discontinuation of Supprelin should be considered at the appropriate time point for the onset of puberty (approximately 11 years for females and 12 years for males).
  - Pediatric use: Safety and effectiveness in pediatric patients below the age of 2 years have not been established. The use of Supprelin in children under 2 years is not recommended.[40]

Additionally, these medications have approved off label uses. This permits usage in other than the approved FDA indications. These approved off label uses are compiled in three compendia: American Hospital Formulary Service Drug Information (AHFS), United States Pharmacopeia-Drug Information (or its successor publications), and DRUGDEX Information System.[6] The

three drugs that are approved for use under the age of 18 have the following compendia authorizations:

- Lupron:
  - Breast Cancer
  - In vitro fertilization
  - Ovarian Cancer
  - Premenstrual syndrome
  - Prostate cancer
  - Prostate cancer, Neoadjuvant treatment
  - Uterine leiomyoma
- Synarel:
  - Benign prostatic hyperplasia
  - Contraception, Female; prophylaxis
  - Contraception, Male; prophylaxis
  - Crohn's disease
  - Hirsutism
  - In vitro fertilization
  - Uterine leiomyoma
- Supprelin:
  - Acute intermittent porphyria
  - Endometriosis
  - Female infertility; Adjunct
  - Polycystic ovary syndrome
  - Uterine leiomyoma

LITERATURE REVIEW

This analysis summarizes information obtained from scientific literature published in credible peer-reviewed journals related to the use of reproductive hormone suppression therapy in children. This section also briefly cites the positions from the relevant medical societies, and summarizes the key articles referenced in support of their positions.

Reproductive Cancer

Research shows that suppression of reproductive hormones in treatment of cancers such as prostate, breast, and ovarian can decrease the recurrence rate or tumor size. The use of reproductive hormone suppression therapy has been the standard of care in the treatment of these cancers for 15-20 years. While there are significant health risks such as sterilization, it has long been established that the benefits outweigh the risks.

Jain, S., et al (July 2015) published a literature review on the role of ovarian suppression in premenopausal women that concluded that numerous prior studies have convincingly shown a clear benefit from adjuvant endocrine therapy; however, the additional toxicities of ovarian suppression should be considered.[19, 9, 49]

Liu, J., et al (March 2015) conducted a population-based study evaluating whether breast cancer patients with an estrogen receptor (ER) or progesterone receptor (PR) status had an increased risk of developing endometrial cancer secondary to the use of hormone suppression therapy. The study concluded that regardless of type, patients with previous history of invasive breast cancer have higher risk of developing a subsequent endometrial cancer, indicating the risk was not increased due to hormone suppression therapy.[22]

Central Precocious Puberty

Central precocious puberty (CPP) develops due to premature pubertal changes and rapid bone development. CPP is associated with lower adult height and increased risk for development of psychological problems.

Fuqua, J.S. (March 2013) stated that the standard treatment for CPP is GnRH analogs. Although there are many different analogs with different routes of administration, the primary agent in the United States for many years was depot intramuscular injections administered every four weeks, but in the last ten years, a subdermal or under the skin implant has been developed, which has been shown to be effective for up to two years.[13, 33, 35]

Wojniusz, S., et al (July 2016) researchers explored the difference in cognitive function, behavior, emotional reactivity, and psychosocial problems between young females treated with GnRH and age-matched controls. They concluded that young females treated with GnRH do not differ in their cognitive functioning, behavioral, and social problems from their same age peers in settings that do not involve emotional processing. However, they did find a significant difference in heart rate that increased with treatment duration and suggested a follow-up study with an emphasis on cardiac health.[48]

Reproductive hormone suppression therapy has been the standard of care for CPP for 15-20 years; as such most research is not current.

Gender Dysphoria

The Diagnostic and Statistical Manual of Mental Disorders (2013) describes gender dysphoria (GD) as an individual's affective or cognitive discontent with their assigned gender (gender at birth). GD refers to the distress that may accompany the incongruence between the individual's experienced or expressed gender and their assigned gender. Evidence of this distress is the hallmark of the disorder. The diagnostic criteria are divided into a category for children and a category for adolescents and adults. The disorder is manifested differently as an individual ages' or enters different developmental stages. Both categories require marked incongruence between the individual's experienced or expressed gender and their assigned gender of a least a six months' duration and clinically significant distress or impairment in social, school (occupation for adults), or other important areas of functioning.

Diagnostic criteria in children include: a strong desire to be the other gender or an insistence that they are the other gender; a preference for wearing clothing associated with the other gender; preference for cross gender roles in simulated play; preference for toys games, or activities usually associated with the other gender; preference for playmates of the other gender; and the dislike of their sexual anatomy.

In adults and adolescents, diagnostic criteria include: a strong desire to be and to be treated as the other gender; a strong desire to have the sex characteristics of the other gender (or for

adolescents the wish to prevent the development of them); and a conviction that they have the typical feelings and reactions of the other gender.[11]

Vrouenrarts, L.J., et al (April 2015) conducted a qualitative study to identify considerations from proponents and opponents of early treatment of children and adolescents with gender dysphoria (GD). The article states that although the Endocrine Society and the World Professional Association for Transgender Health published guidelines for the treatment of adolescents diagnosed with GD in actual practice there is no consensus on whether to use these early medical interventions. The article concluded that more systematic interdisciplinary and (worldwide) multicenter research is required.[45, 17, 20, 21, 24, 44]

Kreukels, B.P. and Cohen-Kettenis, P.T. (August 2011) conducted research on puberty suppression in gender identity disorder (currently known as GD) and compared the views of the proponents of early treatment verse the concerns expressed by physicians. The concerns of physicians include risk of misdiagnosis, long-term physical consequences such as sterilization, effects on bone-mass development, height, body segment disproportion, metabolism, and brain development. Proponents argued misdiagnosis risk reduces if treatment is delayed until reaching the initiation of puberty, the risk of poor decision making in adolescence is worse when they act out in despair, the effects on bone development are neutralized when cross-sex hormones are initiated, there is no proof of negative effects on brain development, and the overwhelming opinion that early intervention is viewed as harm reduction secondary to prevention of an appearance that could provoke abuse and stigmatization. The review concluded that more systematic research in this area is needed to determine the safety of the approach.[18, 14, 17, 20, 21, 24, 27, 44]

Evidence-Based Clinical Practice Guidelines

The American Academy of Pediatrics put out a consensus statement on the use of GnRH analogs in children (March 2009). They concluded that GnRH use was undisputed in the treatment of CPP early-onset (<6 years old). However, the use of GnRH for conditions other than CPP requires additional investigation and cannot be suggested routinely.[3]

The Endocrine Society published guidelines for the endocrine treatment of transsexual persons (September 2009). The society concluded that transsexual persons seeking to develop the physical characteristics of the desired gender require safe, effective hormone regimen that will 1) suppress endogenous hormone secretion determined by the person's genetic/biological sex and 2) maintain sex hormone levels within the normal range for the person's desired gender. They recommend that a mental health professional make the referral and participate in ongoing care and an endocrinologist must confirm the diagnostic criteria. They do not recommend endocrine treatment of prepubertal children. The recommendations are as follows:

- Treatment of transsexual adolescents (Tanner stage 2, generally achieved around 12 years) by suppressing puberty with GnRH analogues until age 16 years.
- Initiation of cross-sex hormones at age 16 years with continued suppression of biological sex hormones.
- Maintaining physiologic levels of gender-appropriate sex hormones and monitoring for known risks throughout adulthood.[15, 14, 27]

COVERAGE POLICY

Florida Medicaid Program

Florida Medicaid covers hormone suppression for all FDA approved use. Florida Medicaid has an off label use criteria for the authorization of drugs. The policy has three criteria that must all be met for authorization.

1. Documentation submitted with trial and failure or intolerance to all FDA- approved medications for the indication **AND**
2. Phase III clinical studies published in peer review journals to support the non-FDA approved use **AND**
3. Usage supported by publications in peer reviewed medical literature **and** one or more citations in at least one of the following compendia:
    a. American Hospital Formulary Service Drug Information (AHFS)
    b. United States Pharmacopeia-Drug Information (or its successor publications)
    c. DRUGDEX Information System[1]

Medicare

Medicare covers hormone suppression for all FDA approved use. *The Medicare Benefit Policy Manual*, chapter 15, page 15, subsection 50.4.2, discusses the unlabeled use of a drug. The policy states that "FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice."[5]

State Medicaid Programs

All state Medicaid programs cover hormone suppression therapy for the approved FDA indications and when the criteria for off label use is met. However, only four states have expressly stated they cover hormone suppression for use in the treatment of gender dysphoria. These states are Colorado, Maryland, Rhode Island and Washington.

In Colorado, services for Medicaid recipients who have a diagnosis of gender dysphoria (GD) or a history of a diagnosis of GD include: behavioral health care, gonadotropin-releasing hormone (GnRH) analogs/agonists, cross-sex hormone therapy, gender confirmation surgery, and pre- and post-operative care.

In Maryland, GnRH treatment is approved at the pharmacy point of sale if the recipient has GD diagnosis.

In, Rhode Island covered services for recipients less than 18 years of age include: behavioral and medical heath, pharmacological and hormonal therapy to delay physical changes of puberty (requires prior authorization), and pharmacological and hormonal therapy that is non-reversible and produces masculinization or feminization (requires prior authorization).

Washington State expanded services in June 2015 for its GD treatment to include: mental health services, puberty-blocking therapy for youths, hormonal therapy, and gender reassignment surgery.

GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS RECOMMENDATION

This report recommends the use of hormone suppression therapy in children as a health service that is consistent with generally accepted professional medical standards for the approved FDA indications, as well as the off label use when the criteria has been met. Hormone suppression therapy has been demonstrated to be an effective treatment option for central precocious puberty and reproductive cancers.

____Concur **____Do not Concur**

Comments:

_____

_____

_____

_____ _____

Deputy Secretary for Medicaid (or designee) *date*

RICK SCOTT
GOVERNOR

ELIZABETH DUDEK
SECRETARY

PUBERTY SUPPRESSION THERAPY
GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS (GAPMS)
DETERMINATION REPORT WITH RECOMMENDATION

Date: September 14, 2016

To: Justin Senior, Deputy Secretary for Medicaid

From: Bureau of Medicaid Policy

Subject: **Puberty Suppression Therapy**

PURPOSE

In order for the use of puberty suppression therapy to be covered under the Florida Medicaid program, it must meet medical necessity criteria as defined in Rule 59G-1.010, Florida Administrative Code (F.A.C.), and be funded through the General Appropriations Act of Chapter 216, Florida Statutes (F.S.).

Pursuant to the criteria set forth in Rule 59G-1.010, F.A.C., the use of puberty suppression therapy must be consistent with generally accepted professional medical standards (GAPMS) as determined by the Medicaid program, and not experimental or investigational.

In accordance with the determination process established in Rule 59G-1.035, F.A.C., the Deputy Secretary for Medicaid will make the final determination as to whether the use of puberty suppression therapy is consistent with generally accepted professional medical standards and not experimental or investigational.

If it is determined that puberty suppression therapy is consistent with generally accepted professional medical standards, this report will be supplemented with an addendum which analyzes additional factors to determine whether this health service should be covered under the Florida Medicaid program.

REPORT WITH RECOMMENDATION

This report with recommendation is presented as the summary assessment considering the factors identified in Rule 59G-1.035, F.A.C., based on the collection of information from credible sources of reliable evidence-based information. The intent is to provide a brief analysis with justification in support of the final recommendation.

The analysis described in this report includes:

- A high level review of relevant disease processes.
- An overview of the health service information.
- Clearance from the government regulatory body (e.g., Food and Drug Administration).

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- Evidence based clinical practice guidelines.
- A review of the literature considered by the relevant medical community or practitioner specialty associations from credible scientific evidence-based literature published in peer reviewed journals and consensus of coverage policy from commercial and other state Medicaid insurers.

HEALTH SERVICE SUMMARY

Hormones

Hormones are important chemical messengers in the body that effectively transfer signals and instructions from one set of cells to another. Hormones are secreted into the bloodstream by a collection of glands inside the body referred to as the endocrine system. A gland is a group of cells that produces and secretes chemicals into the body. The major glands that make up the endocrine system include the hypothalamus, pituitary gland, thyroid and parathyroid, adrenals, pineal body, and the ovaries and testes.

In a laboratory setting, hormones are produced synthetically and are prescribed by physicians to treat disease or hormone deficiencies. An instance where synthetic hormones may be needed is when an individual has their thyroid gland surgically removed; a practitioner may prescribe synthetic thyroid hormones to replace those that their body can no longer produce.

Over 50 different hormones have been identified in the human body, and more are still being discovered. Hormones influence and regulate practically every cell, tissue, organ, and function of the body, including growth, development, metabolism, homeostasis, and sexual and reproductive function.[20]

Reproductive Hormones

The hormones commonly considered as reproductive hormones in the body are testosterone, estrogen, and progesterone. Testosterone is often referred to as a male hormone, and estrogen and progesterone are often referred to as female hormones. However, there are no exclusively male or female hormones that have been identified. The physical manifestations of gender result from differences in the amounts of individual hormones in the body and differences in their patterns of secretion, first in utero and then again during puberty. In other words, testosterone, estrogen, and progesterone are produced by men and women, but in differing amounts and in different patterns.[20]

Reproductive Hormone Suppression Therapy

There are many disease processes in which increased levels of reproductive hormones are released. They include, but are not limited to, prostate cancer, breast cancer, severe endometriosis, and central precocious puberty. To address the over-secretion of reproductive hormones, several drugs have been developed to aid in reducing hormone levels, including those hormones released during puberty.

For the purposes of this report, an analysis is being performed on the use of hormone treatment to suppress puberty. Currently, there are a number of drugs used to suppress puberty, which all use gonadotropin-releasing hormone (GnRH) agonists. Agonists function to stop receptors from connecting with the appropriate transmitter. For a hormone to perform its primary function in the

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brain and body it must find the correct receptor to transmit its response; the GnRH agonists prevent this natural cycle.[20]

Government Regulatory Body Approval

The Food and Drug Administration (FDA) has approved three drugs for the use in children for the purpose of puberty suppression therapy, as follows:

- Lupron[44]
  - Indications for use: Palliative treatment of advanced prostatic cancer and central precocious puberty in children of both sexes.
- Synarel[47]
  - Indications for use: Central precocious puberty (gonadotropin-dependent precocious puberty) in children of both sexes and endometriosis.
- Supprelin[46]
  - Indications for use: Central precocious puberty in both sexes.

Each of these drugs has specific indications for use and dosing information. Additionally, these medications have approved off-label uses. This permits usage in other than the approved FDA indications. These approved off-label uses are compiled in three compendia: American Hospital Formulary Service Drug Information (AHFS), United States Pharmacopeia-Drug Information (or its successor publications), and DRUGDEX Information System.[7] The drugs specified above are authorized in the respective compendia to treat the following conditions:

- Lupron:
  - Breast cancer
  - In vitro fertilization
  - Ovarian cancer
  - Premenstrual syndrome
  - Prostate cancer
  - Prostate cancer, Neoadjuvant treatment
  - Uterine leiomyoma
- Synarel:
  - Benign prostatic hyperplasia
  - Contraception, Female; prophylaxis
  - Contraception, Male; prophylaxis
  - Crohn's disease
  - Hirsutism
  - In vitro fertilization
  - Uterine leiomyoma
- Supprelin:
  - Acute intermittent porphyria
  - Endometriosis
  - Female infertility; Adjunct
  - Polycystic ovary syndrome
  - Uterine leiomyoma

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While all of these drugs may be utilized to treat other conditions, as indicated above and specified in the compendia, none of them are authorized or specified in the compendia for use in treating individuals diagnosed with gender dysphoria.[7]

LITERATURE REVIEW

This analysis summarizes information obtained from scientific literature published in credible peer-reviewed journals related to the use of puberty suppression therapy. This section also briefly cites the positions from the relevant medical societies, and summarizes the key articles referenced in support of their positions.

Central Precocious Puberty

Central precocious puberty (CPP) develops due to premature pubertal changes and rapid bone development. CPP is associated with lower adult height and increased risk for development of psychological problems.

Reproductive hormone suppression therapy (also referred to as puberty suppression therapy in this document) has been the standard of care for CPP for the last 15-20 years. The standard treatment for CPP is GnRH analogs. Although there are many different analogs with different routes of administration, the primary agent in the United States for many years was depot intramuscular injections administered every four weeks, but in the last ten years, a subdermal or under the skin implant has been developed, which has been shown to be effective for up to two years.[17, 39, 41]

In a recent study, researchers explored the difference in cognitive function, behavior, emotional reactivity, and psychosocial problems between young females treated with GnRH and age-matched controls. They concluded that young females treated with GnRH do not differ in their cognitive functioning, behavioral, and social problems from their same age peers. However, they did find a significant difference in heart rate that increased with treatment duration and suggested a follow-up study with an emphasis on cardiac health.[95]

Gender Dysphoria

Gender dysphoria is an individual's affective or cognitive discontent with their assigned gender (gender at birth).[14] Gender dysphoria refers to the distress that may accompany the incongruence between the individual's experienced or expressed gender and their assigned gender. Evidence of this distress is the hallmark of the disorder. The diagnostic criteria are divided into a category for children and a category for adolescents and adults. The disorder is manifested differently as an individual ages or enters different developmental stages. Both categories require marked incongruence between the individual's experienced or expressed gender and their assigned gender of at least a six months' duration and clinically significant distress or impairment in social, school (occupation for adults), or other important areas of functioning.[14]

Diagnostic criteria in children include: a strong desire to be the other gender or an insistence that they are the other gender; a preference for wearing clothing associated with the other gender; preference for cross gender roles in simulated play; preference for toys games, or activities usually associated with the other gender; preference for playmates of the other gender; and the dislike of their sexual anatomy. The prevalence of this diagnosis among the general population ranges from 0.005% to 0.014% in males and 0.002% to 0.003% in females.[14]

Studies have shown that the majority of children (80%) diagnosed with gender dysphoria will not continue to be gender dysphoric after puberty.[31]

In adolescents and adults, diagnostic criteria include: a strong desire to be and to be treated as the other gender and a strong desire to have the sex characteristics of the other gender (or in the case of adolescents, the wish to prevent the development of their assigned gender's characteristics).[14]

Gender dysphoria is associated with high levels of stigmatization, discrimination, and victimization, leading to negative self-concept, increased rates of mental disorder comorbidity, school dropout, and economic marginalization.[14] Adolescents that do not receive treatment during this already vulnerable period of development might engage in risky or self-harming behaviors , such as self-harm, self-mutilation, suicidal ideation, or suicide.[22]

For the 20% of children who persist in their feelings of gender dysphoria, clinicians may begin to explore alternative treatment approaches beyond psychotherapy after the onset of puberty, including medical interventions such as the use of GnRH analogs to suppress puberty.[38] The use of puberty suppression therapy is used as a diagnostic aid in adolescents contending with gender dysphoria.[6, 10, 11, 24, 31, 50] The use of GnRH analogs is generally prescribed in adolescents ages 12-16. In addition to puberty suppression therapy, a physician may also begin to prescribe cross-sex hormones, though the latter does not generally begin until the ages of 16-18.[10, 11]

The use of GnRH analogs will delay reproductive development in this population. However, there remains a great deal of concern and lack of consensus in the medical community of the potential risks, including: misdiagnosis, sterilization, adverse medical effect on the metabolic and endocrine system, impaired bone mass and brain development, etc.[51, 6] To date, there have been no randomized controlled clinical trials on the use of GnRH analogs in the treatment of gender dysphoria (on large cohorts) that have been shown to be efficacious with tolerable side effects. This is in large part due to the small number of patients diagnosed with gender dysphoria, which makes any statement on the general efficacy of a treatment approach challenging.[31] However, there have been case-studies (qualitative) that have been conducted that review the outcomes on small cohorts. These studies have concluded that there are limited negative side effects from the use of puberty suppression drugs in adolescents contending with gender dysphoria.[54, 55]

Clinicians who support the use of puberty suppression therapy in the treatment of gender dysphoria argue that the risks of misdiagnosis are significantly reduced if the treatment is delayed until the initiation of puberty. They also contend that this treatment may relieve emotional distress in the individual (including reducing suicidal ideation in severe cases) and may "buy time" for the child to explore their feelings of gender dysphoria without contending with physical changes that cannot be undone (e.g., breast development).[22] Most treatment protocols recommend extensive psychological evaluations/assessments and psychotherapy by mental health professionals prior to the initiation of medical interventions. This is especially important given the changing thoughts and feelings of prepubescent children versus adolescents with persistent gender dysphoria and in adolescents presenting with co-morbid conditions.

It is important to note that most of the literature reviewed in development of this analysis concluded that more systematic research is required to determine the long-term efficacy of medical treatment for adolescents with gender dysphoria.[21, 24, 25, 28, 50, 51]

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Evidence-Based Clinical Practice Guidelines

The American Academy of Pediatrics published a consensus statement on the use of GnRH analogs in children in March 2009. They concluded that GnRH use was undisputed in the treatment of CPP early-onset (less than six years old). However, the use of GnRH for conditions other than CPP requires additional investigation and cannot be suggested routinely.[3] The consensus statement does not specifically address the use of GnRH in the treatment of gender dysphoria.

The Endocrine Society published guidelines for the endocrine treatment of transsexual persons. The Society concluded that transsexual persons seeking to develop the physical characteristics of the desired gender require safe, effective hormone regimen that will 1) suppress endogenous hormone secretion determined by the person's genetic/biological sex and 2) maintain sex hormone levels within the normal range for the person's desired gender. They recommend that a mental health professional make the referral and participate in ongoing care and an endocrinologist must confirm the diagnostic criteria. They do not recommend endocrine treatment of prepubertal children. The recommendations are as follows:

- Treatment of transsexual adolescents (Tanner stage two, generally achieved around the age of 12 years) by suppressing puberty with GnRH analogues until the age of 16 years.
- Initiation of cross-sex hormones at the age of 16 years with continued suppression of biological sex hormones.
- Maintaining physiologic levels of gender-appropriate sex hormones and monitoring for known risks throughout adulthood.[19, 18, 32]

In making these recommendations, however, the Endocrine Society identified the strength of the evidence used to support its conclusions. For all of the recommendations listed above, the Society acknowledged the strength of the evidence as low or very low.

COVERAGE POLICY

Federal Regulations

Federal regulations for Medicaid specify that a state may limit coverage of a drug with respect to the treatment of a specific disease or condition for an identified population (if any) based on the drug's labeling, if it does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary. In addition, states may exclude a drug when the prescribed use of the drug is not for a medically accepted indication, either approved by the FDA or supported by information from the appropriate compendia. These guidelines apply to a state's administration of its Medicaid prescribed drug benefit in both managed care and non-managed care delivery systems.

States are also required to implement a drug use review program for covered outpatient drugs in order to assure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical results. The program is required to assess data on drug use against predetermined standards, consistent with the following:

1. Compendia, consisting of the following:
   a. American Hospital Formulary Service Drug Information;
   b. United States Pharmacopeia-Drug Information (or its successor publications); and
   c. the DRUGDEX Information System; and
2. The peer-reviewed medical literature.

CONFIDENTIAL

Federal law requires states to provide services to eligible recipients under the age of 21 years, if such services are medically necessary to correct or ameliorate a defect, a condition, or a physical or mental illness. This is known as the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit. Included are diagnostic services, treatment, equipment, supplies, and other measures described in section 1905(a) of the Social Security Act, codified in Title 42 of the United States Code 1396d (a). As such, services for recipients under the age of 21 years exceeding any coverage limitations specified within a state's policies maybe approved, if medically necessary.

Florida Medicaid

In order to be reimbursed by Florida Medicaid, a drug must be medically necessary and either (a) prescribed for medically accepted indications and dosages found in the drug labeling or drug compendia in accordance with section 1927(k) (6) of the Social Security Act, or (b) prior authorized by a qualified clinical specialist approved by the Agency for Health Care Administration (Agency).[1]

The criteria that are utilized under the Florida Medicaid program in the authorization of drugs for off-label purposes are as follows:

1. Documentation submitted with trial and failure or intolerance to all FDA- approved medications for the indication **AND**
2. Phase III clinical studies published in peer review journals to support the non-FDA approved use **AND**
3. Usage supported by publications in peer reviewed medical literature **and** one or more citations in at least one of the following compendia:
   a. American Hospital Formulary Service Drug Information (AHFS)
   b. United States Pharmacopeia-Drug Information (or its successor publications)
   c. DRUGDEX Information System[1]

Florida Medicaid covers reproductive hormone suppression therapy (including puberty suppression therapy) for all FDA approved indications/uses or when the information in the appropriate compendium supports the use of the drug in the treatment of the specific disease state or condition. Since the use of GnRH agonists are not FDA approved or listed in the appropriate compendia for the treatment of gender dysphoria, Florida Medicaid does not authorize these drugs for such uses. However, children/adolescents diagnosed with gender dysphoria are eligible to receive an array of other medical and behavioral health interventions (e.g., individual and family therapy, psychological evaluations/assessments, other medical evaluation and management services) necessary to address their presenting signs and symptoms.

Health plans contracted to provide services under the Florida Medicaid Statewide Medicaid Managed Care program are required to cover all prescription drugs listed in the Agency's Medicaid Preferred Drug List (PDL). In addition, the health plan's prior authorization criteria and protocols may not be more restrictive than those used by the Agency as indicated in the Florida Statutes, the Florida Administrative Code, the Medicaid State Plan and those posted on the Agency website.

Florida Medicaid provides services to eligible recipients under the age of 21 years, if such services are medically necessary to correct or ameliorate a defect, a condition, or a physical or mental illness. Medical necessity in the State of Florida must meet the following conditions:

1. Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
2. Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs;
3. Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational;
4. Be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide; and
5. Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

If a service exceeds the coverage described within a Florida Medicaid policy or the associated fee schedule, a request (along with all supporting documentation) may be submitted to the Agency or its designee for review.

Medicare

Medicare covers reproductive hormone suppression for all FDA approved use. The *Medicare Benefit Policy Manual*, Chapter 15, page 15, subsection 50.4.2, discusses the unlabeled use of a drug. The policy states that "FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice."[5] However, because Medicare covers primarily elderly adults and disabled adults, its coverage policies have little or no application in this analysis.

State Medicaid Programs

All state Medicaid programs cover reproductive hormone suppression therapy for the approved FDA indications and when the criteria for off-label use are met. Some state Medicaid programs are also adopting coverage policies that allow for reimbursements of puberty suppression therapy in adolescents diagnosed with gender dysphoria. It appears at this time as though most states do not cover this service although that may change over time. This report highlights the coverage policies for four Medicaid programs that do cover the service, as follows:

1. Colorado Medicaid covers behavioral health services, GnRH analogs/agonists, cross-sex hormone therapy, gender confirmation surgery, and pre and post-operative care.
2. Maryland Medicaid covers GnRH treatment if the recipient has a diagnosis of gender dysphoria.
3. Rhode Island Medicaid covers behavioral health services, pharmacological and hormonal therapy to delay physical changes of puberty, and pharmacological and hormonal therapy that is non-reversible and produces masculinization or feminization. Some services require prior authorization.
4. Washington State Medicaid covers behavioral health services, puberty suppression therapy, hormonal therapy, and gender reassignment surgery.

GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS RECOMMENDATION

Puberty suppression therapy is considered a health service that is consistent with generally accepted professional medical standards for the approved FDA indications (i.e., central precocious puberty) and for off-label use when supported by citations in at least one of the compendia. Since Florida Medicaid already provides coverage of puberty suppression therapy in the treatment of central precious puberty and for use in treating the conditions cited in the compendia, no further policy coverage analyses are needed to supplement this report on this point.

Based upon the available published literature, it is inconclusive whether puberty suppression therapy is considered a health service that is consistent with generally accepted professional medical standards in the treatment of gender dysphoria. Most of the studies published thus far on the use of puberty suppression in gender dysphoric children/adolescents have concluded that further systematic research is required to determine the long-term safety and efficacy of this approach and there remains a lack of consensus within the medical community on its appropriateness (both from an ethical and safety perspective). As the research on this topic continues to evolve, more conclusive evidence may emerge that supports the long-term efficacy and effectiveness of this treatment approach. At any time, a follow-up analysis can be performed that could change this recommendation.

EPSDT Considerations:

While the Agency cannot make a blanket determination on puberty suppression therapy for gender dysphoria, we also cannot categorically exclude this treatment for children. Clinical guidelines from the Endocrine Society do recommend this therapy for certain adolescents, albeit based upon a combination of weak and very weak evidence. In certain circumstances, the risks of not treating an adolescent may be worse than the potential long-term consequences of treatment. Moreover, it is noted extensively in the literature that adolescents contending with gender dysphoria often experience a myriad of emotional, physical, and societal challenges. Unresolved, the distress can manifest into a host of behavioral health problems including depression, anxiety, and suicidal ideation and self-mutilation. Florida pays for services for children when they protect life and /or prevent significant disability or harm, in accordance with the state's medical necessity definition.

Given these concerns, while it is not recommended that any further analyses be conducted to expand Florida Medicaid's coverage of puberty suppression therapy beyond those indications/uses approved by the FDA or authorized in the appropriate compendium, it is recommended that any individualized request for such therapy be reviewed as a part of the Agency's special services process. Consistent with EPSDT requirements, the request can be evaluated on an individualized basis to determine if the service is medically necessary (e.g. it is administered to protect life and/or prevent significant disability, such as to prevent suicide or self-mutilation) to ensure that all less invasive interventions have been exhausted, and to ensure that this treatment approach presents as the best alternative given the adolescent's psychological state and presenting signs and symptoms.

✓ **Concur** _____ **Do not Concur**

Comments:

Deputy Secretary for Medicaid (or designee)

9/15/16
Date

RICK SCOTT
GOVERNOR

JUSTIN M. SENIOR
INTERIM SECRETARY

CROSS-SEX HORMONE THERAPY
GAPMS DETERMINATION REPORT WITH RECOMMENDATION

Date: ~~April 20, 2022~~ May 20, 2022
To: ~~Beth Kidder, Interim Deputy Secretary for Medicaid~~ Ashley Peterson
From: Bureau of Medicaid Policy
Subject: ~~Cross-Sex Hormone Therapy~~

PURPOSE

~~In order for~~For the use of cross-sex hormone therapy to be covered under the Florida Medicaid program, it must meet medical necessity criteria as defined in Rule 59G-1.010, Florida Administrative Code (F.A.C.), and be funded through the General Appropriations Act of Chapter 216, Florida Statutes (F.S.).

Pursuant to the criteria set forth in Rule 59G-1.010, F.A.C., the use of cross-sex hormone therapy must be consistent with generally accepted professional medical standards (GAPMS) as determined by the Medicaid program, and not experimental or investigational.

In accordance with the determination process established in Rule 59G-1.035, F.A.C., the Deputy Secretary for Medicaid will make the final determination as to whether the use of cross-sex hormone therapy is consistent with generally accepted professional medical standards and not experimental or investigational.

If it is determined that cross-sex hormone therapy is consistent with generally accepted professional medical standards, this report will be supplemented with an addendum which analyzes additional factors to determine whether this health service should be covered under the Florida Medicaid program.

RECOMMENDATION

This report recommends cross-sex hormone therapy as a health service that is consistent with generally accepted professional medical standards and is supported in compendia as off-label use. There are clinical guidelines that have been published for the use of cross-sex hormones by the Endocrine Society, September 2009 and the World Professional Association for Transgender Health (WPATH 7th version). These guidelines are considered standards of care for transgender patients and provide parameters to determine the diagnosis of gender dysphoria, at what age to start treatment of cross-sex hormone therapy, and monitoring parameters that should be in place during treatment.

Veteran's Administration, Centers for Medicaid and Medicare, many commercial and Medicaid plans have protocols in place to provide access of the use of cross-sex hormone therapy in transgender patients.

Commented [GS1]: Newest guidelines published April Dec 2016
Hormone therapy for transgender patients - PMC (nih.gov)

Commented [GS2]: Cross-Sex hormones are usually recommended at the age of sixteen.

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REPORT WITH RECOMMENDATION

This report with recommendation is presented as the summary assessment considering the factors identified in Rule 59G-1.035, F.A.C., based on the collection of information from credible sources of reliable evidence-based information. The intent is to provide a brief analysis with justification in support of the final recommendation.

The analysis described in this report includes:

- A high-level review of relevant disease processes.
- An overview of the health service information.
- Clearance from the government regulatory body (e.g., Food and Drug Administration).
- Evidence based clinical practice guidelines.
- A review of the literature considered by the relevant medical community or practitioner specialty associations from credible scientific evidence-based literature published in peer reviewed journals and
- Consensus of coverage policy from commercial and other state Medicaid insurers.

HEALTH SERVICE SUMMARY

Reproductive Hormones

The hormones commonly considered as reproductive hormones in the body are testosterone, estrogen, and progesterone. Testosterone is often referred to as a male hormone, and estrogen and progesterone are often referred to as female hormones. However, there are not exclusively male or female hormones that have been identified. The physical manifestations of gender result from differences in the amounts of individual hormones in the body and differences in their patterns of secretion, first in utero and then again during puberty. In other words, testosterone, estrogen, and progesterone are produced by men and women, but in differing amounts and in different patterns.

Cross-Sex Hormone Therapy

Commented [GS3]: Cross-Sex Hormone therapy remains the same. (Table 1 and 2 of article)

Cross-sex hormone therapy assists transgender patients to reflect the desired sex through physical changes. This is accomplished by increasing the testosterone in assigned females at birth, in conjunction with suppressing the estrogen in their bodies. Assigned males at birth will have their testosterone levels suppressed while their estrogen levels will be increased.

Currently, there are drugs approved by the FDA that increases testosterone in men with hypogonadism and increase estrogen in women for various approved indications in addition to men with advanced prostate cancer (Analytics, 2016). Estrogen and testosterone are the medications mainly used in cross-sex hormone therapy. Female to Male (FTM) patients, are prescribed testosterone, unless contraindicated. Male to Female patients, are prescribed estrogen, unless contraindicated (Levine, 2013). Anti-androgen agents may be used in conjunction with cross-sex hormone therapy, such as: progestins, gonadotropin releasing hormone agonists, spironolactone, or 5-alpha reductase inhibitors**.**

Testosterone has a variety of available formulations: ~~buccal~~ oral, intramuscular (IM), topical, transdermal, and ~~intranasal~~ subcutaneous. ~~The oral formulation of testosterone is not available in the United States~~. FTM patients most commonly use transdermal/topical, or IM routes of

Commented [GS4]: Testosterone current formulations are include subcutaneous now. (Parental and Implant). Oral Testosterone Undecanoate is now available in the U.S. (Tlando and Jatenzo).

Table 1 of article

administration because it provides better hormone levels. Estrogen also has various formulations available: transdermal, ~~vaginal, spray~~, oral, subcutaneous, and intramuscular. The most common route of administration for (MTF): oral, IM or transdermal (Tangpricha, 2016). For the purposes of this report, an analysis is being performed on the use of cross-sex hormone therapy concentrating on testosterone and estrogen.

Commented [GS5]: Estrogen current formulations include: Oral, Parental (SubQ, IM), Transdermal and SubQ implant. No mention of vaginal or spray formulations.

Government Regulatory Body Approval

The Food and Drug Administration (FDA) has approved testosterone for hypogonadism in men and estrogen is approved in women for various indications (see below) and for men with advanced prostate cancer:

Testosterone (testosterone cypionate, testosterone enanthate, testosterone undecanoate)

- Indications for use: Primary hypogonadism or hypogonadotropic hypogonadism in men
- Off Label Use: various doses used in clinical trials, including testosterone cypionate 200mg IM every 2 weeks for gender identity disorder female- to male transsexual (Analytics, 2016)

- Possible side effects of testosterone FTM therapy: acne, polycythemia, dyslipidemia, transaminitis, weight gain, hypertension and mood lability. After 6 to 8 weeks of hormone treatment of testosterone, deepening of the voice occurs and is irreversible (Gibson et al., 2010)

Testosterone options for transgender men

Route	Formulation	Dosing
Oral (not available in United States)	Testosterone undecanoate	160–240 mg/day
Parental (subcutaneous, intramuscular)	Testosterone enanthate, cypionate	50–200 mg/week
		100–200 mg/10–14 days
Implant (subcutaneous)	Testopel®	75 mg/pellet
Transdermal	Testosterone gel (1%)	2.5–10 g/day
	Testosterone patch	2.5–7.5 mg/day

- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5182227/#:~:text=for%20some%20patients.-,Table%201,2.5%E2%80%937.5%20mg/day,-Open%20in%20a

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Estrogen (conjugated estrogens, esterified estrogens, estradiol, estradiol acetate, estradiol cypionate, estradiol valerate)

- Indications for use: Advanced prostate cancer- androgen dependent men, metastatic breast cancer, lower than normal estrogen levels in women,

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prevention of osteoporosis (postmenopausal~~),vulvovaginal~~), vulvovaginal atrophy (menopausal), and moderate to severe menopausal vasomotor symptoms

Off Label use: Conjugated estrogens, 17-beta estradiol and ethinyl estradiol may be effective in changing the physical external appearance for male to female transsexuals (Analytics, 2016)

Estrogen and anti-androgen options for transgender women

Route	Formulation	Dosing
Oral	Estradiol	2–4 mg daily
Parental (subcutaneous, intramuscular)	Estradiol valerate	5–30 mg every 2 weeks
Transdermal	Estradiol	0.1–0.4 mg twice weekly
Anti-androgens	Progesterone	20–60 mg PO daily
	Medroxyprogesterone acetate	150 mg IM every 3 months
	GnRH agonist (leuprolide)	3.75–7.5 mg IM monthly
	Histrelin implant	50 mg implanted every 12 months
	Spironolactone	100–200 mg PO daily
	Finasteride	1 mg PO daily

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5182227/#:~:text=profiles%20(14).-,Table%202,1%20mg%20PO%20daily,-Open%20in%20a

- Side effects of estrogen in MTF therapy: decreased facial and body hair, fat redistribution, decreased spontaneous erections, softened skin, growth of breast tissue, and growth plate closure, increased risk of thromboembolic disease, liver dysfunction, cholelithiasis, hypertension, and hyperprolactinemia. Breast development will begin almost immediately upon estrogen administration, will proceed in a cyclical fashion, and will be as large as can be expected after approximately two years of treatment.

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LITERATURE REVIEW

Gender Dysphoria

The Diagnostic and Statistical Manual of Mental Disorders defines gender dysphoria (GD) (formally referred to as gender identity disorder) as an individual's affective or cognitive discontent with their assigned gender at birth. GD refers to the ***distress*** that may accompany the incongruence between the individual's experienced or expressed gender and their assigned gender. Evidence of this distress is the hallmark of the disorder. The diagnostic criteria are divided into a category for children and a category for adolescents and adults. The disorder is manifested differently as the individual ages or enters different developmental stages. Both categories require marked incongruence between the individual's experienced or expressed

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gender and their assigned gender of at least a six months' duration and clinically significant distress or impairment in social, school (occupation for adults), or other important areas of functioning (Association, 2014)

Diagnostic criteria in children include: a strong desire to be the other gender or an insistence that they are the other gender; a preference for wearing clothing associated with the other gender; preference for cross gender roles in simulated play; preference for toys, games, or activities usually associated with the other gender; preference for playmates of the other gender; and the dislike of their sexual anatomy. Studies have shown that most children (80%) diagnosed with gender dysphoria will not continue to be gender dysphoric after puberty *(Moller et al., 2009; Wallien & Cohen-Kettenis, 2008; and Drummond et al., 2008).*

Commented [GS6]: Still valid per article "Gender Dysphoria in Children" published November 2018 Gender Dysphoria in Children | American College of Pediatricians (acpeds.org)

For the 20% of children who persist in their feelings of gender dysphoria, clinicians may begin to explore alternative treatment approaches beyond psychotherapy after the onset of puberty, including medical interventions such as the use of gonadotropin releasing hormone (GnRH) analogs to suppress puberty. It is generally introduced in children who have reached a minimum of Tanner Stage 2 (a scale used to determine physical development in children, adolescents and adults based on external primary and secondary sex characteristics) which is usually at the age of 12-16 (Cohen-Kettenis et al.2011). Other drugs, such as progestins and antiandrogens (spironolactone and 5-alpha reductase inhibitors) have been used to suppress physical changes in puberty. In addition to puberty suppression therapy, a physician may also begin to prescribe cross-sex hormones, though the latter does not generally begin until the ages of 16-18 (de Vries et al. 2011).

Cross-sex hormone therapy is the primary medical intervention sought by transgender people. Exogenous hormones have a clear impact on fertility. Patients must be informed and counseled regarding options for fertility and evaluation of medical conditions that can be exacerbated by hormone depletion, prior to treatment with sex hormones of the desired sex in both adolescents and adults. The patient must be made aware of the possibility of infertility/sterilization with the use of cross-sex hormone therapy. Fertility preservation options may include sperm, oocyte, embryo, ovarian tissue or testicular tissue cryopreservation. Transgender patients who undergo fertility preservation or assisted reproduction should be informed of the lack of data on outcomes. The use of cross-sex therapy alone does not guarantee prevention of pregnancy, if sexually active contraception is required. Testosterone is a teratogen and is contraindicated in pregnancy. The effects of long-term exogenous testosterone and estrogen are unclear, but the possible side effects should be addressed (Francisco, Center, and Information, 2016)

It is important to note that most of the literature reviewed in development of this analysis concluded that more systematic research is required to determine the long-term efficacy of medical treatment for adolescents with gender dysphoria (Kaltiala-Heino et al. 2015; Jarin et al. 2016; Lee et al. 2016, March et al. 2015; Vance et al. 2014; Vrouenraets et al 2015)

Clinical Outcome

No perspective, randomized, controlled trials were located that have evaluated the safety and efficacy of the use of cross-sex hormones to produce physical effects in transgender patients. The current information used has been derived primarily from observational study or has been extrapolated from the use of hormones for the approved FDA indications (Tangpricha, 2016).

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This analysis summarizes information obtained from scientific literature published in credible peer-reviewed journals related to the use of cross-sex hormone therapy. This section also briefly cites the positions from the relevant medical societies, and summarizes the key articles referenced in support of their positions.

Recommendations from The Endocrine Society Guidelines are as follows:

- We recommend that the diagnosis of gender identity disorder (GID) be made by a mental health professional (MHP). For children and adolescents, the MHP should also have training in child and adolescent developmental psychopathology.
- Given the high rate of remission of GID after the onset of puberty, we recommend against a complete social role change and hormone treatment in pre-pubertal children with GID
- We recommend that physicians evaluate and ensure that applicants understand the reversible and irreversible effects of hormone suppression (e.g., GnRH analog treatment) and cross-sex hormone treatment before they start hormone treatment.
- We recommend that all transsexual individuals be informed and counseled regarding options for fertility prior to initiation of puberty suppression in adolescents and prior to treatment with sex hormones of the desired sex in both adolescents and adults.
- We suggest that pubertal development of the desired opposite sex be initiated at about the age of 16 year, using a gradually increasing dose schedule of cross-sex steroids.
- We recommend referring hormone-treated adolescents for surgery when 1) the real-life experience (RLE) has resulted in a satisfactory social role change; 2) the individual is satisfied about the hormonal effects; and 3) the individual desires definitive surgical changes.
- We suggest that treatment with GnRH analogs be continued during treatment with cross-sex steroids to maintain full suppression of pituitary gonadotropin levels and, thereby, gonadal steroids. When puberty is initiated with a gradually increasing schedule of sex steroid doses, the initial levels will not be high enough to suppress endogenous sex steroid secretion
- Baseline labs and scheduled routine monitoring for known risks throughout adulthood
- Maintain physiologic levels of appropriate sex hormones in the range of the desired gender and monitor for known risks of gender-appropriate sex hormones
- Lifetime continuation of cross-sex hormone therapy usually required unless medically contraindicated (Hembree et al., 2009)

WPATH Version 7 Standard of Care recommendations for Cross-Sex Hormone therapy:

- Persistent, well-documented gender dysphoria.
- Capacity to make a fully informed decision and to consent for treatment.
- If significant medical or mental health concerns are present, they must be reasonably well controlled.
- Mental health professional competent in diagnosing and treating ordinary problems of children and adolescents; trained in childhood and adolescent developmental psychopathology; and must meet the competency requirements for mental health professionals working with adults.

- A staged process of physical interventions of adolescents is recommended to allow the adolescents and their parents to assimilate fully the effects of earlier interventions: fully reversible interventions (i.e., GnRH analogues, spironolactone, progestins) partially reversible interventions (i.e., hormone therapy to masculinize or feminize the body, cross-sex hormones) and irreversible interventions (surgical procedures).
- Adolescents may be eligible to begin feminizing/masculinizing hormone therapy preferably with parental consent at 16.
- Regimens for hormone therapy in gender dysphoric adolescents differ substantially from those used in adults (Hembree et al., 2009). The hormone regimen is adjusted to account for emotional, somatic and mental development that occurs throughout adolescence.

Possible risk Factors associated with Cross-Sex Hormone therapy:

- Adolescents undergoing partially reversible cross-gender hormone therapy should be monitored for progress in transition and for any potential medical complications.

- MTF patients started on estrogen might develop deep venous thrombosis, prolactinomas, hypertension, hypertriglyceridemia, cardiovascular disease, type 2 diabetes, liver disease, and decreased libido and are at increased risk of breast cancer. Spironolactone can lead to hyperkalemia and decreased blood pressure.

- FTM patients receiving testosterone may develop hyperlipidemia, polycythemia, male pattern baldness, acne, cardiovascular disease, hypertension, type 2 diabetes, breast cancer, cervical cancer, ovarian cancer, uterine cancer, destabilization of certain psychiatric disorders (i.e., bipolar, schizoaffective disorders (Hembree et al.,2009; Tangpricha, 2016)

Monitoring for FTM on hormone therapy:

- Monitor for virilizing and adverse effects every 3 months for first year and then every 6 – 12 months.
- Monitor serum testosterone at follow-up visits with a practical target in the male range (300 – 1000 ng/dl). Peak levels for patients taking parenteral testosterone can be measured 24 – 48 h after injection. Trough levels can be measured immediately before injection.
- Monitor hematocrit and lipid profile before starting hormones and at follow-up visits.
- Bone mineral density (BMD) screening before starting hormones for patients at risk for osteoporosis. Otherwise, screening can start at age 60 or earlier if sex hormone levels are consistently low.
- FTM patients with cervixes or breasts should be screened appropriately. ***(Site reference)***
- Monitor renal function, liver function tests fasting glucose, insulin, hemoglobin A1C, bone density and bone age.
- FTM patients should have axillary lymph nodes examined (Gooren et al., 2008; Jain & Bradbeer, 2007; Sobralske, 2005).

Monitoring for MTF on hormone therapy:

- Monitor for feminizing and adverse effects every 3 months for first year and then every 6– 12 months.
- Monitor serum testosterone and estradiol at follow-up visits with a practical target in the female range (testosterone 30 – 100 ng/dl; E2 <200 pg/ml).
- Monitor prolactin and triglycerides before starting hormones and at follow-up visits.
- Monitor potassium levels if the patient is taking spironolactone.
- Bone mineral density screening before starting hormones for patients at risk for osteoporosis. Otherwise, start screening at age 60 or earlier if sex hormone levels are consistently low.
- MTF patients should be advised to do breast self-exams and be screened for breast and prostate cancer appropriately. Breast self-exams should be advised (Gooren et al., 2008; Jain & Bradbeer, 2007; Sobralske, 2005).

COVERAGE POLICY

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Florida Medicaid covers hormone therapy for all FDA approved indications/uses or when the information in the appropriate compendium supports the use of the drug in the treatment of the specific disease state or condition. Testosterone and estrogen are not FDA approved for cross-sex hormone therapy in patients with gender dysphoria. However, DRUGDEX Information System's compendia addresses off-label use of testosterone cypionate, conjugated estrogens, 17-beta estradiol and ethinyl estradiol in the use of cross-sex hormone therapy.

Children/adolescents diagnosed with gender dysphoria are also eligible to receive an array of other medical and behavioral health interventions (e.g., individual and family therapy, psychological evaluations/assessments, other medical evaluation and management services) necessary to address their presenting signs and symptoms.

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Federal

CMS implemented a new rule by the Department of Health and Human Services implements Section 1557 of the Affordable Care Act (ACA), "Nondiscrimination in Health Programs and Activities." This rule applies to all health programs that receive federal funding or assistance, including state Medicaid agencies, as well as most health insurance issuers. Effective July 18, 2016, are other provisions including provisions related to discrimination based on gender identity, pregnancy, or transgender status. Individuals must be provided equal access to health services without discrimination related to gender or identity. Entities can still review for medical necessity if the review is not discriminatory towards these individuals and utilizes a neutral rule or principal. Categorical exclusion or limits on services related to gender transition are discriminatory as well.

Medicare

Transgender beneficiaries can use hormone therapy, which are coverable under the Medicare Part D prescription drug benefit program. The *Medicare Benefit Policy Manual*, Chapter 15, page 15, subsection 50.4.2, discusses the unlabeled use of a drug. The policy states that "FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice." Medicare provides a special billing code (condition code 45) when gender mis-match claims may be a problem (http://www.transequality.org/sites/default/files/docs/kyr/MedicareAndTransPeople.pdf)

Veteran's Administration

Veteran's Administration Pharmacy Benefits Management has criteria for adult transgender men testosterone replacement therapy in as well as adult transgender women estrogen replacement therapy.
http://www.pbm.va.gov/PBM/clinicalguidance/criteriaforuse/Transgender_Cross_Sex_Hormone_Therapy_in_FtM_Female_to_Male_CFU.pdf

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State Medicaid Programs

All state Medicaid programs cover hormone therapy for the approved FDA indications and when the criteria for off-label use are met. Some state Medicaid programs are also adopting coverage policies that allow for reimbursements of cross-sex therapy in adolescents diagnosed with gender dysphoria. This report highlights the coverage policies for some Medicaid programs that do cover the service, as follows:

1. Colorado Medicaid covers behavioral health services, GnRH analogs/agonists, cross-sex hormone therapy, gender confirmation surgery, physical therapy and pre- and post-operative care.
2. Maryland Medicaid covers cross-sex hormone therapy for recipients 18 and older.
3. Rhode Island Medicaid covers behavioral health services, pharmacological and hormonal therapy to delay physical changes of puberty, and pharmacological and hormonal therapy that is non-reversible and produces masculinization or feminization. Some services require prior authorization.
4. Washington State Medicaid covers behavioral health services, puberty suppression therapy, hormonal therapy, and gender reassignment surgery. They have had policy in place since February 2014 regarding access to care.
5. California, New York and Massachusetts are obligated to pay for gender transition.
6. Oregon covers cross-sex hormone therapy for adolescents and adults who meet eligibility and readiness criteria.
7. Montana covers cross-sex hormone therapy for transgender recipients. Testosterone requires a prior authorization to ensure treatment is for appropriate diagnoses.
8. Indiana covers cross-sex hormone therapy for gender dysphoria recipients.
9. Illinois removed gender restrictions on estradiol and testosterone in 04/01/2015 based on the Endocrine Society recommendations.

Commented [GS7]: Colorado also covers physical therapy, hormone therapy, and surgical procedures
Gender-Affirming Care Billing Manual | Colorado Department of Health Care Policy & Financing

Private Insurers:
The following private insurers have criteria in place to access medications for cross-sex hormone therapy:

Moda Health Plan Inc, Gender Reassignment Medical Necessity:
https://www.modahealth.com/pdfs/med_criteria/GenderReassignment.pdf

Fallonhealth: Transgender Services Clinical Coverage Criteria
http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=20&ved=0ahUKEwjeharT6ubOAhVH5iYKHZYfAIg4ChAWCF8wCQ&url=http%3A%2F%2Fwww.fchp.org%2Fproviders%2Fmedical-management%2F~%2Fmedia%2FFiles%2FProviderPDFs%2FMedicalPolicies%2FTransgenderServices.ashx&usg=AFQjCNHGumXLS82ivBfVGHDP6bXEeJOdbQ

Blue regence Transgender Services Policy
http://blue.regence.com/trgmedpol/medicine/med153.pdf

GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS RECOMMENDATION

Cross-sex hormone therapy may be considered a health service that is consistent with generally accepted professional medical standards for the approved FDA indications (i.e., hypogonadism, hypoestrogenism) and for off-label use when supported by citations in at least one of the compendia. Since Florida Medicaid already provides coverage of hormone therapy in the FDA approved indications and for use in treating the conditions cited in the compendia, no further policy coverage analyses are needed to supplement this report on this point.

Based upon the available published literature, cross-sex hormone therapy should be considered a health service that is consistent with generally accepted professional medical standards in the treatment of gender dysphoria. Most of the studies published thus far on the use of cross-sex hormone therapy in gender dysphoric children/adolescents have concluded that further systematic research is required to determine the long-term safety and efficacy of this approach. The guidelines for transgender patients in the Endocrine Society and WPATH are controversial because they are based primarily on expert opinion rather than scientific data, given the paucity of the outcomes data on the effects of mental health and medical interventions (Vance, Ehrensaft, and Rosenthal, 2014). However, the standards of care for cross-sex hormone therapy seem to be consistent in the approach with diagnosis, monitoring and dosing of the transgender patients. Indeed, hormone therapy and surgery have been found to be medically necessary to alleviate gender dysphoria in many people (American Medical Association, 2008; Anton, 2009; Tangpricha, 2016) Regimens for hormone therapy in gender dysphoric adolescents differ substantially from those used in adults. The hormone regimens for youth are adapted to account for the somatic, emotional, and mental development that occurs throughout adolescence (Hembree et al., 2009). As the research on this topic continues to evolve, more conclusive evidence may emerge that supports the long-term efficacy and effectiveness of this treatment approach.

EPSDT Considerations:

Clinical guidelines from the Endocrine Society and WPATH recommend this therapy for certain adolescents, albeit based upon weak evidence. In certain circumstances, the risks of not treating an adolescent may be worse than the potential long-term consequences of treatment. Moreover, it is noted extensively in the literature that adolescents contending with gender

dysphoria often experience a myriad of emotional, physical, and societal challenges. Unresolved, the distress can manifest into a host of behavioral health problems including depression, anxiety, and suicidal ideation and self-mutilation. Florida pays for services for children when they protect life and /or prevent significant disability or harm, in accordance with the state's medical necessity definition.

Testosterone cypionate, conjugated estrogens, 17-beta estradiol and ethinyl estradiol have documented off-label use in DRUGDEX. Because of this supporting documentation in the compendia, the off-label criteria could be used to evaluate each patient on a case-by-case basis. This report recommends cross-sex hormone therapy as a health service that is consistent with generally accepted professional medical standards. Consistent with EPSDT requirements, the request can be evaluated on an individualized basis to determine if the service is medically necessary (e.g., it is administered to protect life and/or prevent significant disability, such as to prevent suicide or self-mutilation) to ensure that all less invasive interventions have been exhausted, and to ensure that this treatment approach presents as the best alternative given the adolescent's psychological state and presenting signs and symptoms.

REFERENCES

1. Unger C. A. (2016). Hormone therapy for transgender patients. *Translational andrology and urology*, *5*(6), 877–884. https://doi.org/10.21037/tau.2016.09.04

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____ **Concur** ____ **Do Not Concur**

Comments:

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Signature Date

Deputy Secretary for Medicaid (or designee)

RICK SCOTT
GOVERNOR

JUSTIN M. SENIOR
INTERIM SECRETARY

CROSS-SEX HORMONE THERAPY
GAPMS DETERMINATION REPORT WITH RECOMMENDATION

Date: April 19, 2022
To: Beth Kidder, Interim Deputy Secretary for Medicaid
From: Bureau of Medicaid Policy
Subject: **Cross-Sex Hormone Therapy**

PURPOSE

In order for the use of cross-sex hormone therapy to be covered under the Florida Medicaid program, it must meet medical necessity criteria as defined in Rule 59G-1.010, Florida Administrative Code (F.A.C.), and be funded through the General Appropriations Act of Chapter 216, Florida Statutes (F.S.).

Pursuant to the criteria set forth in Rule 59G-1.010, F.A.C., the use of cross-sex hormone therapy must be consistent with generally accepted professional medical standards (GAPMS) as determined by the Medicaid program, and not experimental or investigational.

In accordance with the determination process established in Rule 59G-1.035, F.A.C., the Deputy Secretary for Medicaid will make the final determination as to whether the use of cross-sex hormone therapy is consistent with generally accepted professional medical standards and not experimental or investigational.

If it is determined that cross-sex hormone therapy is consistent with generally accepted professional medical standards, this report will be supplemented with an addendum which analyzes additional factors to determine whether this health service should be covered under the Florida Medicaid program.

RECOMMENDATION

This report recommends cross-sex hormone therapy as a health service that is consistent with generally accepted professional medical standards, and is supported in compendia as off-label use. There are clinical guidelines that have been published for the use of cross-sex hormones by the Endocrine Society, September 2009 and the World Professional Association for Transgender Health (WPATH 7th version). These guidelines are considered standards of care for transgender patients and provide parameters to determine the diagnosis of gender dysphoria, at what age to start treatment of cross-sex hormone therapy, and monitoring parameters that should be in place during treatment.

Veteranôs Administration, Centers for Medicaid and Medicare, many commercial and Medicaid plans have protocols in place to provide access of the use of cross-sex hormone therapy in transgender patients.

Pl. Trial Ex. 238

REPORT WITH RECOMMENDATION

This report with recommendation is presented as the summary assessment considering the factors identified in Rule 59G-1.035, F.A.C., based on the collection of information from credible sources of reliable evidence-based information. The intent is to provide a brief analysis with justification in support of the final recommendation.

The analysis described in this report includes:

- A high level review of relevant disease processes.
- An overview of the health service information.
- Clearance from the government regulatory body (e.g., Food and Drug Administration).
- Evidence based clinical practice guidelines.
- A review of the literature considered by the relevant medical community or practitioner specialty associations from credible scientific evidence-based literature published in peer reviewed journals and
- Consensus of coverage policy from commercial and other state Medicaid insurers.

HEALTH SERVICE SUMMARY

Reproductive Hormones

The hormones commonly considered as reproductive hormones in the body are testosterone, estrogen, and progesterone. Testosterone is often referred to as a male hormone, and estrogen and progesterone are often referred to as female hormones. However, there are no exclusively male or female hormones that have been identified. The physical manifestations of gender result from differences in the amounts of individual hormones in the body and differences in their patterns of secretion, first in utero and then again during puberty. In other words, testosterone, estrogen, and progesterone are produced by men and women, but in differing amounts and in different patterns.

Cross-Sex Hormone Therapy

Cross-sex hormone therapy assists transgender patients to reflect the desired sex through physical changes. This is accomplished by increasing the testosterone in assigned females at birth, in conjunction with suppressing the estrogen in their bodies. Assigned males at birth will have their testosterone levels suppressed while their estrogen levels will be increased.

Currently, there are drugs approved by the FDA that increases testosterone in men with hypogonadism and increase estrogen in women for various approved indications in addition to men with advanced prostate cancer (Analytics, 2016). Estrogen and testosterone are the medications mainly used in cross-sex hormone therapy. Female to Male (FTM) patients, are prescribed testosterone, unless contraindicated. Male to Female patients, are prescribed estrogen, unless contraindicated (Levine, 2013). Anti-androgen agents may be used in conjunction with cross-sex hormone therapy, such as: progestins, gonadotropin releasing hormone agonists, spironolactone, or 5-alpha reductase inhibitors**.**

Testosterone has a variety of available formulations: buccal, intramuscular (IM), topical, transdermal, and intranasal. The oral formulation of testosterone is not available in the United States. FTM patients most commonly use transdermal/topical, or IM routes of administration

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because it provides better hormone levels. Estrogen also has various formulations available: transdermal, vaginal, spray, oral and intramuscular. The most common route of administration for (MTF): oral, IM or transdermal (Tangpricha, 2016). For the purposes of this report, an analysis is being performed on the use of cross-sex hormone therapy concentrating on testosterone and estrogen.

Government Regulatory Body Approval

The Food and Drug Administration (FDA) has approved testosterone for hypogonadism in men and estrogen is approved in women for various indications (see below) and for men with advanced prostate cancer:

Testosterone (testosterone cypionate, testosterone enanthate, testosterone undecanoate)

- Indications for use: Primary hypogonadism or hypogonadotropic hypogonadism in men
- Off Label Use: various doses used in clinical trials, including testosterone cypionate 200mg IM every 2 weeks for gender identity disorder female- to male transsexual (Analytics, 2016)

- Possible side effects of testosterone FTM therapy: acne, polycythemia, dyslipidemia, transaminitis, weight gain, hypertension and mood lability. After 6 to 8 weeks of hormone treatment of testosterone, deepening of the voice occurs and is irreversible (Gibson et al., 2010)

Estrogen (conjugated estrogens, esterified estrogens, estradiol, estradiol acetate, estradiol cypionate, estradiol valerate)

- Indications for use: Advanced prostate cancer- androgen dependent men, metastatic breast cancer, lower than normal estrogen levels in women, prevention of osteoporosis (postmenopausal),vulvovaginal atrophy (menopausal), and moderate to severe menopausal vasomotor symptoms
- Off Label use: Conjugated estrogens, 17-beta estradiol and ethinyl estradiol may be effective in changing the physical external appearance for male to female transsexuals (Analytics, 2016)

- Side effects of estrogen in MTF therapy: decreased facial and body hair, fat redistribution, decreased spontaneous erections, softened skin, growth of breast tissue, and growth plate closure, increased risk of thromboembolic disease, liver dysfunction, cholelithiasis, hypertension, and hyperprolactinemia. Breast development will begin almost immediately upon estrogen administration, will proceed in a cyclical fashion, and will be as large as can be expected after approximately two years of treatment.

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LITERATURE REVIEW

Gender Dysphoria

The Diagnostic and Statistical Manual of Mental Disorders defines gender dysphoria (GD) (formally referred to as gender identity disorder) as an individualôs affective or cognitive discontent with their assigned gender at birth. GD refers to the ***distress*** that may accompany the incongruence between the individualôs experienced or expressed gender and their assigned gender. Evidence of this distress is the hallmark of the disorder. The diagnostic criteria are divided into a category for children and a category for adolescents and adults. The disorder is manifested differently as the individual ages or enters different developmental stages. Both categories require marked incongruence between the individualôs experienced or expressed gender and their assigned gender of at least a six monthsô duration and clinically significant distress or impairment in social, school (occupation for adults), or other important areas of functioning (Association, 2014)

Diagnostic criteria in children include: a strong desire to be the other gender or an insistence that they are the other gender; a preference for wearing clothing associated with the other gender; preference for cross gender roles in simulated play; preference for toys, games, or activities usually associated with the other gender; preference for playmates of the other gender; and the dislike of their sexual anatomy. Studies have shown that the majority of children (80%) diagnosed with gender dysphoria will not continue to be gender dysphoric after puberty *(Moller et al., 2009; Wallien & Cohen-Kettenis, 2008; and Drummond et al., 2008).*

For the 20% of children who persist in their feelings of gender dysphoria, clinicians may begin to explore alternative treatment approaches beyond psychotherapy after the onset of puberty, including medical interventions such as the use of gonadotropin releasing hormone (GnRH) analogs to suppress puberty. It is generally introduced in children who have reached a minimum of Tanner Stage 2 (a scale used to determine physical development in children, adolescents and adults based on external primary and secondary sex characteristics) which is usually at the age of 12-16 (Cohen-Kettenis et al.2011). Other drugs, such as progestins and antiandrogens (spironolactone and 5-alpha reductase inhibitors) have been used to suppress physical changes in puberty. In addition to puberty suppression therapy, a physician may also begin to prescribe cross-sex hormones, though the latter does not generally begin until the ages of 16-18 (de Vries et al. 2011).

Cross-sex hormone therapy is the primary medical intervention sought by transgender people***.*** Exogenous hormones have a clear impact on fertility. Patients must be informed and counseled regarding options for fertility and evaluation of medical conditions that can be exacerbated by hormone depletion, prior to treatment with sex hormones of the desired sex in both adolescents and adults. The patient must be made aware of the possibility of infertility/sterilization with the use of cross-sex hormone therapy. Fertility preservation options may include sperm, oocyte, embryo, ovarian tissue or testicular tissue cryopreservation. Transgender patients who undergo fertility preservation or assisted reproduction should be informed of the lack of data on outcomes. The use of cross-sex therapy alone does not guarantee prevention of pregnancy, if sexually active contraception is required. Testosterone is a teratogen and is contraindicated in pregnancy. The effects of long term exogenous testosterone and estrogen are unclear, but the possible side effects should be addressed (Francisco, Center, and Information, 2016)

It is important to note that most of the literature reviewed in development of this analysis concluded that more systematic research is required to determine the long-term efficacy of

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medical treatment for adolescents with gender dysphoria (Kaltiala-Heino et al. 2015; Jarin et al. 2016; Lee et al. 2016, March et al. 2015; Vance et al. 2014; Vrouenraets et al 2015)

Clinical Outcome

No perspective, randomized, controlled trials were located that have evaluated the safety and efficacy of the use of cross-sex hormones to produce physical effects in transgender patients. The current information used has been derived primarily from observational study or has been extrapolated from the use of hormones for the approved FDA indications (Tangpricha, 2016).

This analysis summarizes information obtained from scientific literature published in credible peer-reviewed journals related to the use of cross-sex hormone therapy. This section also briefly cites the positions from the relevant medical societies, and summarizes the key articles referenced in support of their positions.

Recommendations from The Endocrine Society Guidelines are as follows:

- We recommend that the diagnosis of gender identity disorder (GID) be made by a mental health professional (MHP). For children and adolescents, the MHP should also have training in child and adolescent developmental psychopathology.
- Given the high rate of remission of GID after the onset of puberty, we recommend against a complete social role change and hormone treatment in pre-pubertal children with GID
- We recommend that physicians evaluate and ensure that applicants understand the reversible and irreversible effects of hormone suppression (e.g. GnRH analog treatment) and cross-sex hormone treatment before they start hormone treatment.
- We recommend that all transsexual individuals be informed and counseled regarding options for fertility prior to initiation of puberty suppression in adolescents and prior to treatment with sex hormones of the desired sex in both adolescents and adults.
- We suggest that pubertal development of the desired opposite sex be initiated at about the age of 16 year, using a gradually increasing dose schedule of cross-sex steroids.
- We recommend referring hormone-treated adolescents for surgery when 1) the real-life experience (RLE) has resulted in a satisfactory social role change; 2) the individual is satisfied about the hormonal effects; and 3) the individual desires definitive surgical changes.
- We suggest that treatment with GnRH analogs be continued during treatment with cross-sex steroids to maintain full suppression of pituitary gonadotropin levels and, thereby, gonadal steroids. When puberty is initiated with a gradually increasing schedule of sex steroid doses, the initial levels will not be high enough to suppress endogenous sex steroid secretion
- Baseline labs and scheduled routine monitoring for known risks throughout adulthood
- Maintain physiologic levels of appropriate sex hormones in the range of the desired gender and monitor for known risks of gender-appropriate sex hormones
- Lifetime continuation of cross-sex hormone therapy usually required unless medically contraindicated (Hembree et al., 2009)

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WPATH Version 7 Standard of Care recommendations for Cross-Sex Hormone therapy:

- Persistent, well-documented gender dysphoria;
- Capacity to make a fully informed decision and to consent for treatment;
- If significant medical or mental health concerns are present, they must be reasonably well controlled.
- Mental health professional competent in diagnosing and treating ordinary problems of children and adolescents; trained in childhood and adolescent developmental psychopathology; and must meet the competency requirements for mental health professionals working with adults.
- A staged process of physical interventions of adolescents is recommended to allow the adolescents and their parents to assimilate fully the effects of earlier interventions: fully reversible interventions (i.e. GnRH analogues, spironolactone, progestins) partially reversible interventions (i.e. hormone therapy to masculinize or feminize the body, cross-sex hormones) and irreversible interventions (surgical procedures).
- Adolescents may be eligible to begin feminizing/masculinizing hormone therapy preferably with parental consent at 16.
- Regimens for hormone therapy in gender dysphoric adolescents differ substantially from those used in adults (Hembree et al., 2009). The hormone regimen is adjusted to account for emotional, somatic and mental development that occurs throughout adolescence.

Possible risk Factors associated with Cross-Sex Hormone therapy:

- Adolescents undergoing partially reversible cross-gender hormone therapy should be monitored for progress in transition and for any potential medical complications.

- MTF patients started on estrogen might develop deep venous thrombosis, prolactinomas, hypertension, hypertriglyceridemia, cardiovascular disease, type 2 diabetes, liver disease, and decreased libido and are at increased risk of breast cancer. Spironolactone can lead to hyperkalemia and decreased blood pressure.

- FTM patients receiving testosterone may develop hyperlipidemia, polycythemia, male pattern baldness, acne, cardiovascular disease, hypertension, type 2 diabetes, breast cancer, cervical cancer, ovarian cancer, uterine cancer, destabilization of certain psychiatric disorders (i.e. bipolar, schizoaffective disorders (Hembree et al.,2009; Tangpricha, 2016)

Monitoring for FTM on hormone therapy:

- Monitor for virilizing and adverse effects every 3 months for first year and then every 6 ï 12 months.
- Monitor serum testosterone at follow-up visits with a practical target in the male range (300 ï 1000 ng/dl). Peak levels for patients taking parenteral testosterone can be measured 24 ï 48 h after injection. Trough levels can be measured immediately before injection.
- Monitor hematocrit and lipid profile before starting hormones and at follow-up visits.

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- Bone mineral density (BMD) screening before starting hormones for patients at risk for osteoporosis. Otherwise, screening can start at age 60 or earlier if sex hormone levels are consistently low.
- FTM patients with cervixes or breasts should be screened appropriately. ***(site reference)***
- Monitor renal function, liver function tests fasting glucose, insulin, hemoglobin A1C, bone density and bone age.
- FTM patients should have axillary lymph nodes examined (Gooren et al., 2008; Jain & Bradbeer, 2007; Sobralske, 2005).

Monitoring for MTF on hormone therapy:

- Monitor for feminizing and adverse effects every 3 months for first year and then every 6ï 12 months.
- Monitor serum testosterone and estradiol at follow-up visits with a practical target in the female range (testosterone 30 ï 100 ng/dl; E2 <200 pg/ml).
- Monitor prolactin and triglycerides before starting hormones and at follow-up visits.
- Monitor potassium levels if the patient is taking spironolactone.
- Bone mineral density screening before starting hormones for patients at risk for osteoporosis. Otherwise, start screening at age 60 or earlier if sex hormone levels are consistently low.
- MTF patients should be be advised to do breast self-exams and be screened for breast and prostate cancer appropriately. Breast self exams should be advised (Gooren et al., 2008; Jain & Bradbeer, 2007; Sobralske, 2005).

COVERAGE POLICY

Federal Regulations

Federal regulations for Medicaid specify that a state may limit coverage of a drug with respect to the treatment of a specific disease or condition for an identified population (if any) based on the drugôs labeling, if it does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary. In addition, states may exclude a drug when the prescribed use of the drug is not for a medically accepted indication, either approved by the FDA or supported by information from the appropriate compendia. These guidelines apply to a stateôs administration of its Medicaid prescribed drug benefit in both managed care and non-managed care delivery systems.

States are also required to implement a drug use review program for covered outpatient drugs in order to assure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical results. The program is required to assess data on drug use against predetermined standards, consistent with the following:

- Compendia, consisting of the following:
    1. American Hospital Formulary Service Drug Information;
    2. United States Pharmacopeia-Drug Information (or its successor publications); and
    3. the DRUGDEX Information System; and
- The peer-reviewed medical literature.

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Federal law requires states to provide services to eligible recipients under the age of 21 years, if such services are medically necessary to correct or ameliorate a defect, a condition, or a physical or mental illness. This is known as the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit. Included are diagnostic services, treatment, equipment, supplies, and other measures described in section 1905(a) of the Social Security Act, codified in Title 42 of the United States Code 1396d (a). As such, services for recipients under the age of 21 years exceeding any coverage limitations specified within a state's policies maybe approved, if medically necessary.

Florida Medicaid

In order to be reimbursed by Florida Medicaid, a drug must be medically necessary and either (a) prescribed for medically accepted indications and dosages found in the drug labeling or drug compendia in accordance with section 1927(k) (6) of the Social Security Act, or (b) prior authorized by a qualified clinical specialist approved by the Agency for Health Care Administration (Agency).

The criteria that are utilized under the Florida Medicaid program in the authorization of drugs for off-label purposes are as follows:

1. Documentation submitted with trial and failure or intolerance to all FDA- approved medications for the indication **AND**
2. Phase III clinical studies published in peer review journals to support the non-FDA approved use **AND**
3. Usage supported by publications in peer reviewed medical literature **and** one or more citations in at least one of the following compendia:
    a. American Hospital Formulary Service Drug Information (AHFS)
    b. United States Pharmacopeia-Drug Information (or its successor publications)
    c. DRUGDEX Information System

Florida Medicaid covers hormone therapy for all FDA approved indications/uses or when the information in the appropriate compendium supports the use of the drug in the treatment of the specific disease state or condition. Testosterone and estrogen are not FDA approved for cross-sex hormone therapy in patients with gender dysphoria. However, DRUGDEX Information System's compendia addresses off-label use of testosterone cypionate, conjugated estrogens, 17-beta estradiol and ethinyl estradiol in the use of cross-sex hormone therapy.

Children/adolescents diagnosed with gender dysphoria are also eligible to receive an array of other medical and behavioral health interventions (e.g., individual and family therapy, psychological evaluations/assessments, other medical evaluation and management services) necessary to address their presenting signs and symptoms.

Health plans contracted to provide services under the Florida Medicaid Statewide Medicaid Managed Care program are required to cover all prescription drugs listed in the Agency's Medicaid Preferred Drug List (PDL). In addition, the health plan's prior authorization criteria and protocols may not be more restrictive than those used by the Agency as indicated in the Florida Statutes, the Florida Administrative Code, the Medicaid State Plan and those posted on the Agency website.

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Florida Medicaid provides services to eligible recipients under the age of 21 years, if such services are medically necessary to correct or ameliorate a defect, a condition, or a physical or mental illness. Medical necessity in the State of Florida must meet the following conditions:

1. Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
2. Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patientôs needs;
3. Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational;
4. Be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide; and
5. Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

If a service exceeds the coverage described within a Florida Medicaid policy or the associated fee schedule, a request (along with all supporting documentation) may be submitted to the Agency or its designee for review.

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https://www.modahealth.com/pdfs/med_criteria/GenderReassignment.pdf

Fallonhealth: Transgender Services Clinical Coverage Criteria
http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=20&ved=0ahUKEwjeharT6ubOAhVH5iYKHZYfAIg4ChAWCF8wCQ&url=http%3A%2F%2Fwww.fchp.org%2Fproviders%2Fmedical-management%2F~%2Fmedia%2FFiles%2FProviderPDFs%2FMedicalPolicies%2FTransgenderServices.ashx&usg=AFQjCNHGumXLS82ivBfVGHDP6bXEeJOdbQ

Blue regence Transgender Services Policy
http://blue.regence.com/trgmedpol/medicine/med153.pdf

GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS RECOMMENDATION

Cross-sex hormone therapy may be considered a health service that is consistent with generally accepted professional medical standards for the approved FDA indications (i.e., hypogonadism, hypoestrogenism) and for off-label use when supported by citations in at least one of the compendia. Since Florida Medicaid already provides coverage of hormone therapy in the FDA approved indications and for use in treating the conditions cited in the compendia, no further policy coverage analyses are needed to supplement this report on this point.

Based upon the available published literature, cross-sex hormone therapy should be considered a health service that is consistent with generally accepted professional medical standards in the treatment of gender dysphoria. Most of the studies published thus far on the use of cross-sex hormone therapy in gender dysphoric children/adolescents have concluded that further systematic research is required to determine the long-term safety and efficacy of this approach. The guidelines for transgender patients in the Endocrine Society and WPATH are controversial because they are based primarily on expert opinion rather than scientific data, given the paucity of the outcomes data on the effects of mental health and medical interventions (Vance, Ehrensaft, and Rosenthal, 2014). However, the standards of care for cross-sex hormone therapy seem to be consistent in the approach with diagnosis, monitoring and dosing of the transgender patients. Indeed, hormone therapy and surgery have been found to be medically necessary to alleviate gender dysphoria in many people (American Medical Association, 2008; Anton, 2009; Tangpricha, 2016) Regimens for hormone therapy in gender dysphoric adolescents differ substantially from those used in adults. The hormone regimens for youth are adapted to account for the somatic, emotional, and mental development that occurs throughout adolescence (Hembree et al., 2009). As the research on this topic continues to evolve, more conclusive evidence may emerge that supports the long-term efficacy and effectiveness of this treatment approach.

Document ID: 0.7.322.6653-000001

EPSDT Considerations:

Clinical guidelines from the Endocrine Society and WPATH recommend this therapy for certain adolescents, albeit based upon weak evidence. In certain circumstances, the risks of not treating an adolescent may be worse than the potential long-term consequences of treatment. Moreover, it is noted extensively in the literature that adolescents contending with gender dysphoria often experience a myriad of emotional, physical, and societal challenges. Unresolved, the distress can manifest into a host of behavioral health problems including depression, anxiety, and suicidal ideation and self-mutilation. Florida pays for services for children when they protect life and /or prevent significant disability or harm, in accordance with the stateôs medical necessity definition.

Testosterone cypionate, conjugated estrogens, 17-beta estradiol and ethinyl estradiol have documented off-label use in DRUGDEX. Because of this supporting documentation in the compendia, the off-label criteria could be used to evaluate each patient on a case by case basis. This report recommends cross-sex hormone therapy as a health service that is consistent with generally accepted professional medical standards. Consistent with EPSDT requirements, the request can be evaluated on an individualized basis to determine if the service is medically necessary (e.g. it is administered to protect life and/or prevent significant disability, such as to prevent suicide or self-mutilation) to ensure that all less invasive interventions have been exhausted, and to ensure that this treatment approach presents as the best alternative given the adolescentôs psychological state and presenting signs and symptoms.

____ Concur **____ Do Not Concur**

Comments:

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Signature Date

Deputy Secretary for Medicaid (or designee)

Document ID: 0.7.322.6653-000001

RICK SCOTT
GOVERNOR

JUSTIN M. SENIOR
SECRETARY

CROSS-SEX HORMONE THERAPY
GAPMS DETERMINATION REPORT WITH RECOMMENDATION

Date: {DATE}
To: Beth Kidder, Deputy Secretary for Medicaid
From: Bureau of Medicaid Policy
Subject: **Cross-Sex Hormone Therapy**

PURPOSE

In order for the use of cross-sex hormone therapy to be covered under the Florida Medicaid program, it must meet medical necessity criteria as defined in Rule 59G-1.010, Florida Administrative Code (F.A.C.), and be funded through the General Appropriations Act of Chapter 216, Florida Statutes.

Pursuant to the criteria set forth in Rule 59G-1.010, F.A.C., the use of cross-sex hormone therapy must be consistent with generally accepted professional medical standards (GAPMS) as determined by the Medicaid program, and not experimental or investigational.

In accordance with the determination process established in Rule 59G-1.035, F.A.C., the Deputy Secretary for Medicaid will make the final determination as to whether the use of cross-sex hormone therapy is consistent with generally accepted professional medical standards and not experimental or investigational.

If it is determined that cross-sex hormone therapy is consistent with generally accepted professional medical standards, this report will be supplemented with an addendum which analyzes additional factors to determine whether this health service should be covered under the Florida Medicaid program.

RECOMMENDATION

This report recommends cross-sex hormone therapy as a health service that is consistent with generally accepted professional medical standards, and is supported in compendia as off-label use. There are clinical guidelines that have been published for the use of cross-sex hormones by the Endocrine Society, September 2009 and the World Professional Association for Transgender Health (WPATH 7th version). These guidelines are considered standards of care for transgender patients and provide parameters to determine the diagnosis of gender dysphoria, at what age to start treatment of cross-sex hormone therapy, and monitoring parameters that should be in place during treatment.

The Centers for Medicare and Medicaid Services (CMS), many commercial and Medicaid plans have protocols in place to provide access of the use of cross-sex hormone therapy in transgender patients.

Pl. Trial Ex. 238

REPORT WITH RECOMMENDATION

This report with recommendation is presented as the summary assessment considering the factors identified in Rule 59G-1.035, F.A.C., based on the collection of information from credible sources of reliable evidence-based information. The intent is to provide a brief analysis with justification in support of the final recommendation.

The analysis described in this report includes:

- A high level review of relevant disease processes.
- An overview of the health service information.
- Clearance from the government regulatory body (e.g., Food and Drug Administration).
- Evidence based clinical practice guidelines.
- A review of the literature considered by the relevant medical community or practitioner specialty associations from credible scientific evidence-based literature published in peer reviewed journals.
- Consensus of coverage policy from commercial and other state Medicaid insurers.

HEALTH SERVICE SUMMARY

Reproductive Hormones

The hormones commonly considered as reproductive hormones in the body are testosterone, estrogen, and progesterone. Testosterone is often referred to as a male hormone, and estrogen and progesterone are often referred to as female hormones. However, there are no exclusively male or female hormones that have been identified. The physical manifestations of gender result from differences in the amounts of individual hormones in the body and differences in their patterns of secretion, first in utero and then again during puberty. In other words, testosterone, estrogen, and progesterone are produced by men and women, but in differing amounts and in different patterns.

Cross-Sex Hormone Therapy

Cross-sex hormone therapy assists transgender patients to reflect the desired sex through physical changes. This is accomplished by increasing the testosterone in Female to Male (FTM) patients, in conjunction with suppressing the estrogen in their bodies. Male to Female (MTF) patients' testosterone levels are suppressed while their estrogen levels are increased.

Currently, there are drugs approved by the FDA that increases testosterone in men with hypogonadism and increase estrogen in women for various approved indications in addition to men with advanced prostate cancer (*Analytics, 2016*). Estrogen and testosterone are the medications mainly used in cross-sex hormone therapy. FTM patients, are prescribed testosterone, unless contraindicated. MTF patients, are prescribed estrogen, unless contraindicated (*Levine, 2013*). Anti-androgen agents may be used in conjunction with cross-sex hormone therapy, such as: progestins, gonadotropin releasing hormone agonists (GnRH), spironolactone, or 5-alpha reductase inhibitors.

Testosterone has a variety of routes of administration: buccal, intramuscular (IM), topical, transdermal, and intranasal. The oral formulation of testosterone is not available in the United States. FTM patients most commonly use transdermal/topical, or IM routes of administration because it provides better hormone levels. Estrogen also has various routes of administration

available: transdermal, vaginal, spray, oral and intramuscular. The most common route of administration for MTF: oral, IM or transdermal (*Tangpricha, 2016*). For the purposes of this report, an analysis is being performed on the use of cross-sex hormone therapy concentrating on testosterone and estrogen.

Government Regulatory Body Approval

The Food and Drug Administration (FDA) has approved testosterone for hypogonadism in men and estrogen is approved in women for various indications (see below) and for men with advanced prostate cancer. The available formulations of testosterone are testosterone cypionate, testosterone enanthate and testosterone undecanoate. The available formulations of estrogen are conjugated estrogens, esterified estrogens, estradiol, estradiol acetate, estradiol cypionate and estradiol valerate.

Testosterone:

- Indications for use: Primary hypogonadism or hypogonadotropic hypogonadism in men.
- Off Label Use: various doses used in clinical trials, including testosterone cypionate 200mg IM every 2 weeks for gender identity disorder FTM transsexual (*Analytics, 2016*).
- Possible side effects of testosterone FTM therapy: acne, polycythemia, dyslipidemia, transaminitis, weight gain, hypertension and mood lability. After 6 to 8 weeks of hormone treatment of testosterone, deepening of the voice occurs and is irreversible (*Gibson et al., 2010*).

Estrogen:

- Indications for use: Advanced prostate cancer- androgen dependent men, metastatic breast cancer, lower than normal estrogen levels in women, prevention of osteoporosis (postmenopausal),vulvovaginal atrophy (menopausal), and moderate to severe menopausal vasomotor symptoms.
- Off Label use: Conjugated estrogens, 17-beta estradiol and ethinyl estradiol may be effective in changing the physical external appearance for MTF transsexuals (*Analytics, 2016*).
- Side effects of estrogen in MTF therapy: decreased facial and body hair, fat redistribution, decreased spontaneous erections, softened skin, growth of breast tissue, and growth plate closure, increased risk of thromboembolic disease, liver dysfunction, cholelithiasis, hypertension, and hyperprolactinemia. Breast development will begin almost immediately upon estrogen administration, will proceed in a cyclical fashion, and will be as large as can be expected after approximately two years of treatment.

LITERATURE REVIEW

Gender Dysphoria

The Diagnostic and Statistical Manual of Mental Disorders defines gender dysphoria (GD) (formally referred to as gender identity disorder) as an individual's affective or cognitive discontent with their assigned gender at birth. GD refers to the ***distress*** that may accompany the incongruence between the individual's experienced or expressed gender and their assigned gender. Evidence of this distress is the hallmark of the disorder. The diagnostic criteria are divided into a category for children and a category for adolescents and adults. The disorder is manifested differently as the individual ages or enters different developmental stages. Both categories require marked incongruence between the individual's experienced or expressed gender and their assigned gender of at least a six months' duration and clinically significant distress or impairment in social, school (occupation for adults), or other important areas of functioning (*Association, 2014*).

Diagnostic criteria in children include: a strong desire to be the other gender or an insistence that they are the other gender; a preference for wearing clothing associated with the other gender; preference for cross gender roles in simulated play; preference for toys, games, or activities usually associated with the other gender; preference for playmates of the other gender; and the dislike of their sexual anatomy. Studies have shown that the majority of children (80%) diagnosed with gender dysphoria will not continue to be gender dysphoric after puberty (*Moller et al., 2009; Wallien & Cohen-Kettenis, 2008; and Drummond et al., 2008*).

For the 20% of children who persist in their feelings of gender dysphoria, clinicians may begin to explore alternative treatment approaches beyond psychotherapy after the onset of puberty, including medical interventions such as the use of GnRH analogs to suppress puberty. It is generally introduced in children who have reached a minimum of Tanner Stage 2 (a scale used to determine physical development in children, adolescents and adults based on external primary and secondary sex characteristics) which is usually at the age of 12-16 (*Cohen-Kettenis et al., 2011*). Other drugs, such as progestins and antiandrogens (spironolactone and 5-alpha reductase inhibitors) have been used to suppress physical changes in puberty. In addition to puberty suppression therapy, a physician may also begin to prescribe cross-sex hormones, though the latter does not generally begin until the ages of 16-18 (*de Vries et al., 2011*).

Cross-sex hormone therapy is the primary medical intervention sought by transgender people. Exogenous hormones have a clear impact on fertility. Patients must be informed and counseled regarding options for fertility and evaluation of medical conditions that can be exacerbated by hormone depletion, prior to treatment with sex hormones of the desired sex in both adolescents and adults. The patient must be made aware of the possibility of infertility/sterilization with the use of cross-sex hormone therapy. Fertility preservation options may include sperm, oocyte, embryo, ovarian tissue or testicular tissue cryopreservation. Transgender patients who undergo fertility preservation or assisted reproduction should be informed of the lack of data on outcomes. The use of cross-sex hormone therapy alone does not guarantee prevention of pregnancy, therefore if sexually active, contraception is required. Testosterone can cause birth defects and is contraindicated in pregnancy. The effects of long term exogenous testosterone and estrogen are unclear, but the possible side effects should be addressed (*Francisco, Center, and Information, 2016*).

It is important to note that most of the literature reviewed in development of this analysis concluded that more systematic research is required to determine the long-term efficacy of medical treatment for adolescents with gender dysphoria (*Kaltiala-Heino et al., 2015; Jarin et al., 2016; Lee et al., 2016, March et al., 2015; Vance et al., 2014; Vrouenraets et al., 2015*) .

Clinical Outcome

No perspective, randomized, controlled trials were located that have evaluated the safety and efficacy of the use of cross-sex hormones to produce physical effects in transgender patients. The current information used has been derived primarily from observational study or has been extrapolated from the use of hormones for the approved FDA indications (Tangpricha, 2016).

This analysis summarizes information obtained from scientific literature published in credible peer-reviewed journals related to the use of cross-sex hormone therapy. This section also briefly cites the positions from the relevant medical societies, and summarizes the key articles referenced in support of their positions.

Recommendations from The Endocrine Society Guidelines are as follows:

- We recommend that the diagnosis of gender identity disorder (GID) be made by a mental health professional (MHP). For children and adolescents, the MHP should also have training in child and adolescent developmental psychopathology.
- Given the high rate of remission of GID after the onset of puberty, we recommend against a complete social role change and hormone treatment in pre-pubertal children with GID.
- We recommend that physicians evaluate and ensure that applicants understand the reversible and irreversible effects of hormone suppression (e.g. GnRH analog treatment) and cross-sex hormone treatment before they start hormone treatment.
- We recommend that all transsexual individuals be informed and counseled regarding options for fertility prior to initiation of puberty suppression in adolescents and prior to treatment with sex hormones of the desired sex in both adolescents and adults.
- We suggest that pubertal development of the desired opposite sex be initiated at about the age of 16 year, using a gradually increasing dose schedule of cross-sex steroids.
- We recommend referring hormone-treated adolescents for surgery when 1) the real-life experience (RLE) has resulted in a satisfactory social role change; 2) the individual is satisfied about the hormonal effects; and 3) the individual desires definitive surgical changes.
- We suggest that treatment with GnRH analogs be continued during treatment with cross-sex steroids to maintain full suppression of pituitary gonadotropin levels and, thereby, gonadal steroids. When puberty is initiated with a gradually increasing schedule of sex steroid doses, the initial levels will not be high enough to suppress endogenous sex steroid secretion.
- Baseline labs and scheduled routine monitoring for known risks throughout adulthood
- Maintain physiologic levels of appropriate sex hormones in the range of the desired gender and monitor for known risks of gender-appropriate sex hormones.
- Lifetime continuation of cross-sex hormone therapy usually required unless medically contraindicated (*Hembree et al., 2009*).

WPATH Version 7 Standard of Care recommendations for Cross-Sex Hormone therapy:

- Persistent, well-documented diagnosis of gender dysphoria.
- Capacity to make a fully informed decision and to consent for treatment.
- If significant medical or mental health concerns are present, they must be reasonably well controlled.
- A mental health professional competent in diagnosing and treating ordinary problems of children and adolescents; trained in childhood and adolescent developmental psychopathology; and must meet the competency requirements for mental health professionals working with adults.
- A staged process of physical interventions of adolescents is recommended to allow the adolescents and their parents to assimilate fully the effects of earlier interventions: fully reversible interventions (i.e. GnRH analogues, spironolactone, progestins) partially reversible interventions (i.e. hormone therapy to masculinize or feminize the body, cross-sex hormones) and irreversible interventions (surgical procedures).
- Adolescents may be eligible to begin feminizing/masculinizing hormone therapy preferably with parental consent at 16.
- Regimens for hormone therapy in gender dysphoric adolescents differ substantially from those used in adults (*Hembree et al., 2009*).
- The hormone regimen is adjusted to account for emotional, somatic and mental development that occurs throughout adolescence.

Possible risk Factors associated with Cross-Sex Hormone therapy:

- Adolescents undergoing partially reversible cross-sex hormone therapy should be monitored for progress in transition and for any potential medical complications.

- Male to Female (MTF) patients started on estrogen might develop deep venous thrombosis, prolactinomas, hypertension, hypertriglyceridemia, cardiovascular disease, type 2 diabetes, liver disease, and decreased libido and are at increased risk of breast cancer. Spironolactone can lead to hyperkalemia and decreased blood pressure.

- Female to Male (FTM) patients receiving testosterone may develop hyperlipidemia, polycythemia, male pattern baldness, acne, cardiovascular disease, hypertension, type 2 diabetes, breast cancer, cervical cancer, ovarian cancer, uterine cancer, destabilization of certain psychiatric disorders (i.e. bipolar, schizoaffective disorders (*Hembree et al., 2009; Tangpricha, 2016*).

Monitoring for FTM on hormone therapy:

- Monitor for virilizing and adverse effects every 3 months for first year and then every 6 – 12 months.
- Monitor serum testosterone at follow-up visits with a practical target in the male range (300 – 1000 ng/dl). Peak levels for patients taking parenteral testosterone can be measured 24 – 48 h after injection. Trough levels can be measured immediately before injection.
- Monitor hematocrit and lipid profile before starting hormones and at follow-up visits.

- Bone mineral density (BMD) screening before starting hormones for patients at risk for osteoporosis. Otherwise, screening can start at age 60 or earlier if sex hormone levels are consistently low.
- FTM patients with cervixes or breasts should be screened appropriately.
- Monitor renal function, liver function tests, fasting glucose, insulin, hemoglobin A1C, bone density and bone age.
- FTM patients should have axillary lymph nodes examined (*Gooren et al., 2008; Jain & Bradbeer, 2007; Sobralske, 2005*).

Monitoring for MTF on hormone therapy:

- Monitor for feminizing and adverse effects every 3 months for first year and then every 6– 12 months.
- Monitor serum testosterone and estradiol at follow-up visits with a practical target in the female range (testosterone 30 – 100 ng/dl; estradiol <200 pg/ml).
- Monitor prolactin and triglycerides before starting hormones and at follow-up visits.
- Monitor potassium levels if the patient is taking spironolactone.
- Bone mineral density screening before starting hormones for patients at risk for osteoporosis. Otherwise, start screening at age 60 or earlier if sex hormone levels are consistently low.
- MTF patients should be be advised to do breast self-exams and be screened for breast and prostate cancer appropriately. Breast self-exams should be advised (*Gooren et al., 2008; Jain & Bradbeer, 2007; Sobralske, 2005*).

COVERAGE POLICY

Federal Regulations

Federal regulations for Medicaid specify that a state may limit coverage of a drug with respect to the treatment of a specific disease or condition for an identified population (if any) based on the drug's labeling, if it does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary or preferred drug list. In addition, states may exclude a drug when the prescribed use of the drug is not for a medically accepted indication, either approved by the FDA or supported by information from the appropriate compendia. These guidelines apply to a state's administration of its Medicaid prescribed drug benefit in both managed care and non-managed care delivery systems.

States are also required to implement a drug use review program for covered outpatient drugs in order to assure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical results. The program is required to assess data on drug use against predetermined standards, consistent with the following:

- Compendia, consisting of the following:
  - American Hospital Formulary Service Drug Information;
  - United States Pharmacopeia-Drug Information (or its successor publications); and
  - the DRUGDEX Information System; and
- The peer-reviewed medical literature.

Federal law requires states to provide services to eligible recipients under the age of 21 years, if such services are medically necessary to correct or ameliorate a defect, a condition, or a physical or mental illness. This is known as the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit. Included are diagnostic services, treatment, equipment, supplies, and other measures described in section 1905(a) of the Social Security Act, codified in Title 42 of the United States Code 1396d (a). As such, services for recipients under the age of 21 years exceeding any coverage limitations specified within a state's policies may be approved, if medically necessary.

Florida Medicaid

In order to be reimbursed by Florida Medicaid, a drug must be medically necessary and either (a) prescribed for medically accepted indications and dosages found in the drug labeling or drug compendia in accordance with section 1927(k) (6) of the Social Security Act, or (b) prior authorized by a qualified clinical specialist approved by the Agency for Health Care Administration (Agency).

The criterion that is utilized under the Florida Medicaid program in the authorization of drugs for off-label purposes are as follows:

- Documentation submitted with trial and failure or intolerance to all FDA- approved medications for the indication.
- Phase III clinical studies published in peer review journals to support the non-FDA approved use.
- Usage supported by publications in peer reviewed medical literature **and** one or more citations in at least one of the following compendia:
  - American Hospital Formulary Service Drug Information (AHFS)
  - United States Pharmacopeia-Drug Information (or its successor publications)
  - DRUGDEX Information System

Florida Medicaid covers hormone therapy for all FDA approved indications/uses or when the information in the appropriate compendium supports the use of the drug in the treatment of the specific disease state or condition. Testosterone and estrogen are not FDA approved for cross-sex hormone therapy in patients with gender dysphoria. However, DRUGDEX Information System's compendia addresses off-label use of testosterone cypionate, conjugated estrogens, 17-beta estradiol and ethinyl estradiol in the use of cross-sex hormone therapy.

Children/adolescents diagnosed with gender dysphoria are also eligible to receive an array of other medical and behavioral health interventions (e.g., individual and family therapy, psychological evaluations/assessments, other medical evaluation and management services) necessary to address their presenting signs and symptoms.

Health plans contracted to provide services under the Florida Medicaid Statewide Medicaid Managed Care program are required to cover all prescription drugs listed in the Agency's Medicaid Preferred Drug List (PDL). In addition, the health plan's prior authorization criteria and protocols may not be more restrictive than those used by the Agency as indicated in the Florida Statutes, the Florida Administrative Code, the Medicaid State Plan and those posted on the Agency website.

Florida Medicaid provides services to eligible recipients under the age of 21 years, if such services are medically necessary to correct or ameliorate a defect, a condition, or a physical or mental illness. Medical necessity in the State of Florida must meet the following conditions:

- Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
- Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs;
- Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational;
- Be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide; and
- Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

If a service exceeds the coverage described within a Florida Medicaid policy or the associated fee schedule, a request (along with all supporting documentation) may be submitted to the Agency or its designee for review.

Centers for Medicare and Medicaid Services

A new rule by the Department of Health and Human Services implements Section 1557 of the Affordable Care Act (ACA), "Nondiscrimination in Health Programs and Activities." This rule applies to all health programs that receive federal funding or assistance, including state Medicaid agencies, as well as most health insurance issuers. On July 18, 2016, other provisions went into effect related to discrimination, based on gender identity, pregnancy, or transgender status. Individuals must be provided equal access to health services without discrimination related to gender or identity. Entities can still review for medical necessity as long as the review is not discriminatory towards these individuals and utilizes a neutral rule or principal. Categorical exclusion or limits on services related to gender transition are discriminatory as well.

Medicare

Transgender beneficiaries can use hormone therapy, which are reimbursable under the Medicare Part D prescription drug benefit program. The *Medicare Benefit Policy Manual*, Chapter 15, page 15, subsection 50.4.2, discusses the unlabeled use of a drug. The policy states that "FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice." Medicare provides a special billing code (condition code 45) when gender mis-match claims may be a problem.

State Medicaid Programs

All state Medicaid programs cover hormone therapy for the approved FDA indications and when the criteria for off-label use are met. Some state Medicaid programs are also adopting coverage policies that allow for reimbursements of cross-sex therapy in adolescents diagnosed with gender dysphoria. This report highlights the coverage policies for some Medicaid programs that do cover the service, as follows:

- Colorado Medicaid covers behavioral health services, GnRH analogs/agonists, cross-sex hormone therapy, gender confirmation surgery, and pre and post-operative care.
- Maryland Medicaid covers cross-sex hormone therapy for recipients 18 and older.
- Rhode Island Medicaid covers behavioral health services, pharmacological and hormonal therapy to delay physical changes of puberty, and pharmacological and hormonal therapy that is non-reversible and produces masculinization or feminization. Some services require prior authorization.
- Washington State Medicaid covers behavioral health services, puberty suppression therapy, hormonal therapy, and gender reassignment surgery. Policy has been implemented since February 2014 regarding access to care.
- California, New York and Massachusetts Medicaid are obligated to pay for gender transition.
- Oregon Medicaid covers cross-sex hormone therapy for adolescents and adults who meet eligibility and readiness criteria.
- Montana Medicaid covers cross-sex hormone therapy for transgender recipients. Testosterone requires a prior authorization to ensure treatment is for appropriate diagnoses.
- Indiana Medicaid covers cross-sex hormone therapy for gender dysphoric recipients.
- Illinois Medicaid removed gender restrictions on estradiol and testosterone in April 2015 referencing the Endocrine Society recommendations.

Private Insurers:

The following private insurers have criteria in place to access medications for cross-sex hormone therapy:

- Moda Health Plan Inc., Gender Reassignment Medical Necessity:
- Fallon Health, Transgender Services Clinical Coverage Criteria
- Blue Regence Transgender Services Policy

GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS RECOMMENDATION

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DRAFT

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___ Concur **____ Do Not Concur**

Comments:

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Signature Date

Deputy Secretary for Medicaid (or designee)

DRAFT

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RICK SCOTT
GOVERNOR

JUSTIN M. SENIOR
SECRETARY

Gender Confirmation Surgery
GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS (GAPMS)
DETERMINATION REPORT WITH RECOMMENDATION

Date: July 19, 2017

To: Beth Kidder, Deputy Secretary for Medicaid

From: Bureau of Medicaid Policy

Subject: **Gender Confirmation Surgery**

PURPOSE

In order for the use of gender confirmation surgery to be covered under the Florida Medicaid program, it must meet medical necessity criteria as defined in Rule 59G-1.010, Florida Administrative Code. (F.A.C.), and be funded through the General Appropriations Act of Chapter 216, Florida Statutes (F.S.).

Pursuant to the criteria set forth in 59G-1.010, F.A.C., the use of gender confirmation surgery must be consistent with generally accepted professional medical standards (GAPMS) as determined by the Medicaid program, and not experimental or investigational.

In accordance with the determination process established in rule 59G-1.035, F.A.C., the Deputy Secretary for Medicaid will make the final determination as to whether gender confirmation surgery is consistent with generally accepted professional medical standards and not experimental or investigational.

If it is determined that gender confirmation surgery is consistent with generally accepted professional medical standards, this report will be supplemented with an addendum which analyzes additional factors to determine whether this health service should be covered under the Florida Medicaid program.

REPORT WITH RECOMMENDATION

This report with recommendation is presented as the summary assessment considering the factors identified in 59G-1.035, F.A.C. based on the collection of information from credible sources of reliable evidence-based information. The intent is to provide a brief analysis with justification in support of the final recommendation.

The analysis described in this report includes:

- A high-level review of relevant disease processes
- An overview of the health service information
- Clearance from the government regulatory body (e.g. U.S. Food and Drug Administration)

Pl. Trial Ex. 238

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Transgender people are frequently victims of discrimination, including mistreatment by health care professionals, rejection, and harassment in places of public accommodation. Discrimination can occur when accessing housing, health care, employment, education, public assistance, and other social services. These negative experiences worsen health disparities, such as depression, anxiety, exposure to violence, and HIV infection, which are already disproportionately high in this population. For example, a transgender individual facing homelessness or employment discrimination may engage in survival sex (exchanging sex for food, clothing, shelter, or other basic needs), increasing their risk for exposure to violence and HIV infection. Transgender individuals who are also low income, of color, or members of other marginalized communities face even higher rates of discrimination and disparities (Baker, 2017; American Psychological Association, 2015; American College of Obstetricians and Gynecologists, 2011; World Health Organization, 2017). The transgender population also experiences an extremely high prevalence of suicidal ideation and suicide attempts. Across the United States, Europe, and Canada, studies have shown prevalence rates of suicide attempts among transgender individuals to range from 22-43% over a lifetime and 9-10% in the previous year. In comparison, just 0.6% of the general Canadian population reported a previous year attempt (Bauer, Scheim, Pyne, Travers, & Hammond, 2015).

Treatment

Treatment, according to the WPATH (2016), can include legal name and sex or gender change on identity documents, medically necessary hormone treatment, counseling, psychotherapy, and other medical procedures required to effectively address an individual's gender dysphoria. The WPATH emphasize that not every patient will have a medical need for identical procedures and clinically appropriate treatments must be determined on an individualized and contextual basis in consultation with the patient's medical providers. For adolescents, treatment may also include pubertal delay (de Vries, McGuire, Steensman, Wagenaar, Doreleijers, & Cohen-Kettenis, 2014). This report will focus on individuals age 18 and older. It is important to note that not all transgender individuals pursue medical or surgical treatment (American Academy of Family Physicians, 2016; American Academy of Pediatrics, 2013), as not everyone with gender nonconforming behavior experiences distress or suffering (Selvaggi et al., 2012). Some people are able to realize their gender identity without surgery, but for others, gender confirmation surgery is an essential, medically necessary step to treat their gender dysphoria (Hess et al., 2014). In 2015, the prevalence of gender confirmation surgery was reported to be 1 in 100,000 (or approximately 3,000-9,000) in the United States (Padula, Heru, & Campbell, 2015), though the transgender population is estimated at 1.4 million adults (Baker, 2017). Genital surgery for FtM patients is performed in only about a third of transgender males (Barrett, 2014). For those who do seek treatment, access to affordable, culturally competent, and reliable health care has been shown to reduce negative health outcomes, such as psychological distress, substance use, HIV vulnerability, suicidal ideation, suicide attempt, suicide, and homicide (American Public Health Association, 2016).

Hormone Therapy

Cross-sex hormones for male-to-female (MtF) individuals include estrogen alone or in combination with spironolactone. Female-to-male (FtM) individuals are prescribed testosterone. The Endocrine Society published guidelines for initiating and monitoring transgender hormone therapy in 2009. Risks associated with hormone therapy include cancer, hypertension, thrombosis, weight changes, hyperkalemia, and polycythemia. The risks are the same for transgender individuals and for biological males and females receiving hormone therapy for other purposes. However, the risks of cross-sex hormone therapy stem from and are worsened by inadvertent or intentional use of excessive doses of sex hormones or inadequate doses to

notification procedures prior to commercial distribution, supplying information pertaining to safety and effectiveness through a 510(k) summary (FDA, 2016).

LITERATURE REVIEW

This analysis summarizes information obtained from scientific literature published in credible peer-reviewed journals related to gender confirmation surgery. This section also briefly cites the positions from the relevant medical societies.

Psychological Outcomes

Much ~~research has evaluated psychological outcomes and quality of life following gender confirmation surgery.~~ Duišin, Batinić, Barišić, Djordjevic, Vujović, and Bizic (2014) stated gender confirmation surgery has proven to be an effective intervention for people with gender dysphoria, as confirmed by multiple follow-up studies reporting high levels of postsurgical satisfaction and improvements in quality of life and general functioning. After analyzing surgical outcomes and reviewing available literature, Rossi Neto, Hintz, Krege, Rübben, and vom Dorp (2012) concluded surgical outcomes have a positive impact on patient quality of life due to improved social relationships and psychological/psychiatric functioning, and that gender confirmation surgery is the best treatment option for gender dysphoria. Costa and Colizzi (2016) report the literature has shown gender confirmation procedures appear to be beneficial in reducing mental distress. The Endocrine Society (2009) indicates the mental health of individuals undergoing these surgeries seems to be improved by participating in a treatment program that includes hormones and surgery. Meriggiola et al. (2010) state medical and surgical sex reassignments represent effective treatment. Early and prompt treatment of gender dysphoria seems to be associated with better outcomes (Barrett, 2014; de Vries et al., 2014). Lowenberg, Lax, Rossi Neto, and Krege (2010), as reported in Hess et al. (2014) found that even though just 69% of patients were satisfied with their overall life situation following gender confirmation surgery, 96% would opt for surgery again. Rotondi et al. (2013) state medical and social transitioning is important and necessary in order to maximize health, personal safety, psychological well-being, and self-fulfillment, as non-treatment of transgender patients is associated with worsening psychological outcomes. Barriers to transition-related health care can result in the use of nonprescribed hormones and "do-it-yourself" surgeries, such as removal of testes or breasts.

Research shows that gender confirmation surgeries reduce psychological distress and improve quality of life. Birkett, Newcomb, and Mustanski (2015) conducted a longitudinal study among LGBTQ youth to characterize trajectories of psychological distress and victimization. Results were consistent with minority stress theory, which suggests that increased victimization and other stigma-related stressors might influence chronic stress and coping. Social support was significantly associated with lower levels of psychological distress, but prior social support did not have a significant impact on later levels of psychological distress, indicating supportive relationships might not be enough to buffer psychological distress if experiences of victimization continue. De Vries et al. (2014) reported on young adult psychological outcomes after puberty suppression and gender confirmation surgery performed between 2008-2012. The authors found that not only was gender dysphoria resolved, but well-being was comparable to peers in many respects. After gender confirmation surgery, psychological functioning improved steadily over time, with rates of clinical problems comparable to that seen in the general population. Quality of life, satisfaction with life, and subjective happiness were comparable to same-aged peers. All of the young adults in their study were generally satisfied with their physical appearance and none regretted treatment. Puberty suppression had caused their bodies to not further develop contrary to their experienced gender. The authors believe a treatment protocol

may delete

attempts, 55% who attempted suicide reported depressive symptoms compared to only 33% who reported depressive symptoms and no history of attempts.

Hess et al. (2014) assessed satisfaction following MtF gender confirmation surgery among 254 patients from 2004-2010. Results indicated 61.2% of patients were "satisfied" and an additional 26.2% were "very satisfied" with their outward appearance as women. Regarding the gender confirmation surgery process, 45.5% were "very satisfied," 30% were "satisfied," 22.7% were "mostly satisfied," and only 1.8% were "dissatisfied." Overall, approximately 75% of patients reported being "satisfied" or "very satisfied" with the aesthetic outcome, and an additional 22.3% were "mostly satisfied." Seventy-two percent of patients were "satisfied" or "very satisfied" with the functional outcome of surgery, and an additional 19.4% of patients were "mostly satisfied." Most participants (68.4%) felt their lives had "definitely" become easier since surgery, 14.7% found life to be "somewhat easier," 9.5% found life to be "somewhat harder," and 7.4% felt their lives were "harder." Expectations of life as female were "completely fulfilled" for 50% of respondents, "mostly fulfilled" for 40.2%, "mostly not fulfilled" for 5.9%, and "not fulfilled at all" for 3.9%. There was a correlation between how respondents saw themselves and whether they felt life had become easier or their expectations of life as female had been fulfilled. Those who saw themselves completely as women had higher scores for current life satisfaction than those who only saw themselves as more female than male. The authors found their results comparable to other studies assessing outcomes among similarly sized populations. Subjective satisfaction rates in the other studies ranged from 80-94%.

Surgical Outcomes

Multiple studies have been conducted on physical health outcomes following gender confirmation surgery. Results indicate outcomes are mostly successful in helping patients reach their treatment goals and in alleviating gender dysphoria. The overwhelming majority of research supports gender confirmation surgery as a safe and effective treatment. Bogliolo, Cassani, Babilonti, Gardella, Zanellini, Dominoni, et al. (2014) stated cross-sex surgery should be offered to all transgender individuals who do not desire fertility because surgery can result in improved quality of life in multiple areas (socioprofessional, relationship, psychological), improved social and sexual functioning, and reduced risks of hormone-dependent cancers related to long-term hormone exposure. They found that transgender patients undergoing hysterectomies experienced low rates of complications, none of which were because the patients were transgender. Selvaggi et al. (2012) stated follow-up studies have shown surgery has positive effects on postoperative outcomes, such as subjective well-being, cosmetics, and sexual functioning. They stress the importance of an in-depth consultation between surgeons and patients to discuss extensively the different techniques available and the advantages and disadvantages of each, the limitations of a procedure to achieve "ideal" results, and the inherent risks and complications of ~~the various~~ each technique. Surgeons must be sure that patients have realistic expectations of the outcomes, and that the achievable result would alleviate the patient's gender dysphoria.

Across studies, rates of serious complications are generally low and most are typical of any surgical procedure (such as wound healing difficulties and bleeding). Some complications are specific to individual procedures, others can be attributed to patient noncompliance (such as vaginal prolapse due to not using vaginal dilators as instructed after surgery) and smoking (Monstrey et al., 2011). Complications associated with either MtF or FtM gender confirmation surgery include:

- Well leg compartment syndrome (Masumori & Tsukamoto, 2013)
- Hematoma

Bucci et al. (2014) evaluated neovaginal prolapse among MtF individuals by studying two different surgical techniques. With the first technique, which used two sutures, 1.53% of patients experienced total prolapse and 10.76% experienced partial prolapse. With the second technique, which used four sutures, no instances of total prolapse occurred and only 4.14% of patients experienced partial prolapse. Most patients reported the prolapse occurred following prolonged sexual intercourse in "uncomfortable places" without the use of any lubricant. The authors concluded that the use of four stitches results in a lower risk of prolapse. Specifically, two sutures in one area reduces the risk of total prolapse and two additional sutures in another substantially reduces the risk of partial prolapse. They also strongly recommend the regular use of vaginal stents after surgery to maintain adequate depth and diameter, ensure the skin cylinder adheres to the cavity, facilitate recovery, reduce the risk of stenosis, and reduce the risk of infection~~, by assuring adequate drainage of fluids collected inside the neovagina~~.

De Stefani et al. (2004) recommended using microlaparoscopy in MtF surgery to reduce the risk of rectal injury. With microlaparoscopy, the dissection of the rectovesical space to create the neovaginal cavity can be directly guided, reducing risk of injury to the surrounding structures. It also allows complementary maneuvers, such as suturing the apex of the neovagina to the bottom of the perineal cavity. It is simple to perform and only adds about 15 minutes to the total operation time.

Garaffa et al. (2010) studied the radial artery-based forearm free flap (RAFFF) in FtM transitions among 27 patients who had previously undergone pre-fashioned pedicled pubic phalloplasty. The revisions were carried out in two stages. At the time of follow-up, 19 patients had completed both stages. Among all patients at the time of follow-up, 93% had a neourethra that reached the tip of the phallus and were fully satisfied with cosmetic and functional results. All 19 patients who completed both stages were able to void from the tip of the phallus while standing with no irritative or obstructive urinary symptoms and with minimal residual bladder urine (as assessed by ultrasonography). Complications occurring after stage one included complete necrosis of the RAFFF urethroplasty (2 patients), abscess formation in the phallus (1 patient), urethral stricture (1 patient), and incomplete graft take (3 patients). Complications occurring after stage two were hematoma (1 patient), abscess (1 patient), and urinary fistula (both patients). Aside from the two patients who experienced necrosis, only three developed complications requiring further revision surgery.

Cost Effectiveness

Padula et al. (2015) analyzed the cost-effectiveness of health insurance coverage for medically necessary and preventive services compared to no coverage in the U.S. adult transgender population using data collected from a review of over 30 randomized controlled trials, observational data, and case series. Effectiveness was measured as quality-adjusted life years (QALYs) in both groups. Those without benefits had less favorable outcomes, including depression, HIV, and death. For those with provider coverage, there was an annual cost of $2175 associated with medically necessary services and preventive care. Provider coverage was cost-effective relative to no health benefits at 5 and 10 years from a willingness-to-pay threshold of $100,000/QALY. The 5-year incremental cost-effectiveness was greater than that at 10 years, as upfront costs of transitional therapy were not yet offset by costly long-term outcomes associated with lack of coverage (HIV, drug abuse). The 5-year budget impact analysis indicated a cost of $0.016 per member per month. The incremental cost effectiveness ratio of provider coverage for medically necessary services and preventive care at 10 years was estimated at $9,3000/QALY, suggesting that coverage would be relatively efficient on a per-patient basis. Probabilistic sensitivity analysis showed that coverage was cost-effective compared to no coverage in 8,477 out of 10,000 simulations. The authors point out that the

is cost-effective, and is the only treatment option for individuals whose gender dysphoria is not relieved by hormone therapy or other treatments.

Evidence-Based Clinical Practice Guidelines

The World Professional Association for Transgender Health (WPATH) was founded in 1979 and is an international, interdisciplinary, professional association devoted to the understanding and treatment of individuals with gender dysphoria. Members come from medical, mental health, social science, and legal backgrounds. They have developed the WPATH Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People (SOC), first issued in 1979 and periodically revised to reflect advances in evidence-based clinical practice and scientific research. The standards were last updated in 2012 (Version 7). The SOC articulate the "professional consensus about the psychiatric, psychological, medical and surgical management of GD" [gender dysphoria], ~~The SOC~~ reflect the WPATH's conclusion that treatment is medically necessary. The board of directors' opinion, based on clinical and peer reviewed evidence, is that gender affirming/confirming treatments and surgical procedures, properly indicated and performed according to the SOC, have proven beneficial and effective in the treatment of individuals with transsexualism or gender dysphoria. Furthermore, they state gender confirmation surgery plays an undisputed role in contributing toward favorable outcomes. Multiple professional societies have issued statements in support of the SOC, such as the American Medical Association, the Endocrine Society, the American Psychiatric Association, the American Psychological Association, the American Academy of Family Physicians, the National Commission of Correctional Health Care, the American Public Health Association, the National Association of Social Workers, the American College of Obstetrics and Gynecology, the American Society of Plastic Surgeons, and the World Health Organization (WPATH, 2016).

The Endocrine Society's Clinical Practice Guideline, published in 2009, frequently references the WPATH SOC and peer-reviewed research. The guideline recommends hormonal therapy and surgery for sex reassignment for transsexual adults as a treatment for transsexualism or gender identity disorder [known as gender dysphoria in the DSM-5]. Surgery is recommended only after both the physician responsible for endocrine transition therapy and the mental health professional find surgery advisable, and the individual has completed at least one of year of consistent and compliant hormone treatment. It is further recommended that the physician responsible for endocrine treatment medically clear the individual for sex reassignment surgery and collaborate with the surgeon regarding hormone use during and after surgery. The Endocrine Society recommends deferring surgery until an individual is at least 18 years old.

In 2005, the American Psychological Association (APA) Council of Representatives authorized the creation of the Task Force on Gender Identity and Gender Variance. In 2009, the APA Council of Representatives adopted the Resolution on Transgender, Gender Identity, & Gender Expression Non-Discrimination, which, among other endeavors, supports the provision of adequate and necessary mental and medical health care; recognizes the efficacy, benefit, and medical necessity of gender transition; and supports access to appropriate treatment in institutional settings. The APA published the Guidelines for Psychological Practice with Transgender and Gender Nonconforming People (TGNC) in 2015 to assist psychologists in the provision of culturally competent, developmentally appropriate, and trans-affirmative psychological practice with TGNC people. The APA indicate the Guidelines are intended to complement other treatment guidelines, such as those set forth by the WPATH SOC and the Endocrine Society.

move to end

The World Health Organization (2017) states transgender people share many of the same health needs as the general population, but they may also have other specialist health care needs, such as gender-affirming hormone therapy and surgery. The WHO also discusses barriers to treatment and outlines best practices in the public provision of gender-affirming health care.

The American Academy of Family Physicians (2016) published recommended curriculum guidelines for family medicine residents regarding lesbian, gay, bisexual, and transgender (LGBT) health. The guidelines recommend: basic understanding of surgical options for transitioning, including common post-operative complications and follow-up issues; familiarity with various treatment recommendations (e.g., the Endocrine Society Clinical Practice Guidelines, the WPATH SOC); referring appropriately to support services for patients needing additional care for gender transition, mental health, sexual health, social services, or other services related to LGBT identity; and managing the transition-related health care of transgender patients of all ages through either hormone administration (and/or puberty-blocking medications) or appropriate referral, as well as referral to any necessary mental health services and/or gender affirmation surgeries and related follow-up care.

The American Public Health Association (2016) encourages public health and health care practices that are inclusive of transgender and gender nonconforming people.

The National Association of Social Workers (2008) "supports the rights of all individuals to receive health insurance and other health coverage without discrimination on the basis of gender identity, and specifically without exclusion of services related to transgender or transsexual transition...which may include hormone replacement therapy, surgical interventions, prosthetic devices, and other medical procedures" (Lambda Legal, 2016).

The National Commission on Correctional Health Care published a position statement regarding transgender, transsexual, and gender nonconforming health care in correctional settings in 2009, which was updated in April 2015. The statement indicates correctional health staff should manage transgender patients in a manner that respects their biomedical and psychological needs. There are 25 principles, including the following:

- Management of medical or surgical transgender care should follow accepted standards developed by professionals with expertise in transgender health (such as WPATH SOC), and treatment decisions should be made on a case-by-case basis
- There should be no blanket administrative or other policies that restrict specific medical treatments; policies that make treatments available only to those who received them prior to incarceration or that limit transition and/or maintenance are inappropriate, out of step with medical standards, and should be avoided
- Accepted treatments for gender dysphoria should be made available to people with gender dysphoria; providing mental health care, while necessary, is not sufficient
- Psychotherapy such as "reparative" or "conversion" therapy or attempts to alter gender identity should never be employed
- Sex reassignment surgery should be considered on a case-by-case basis and provided when determined to be medically necessary for a patient
- Treatment for genital self-harm or for complications arising from self-treatment should be provided when medically necessary

California, Colorado, Connecticut, the District of Columbia, Massachusetts, Minnesota, New York, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington have specific policies regarding gender confirmation surgery. Overall, the states have similar prerequisite criteria for surgery, which are largely consistent with the WPATH standards of care, though Vermont has more stringent criteria. In general, the following criteria are required, with minor variations from state to state:

- Must be at least 18 years of age and have the capacity to provide fully informed consent (Vermont requires individuals to be at least 21)
- Must have completed 12 months of continuous cross-sex hormone treatment unless hormone therapy is contraindicated (Vermont requires 24 months)
- Must provide two signed letters of referral from licensed providers who have independently assessed the individual and are recommending surgery
  - Some states indicate both letters must be from licensed mental health providers and some states indicate the letters can be from a licensed mental health provider, a licensed medical provider, or a combination of both
  - Referral letters must indicate a diagnosis of gender dysphoria and medical necessity
- Must live full-time in a gender role congruent with gender identity for 12 consecutive months
- Significant medical or mental health concerns, if present, must be optimally managed and reasonably well-controlled

All states cover the basic genital reconstruction procedures, mastectomy, and hysterectomy. All states also cover augmentation mammoplasty, though most require that the individual have insufficient breast growth after at least two years of hormone therapy before covering the procedure. Five states (Connecticut, District of Columbia, New York, Pennsylvania, and Washington) also cover other transition procedures that are typically considered cosmetic, such as facial feminization procedures, electrolysis, or voice surgery and/or speech therapy. Connecticut allows mastectomy and creation of a male chest in adolescent FtM transgender individuals ~~reassignment~~, preferably after ample time of living in the desired gender role and after one year of testosterone treatment.

Commercial Insurers

The following is a sampling of some of the commercial insurance providers who cover gender confirmation surgery for the treatment of gender dysphoria:

- Capital Health Plan
- Florida Blue
- BlueCross/BlueShield of California
- BlueCross/BlueShield of Texas
- BlueCross/BlueShield of Arizona
- BlueCross/BlueShield of Tennessee
- BlueCross/BlueShield of South Carolina
- Aetna
- Humana
- Cigna
- United HealthCare
- Tufts Health Plan
- Regence

DRUG UTILIZATION REVIEW BOARD

Agency for Health Care Administration

Tampa Marriott Westshore

Saturday, September 26, 2015

8:08 a.m - 10:55 a.m.

REPORTED BY: JACQUELINE L. REICHERT
Integra Reporting Group
Court Reporter
Notary Public
Commission No. EE 160968
Expires 3/27/16

Pl. Trial Ex. 238

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P R O C E E D I N G S

THE CHAIRPERSON: Good morning. Welcome to the Drug Utilization Review Board, the time now is 8:08 on September 26th. It's Saturday. We have a lot of new members here this morning and for roll call what I'd like to do is go around the room and have everyone introduce themselves. And we'll start with Moses.

DR. ALLEN: Sure. Moses Allen. I'm currently pharmacy director -- currently pharmacy director at Prestige Health Choice in Tampa, Florida.

MS. FAGAN: Good morning. I am Diane Fagan. I work with WellCare here in Tampa and I live in Sarasota and I'm happy to be here. Thank you.

MR. HAMILTON: Please use your microphones, our meetings are recorded. Still not working? Still have no microphones? Sorry about that. Speak up as best you can. No, they're not working.

DR. MARTORANA: I'm Dr. Jeff Martorana. I'm a family physician. I'm chief medical officer at Sunshine Health Office in Sunrise,

Florida.

DR. OLSON: Kevin Olson. I work at All Children's John Hopkins. I'm manager of our home care and retail pharmacy divisions.

DR. ROMAY: Good morning. Alfred Romay, I'm the director of pharmacy over at Molina Healthcare of Florida.

DR. SAEZ: Hi. My name Dr. Luis Saez and I work with BHC at Fort Lauderdale, Florida, with HIV.

DR. ZITIELLO: I'm Amy Zitiello. I am a medical director with Amerigroup and a pediatrician.

DR. HAYDEN: My name is Anna Hayden. I'm a family physician out of Broward Health. I'm also a clinical professor for Nova Southeastern College of Osteopathic Medicine, and I'm also certified in HIV medicine as well.

MS. SMITH: I'm Beverly Smith. I'm the assistant general counsel for the Agency of Health Care Administration and serving as Medicaid counsel.

MS. HARRIS: Good morning. I'm Shevaun Harris. I'm with the Bureau Chief over

Medicaid Policy with the Agency for Health Care Administration.

DR. CRAIG: Good morning. I'm Sara Craig, senior pharmacist with pharmacy policy with the Agency for Health Care Administration.

MS. WILLIAMS: Good morning. I'm Susan Williams. I'm also with the Agency for Health Care Administration and I'm a senior pharmacist.

MR. HAMILTON: Good morning everyone. I'm Vern Hamilton with the Agency. I'm the pharmacy policy liaison.

DR. BORGERT: Good morning everyone. My name is Becky Borgert, I'm a pharmacist with Magellan Healthcare.

DR. MOORE: Good morning. I'm Elboni Moore, I'm the clinical account manager with Magellan.

THE CHAIRPERSON: Ms. Harris, would you like to do the opening remarks?

MS. HARRIS: Yes. Thank you. Good morning, everyone. I'll be very brief this morning. I just want to welcome all of our new DUR Board members. On behalf of the

Agency we are very thankful and appreciative of your willingness to serve in this capacity. And returning members, thank you for those who are willing to continue to serve on the board, Dr. Hayden and others here. I'm sorry, I'm having a hard time reading.

Just one quick update. If you are one of the individuals who participate in our Pharmaceutical Therapeutics Committee meeting, we are in the process of trying to appoint new members to that particular committee. And so I believe the appointments have been made and will be going out -- or have already gone out I think yesterday.

And so we had to postpone the meeting that was scheduled for yesterday. We will be getting the meeting rescheduled in the next few weeks. So please pay attention to our pharma notices and our healthcare alerts that we post on our website. We will get more information out as soon as possible on when that meeting will be rescheduled.

That's it for me, unless anyone has questions? Okay. Thank you.

MS. HAYDEN: Thank you very much. I think my mic is working now.

Next on our agenda item is the voting for chair and vice-chair. We had -- Dr. Burno was our previous vice chair and he had retired out and he's now considered a full-time snowbird, and I just wanted to recognize him for his years of service on this committee.

So as for chair, I'd love to serve as chair again. I have no disclosures to report here. There's no conflict of interest on my behalf. So I'd be happy to serve as chair. I guess we have to vote on that. And vice chair, we need a volunteer. In case I'm not here to chair, we have to have, you know, someone running the meeting.

DR. OLSON: I --

THE CHAIRPERSON: Thank you for volunteering, Dr. Olson.

DR. OLSON: Even though she's not here I was going to volunteer Vanessa as vice chairman, but... Even though she's not here.

THE CHAIRPERSON: Well --

DR. MARTORANA: I'll be happy to serve as

vice chair.

DR. ALLEN: So I guess to make it official, I guess I will make -- I nominate Dr. Hayden as the official chair of the DUR Committee and Dr. M as the vice chair?

THE CHAIRPERSON: Doctor who?

DR. ALLEN: I'm sorry. Dr. Martorana. He also goes by Dr. M.

THE CHAIRPERSON: So we'll take a vote on the -- and we need a second.

DR. ZITIELLO: Second.

THE CHAIRPERSON: So all those in favor signify by saying "aye."

THE BOARD: Aye.

THE CHAIRPERSON: Very good. So I'll be happy to serve again.

And as for the vice chair we have Dr. Jeffrey. Do we have a second?

DR. ALLEN: I'll second.

THE CHAIRPERSON: All those in favor signify by saying "aye."

THE BOARD: Aye.

THE CHAIRPERSON: Very good. Congratulations. Very nice.

Next on our agenda is the approval of the

Drug Utilization Review Minutes from the June 27th meeting. Has everyone had the opportunity to review that? Do we have a motion for approval?

DR. ALLEN: I have a question regarding the minutes.

THE CHAIRPERSON: Yes, sir.

DR. ALLEN: On page 2, I believe paragraph 5, there was a question from -- well, you, Dr. Hayden, regarding the comprehensive annual review. And I think Arlene Elliott was checking into it, I guess the report was supposed to be posted online, and I guess she wasn't sure. And I think it would be valuable for the committee members, particularly since a couple of us are new.

THE CHAIRPERSON: Yeah. There's an annual report that goes out yearly, it's a -- it's a comprehensive report that used to go out. I haven't seen it in a while and so I asked about it at the last meeting.

Ms. Harris.

MS. HARRIS: So I am fairly confident that the one for this year was listed into the legislature. We'll go back and make sure

it is posted on our website. And what we can do is send the report out to all of the board members after this meeting.

THE CHAIRPERSON: I think it was posted online somewhere and I haven't been able to -- it was posted years ago. It was a public record, so I guess I didn't see it.

MS. HARRIS: We can send it out.

THE CHAIRPERSON: Thank you. Any other comments on the minutes?

Do I have a motion -- I'll make a motion to approve the previous minutes. Do I have a second?

DR. ALLEN: Second.

THE CHAIRPERSON: All those in the favor signify by saying "aye."

THE BOARD: Aye.

THE CHAIRPERSON: Any further discussion, anything? I guess we have approval though. Thank you.

Next on our agenda is just informational from the last P&T minutes from June 26th, there's no action on that. And any comments or any discussion on the previous P&T minutes?

We used -- Elboni will be our liaison from P&T and DUR. They make recommendations and we go back and forth and creating some pathway of a conduit and some -- making the recommendations when they make their review as well. So Elboni will be serving as our liaison. Our previous liaison was Dr. Natasha Robinson, and I believe she was reappointed to P&T as well. So thank you, Elboni.

Next we have the quarterly DUR with Rebecca and she will be presenting on that. We have the overhead projector and also paper copies.

DR. BORGERT: Good morning, everyone. As I said, my name is Becky Borgert. I'm a pharmacist with Magellan RX. And just to -- I know a lot of people are new today. I'm just going to kind of give a little background on how we normally do this just so you kind of have an idea. I know that there was a call, and Elboni was on the call on Tuesday, so forgive me if I repeat some of this.

But typically a few weeks before the

meeting a quarterly report will come out, so it's a Word document. And it is basically the basis for what will be presented, you know, as a presentation at this meeting. Sometimes, you know, there's obviously space for a little more background information to go in that report. It's a Word document as opposed to a PowerPoint slide presentation.

Sometimes not all the data has been analyzed and is available at the time the report deadline is due, so sometimes it will say, you know, more data will be needed, or more information will be presented at the meeting.

If there's any proposed -- this is important. If there's any proposed banner messages that we're going to vote on for approval, those will be in the quarterly report so we don't just type a bunch of words on a slide up here for you to read. So those will be important to look over, because we'll refer to those and then vote on those perhaps at the meeting, depending on how the discussion goes.

So that's kind of how the quarterly

report kind of fits in with what we do here today. And then the other thing I wanted to do is kind of give you an overview of how we typically formatted this.

So we'll start with follow-up and updates. And what this is, just basically any topics that we have new information about that we've presented on in the past. So, for example, you'll hear me refer to something that we call opposed implementation analysis, because what we try to do is we try to measure any intervention that we do as a result of this committee.

So it's not perfect because, you know, it's not always apples to apples because, you know, the Medicaid population is not static, so you're not always looking at the same patients before and after, but we try to do the best we can.

So if we have an intervention, be it -- you know, say we initiated an automated prior authorization, or we put in some quantity limits, or we've made some other recommendations. We try to look at, you know, what that data looked like before the

edit was deployed and then pick a similar time frame -- similar length of time after the edit was deployed and look at the data at that point and try to draw some comparisons.

Like I said, it's not perfect. It's probably not statistically -- you know, it wouldn't pass the statistical mustard necessarily, but we look at claims, recipients, and total pay. Just to kind of get a ballpark idea of -- you know, a way of trying to measure the impact of what we do. So that's typically what we do in follow-up and updates.

And after that we'll go into new business. And then new business typically contains two parts. The first thing we do is talk about upcoming P&T classes. And as Dr. Hayden just said, Elboni has volunteered to serve as the P&T/DUR board liaison. Because in our vision, at least, ideally the DUR Board would work in tandem with the P&T Committee.

And typically, although the P&T Committee can sort of get into the nitty-gritty of criteria, technically typically they don't.

So that's more of the role of this board is, you know, looking at utilization and looking at how the drugs are being used, not just if they're preferred or not preferred.

So we would like for this board to be able to think about those types of issues and provide feedback to the P&T Committee. In order to be able to do that in a timely manner, because we meet the day after P&T, we always have to be looking ahead at what P&T classes are coming up for review.

So that's another thing that you'll find in your quarterly report is that I gave you a full list of January 2016 and March 2016 the classes that are scheduled to be reviewed at the P&T Committee. Because basically it's a a set schedule and we review the same classes at each -- whatever the designated quarter is.

So sometimes we'll look at, you know, upcoming -- the very next upcoming, so in this case we might look at -- in here we're going to look at through January P&T classes that are coming up. And if there's something simple that we see that you might want to

recommend to the DUR Board, that's easy.

Or in some cases there might be something where you'd say, you know, "I'd like for you to go back and pull some utilization data or look at something," in which case that would probably have to be -- that's why we look at say two meetings ahead.

Because if that were the case, that you wanted to pull something for something that's going to be looked at and the P&T is going to be reviewing in March, that would give us an opportunity to pull the data in this quarter, come back to the DUR Board with that information in January, have a discussion about it, and then have a recommendation ready to go for the March P&T committee meeting. So that's kind of how the whole P&T/DUR Board working in tandem goes generally speaking.

The other part of new business is our quarterly topics. Typically we have three to four of these a quarter. It can vary, but typically we'll try to select three to four topics to look at for the next quarter.

And finally, the last thing we do is we

look at proposed topics for the next quarter. And as I said, in the MCO meeting yesterday, which I know some of you were attending, we love for the DUR Board members to come to us with ideas, things that they see in their practice. You know, mostly ideas that you have from your own practice, your place where you work.

But Magellan usually comes with a few things too, just in case, you know, we don't have any other recommendations, we'll throw some ideas out there for discussion to see if that's something the board would like to look at. So I just wanted to -- before I just dive right in -- since it's the first meeting for a lot of you, I just wanted to give you that review of that format of how this meeting usually flows.

Are there any questions about that? Okay.

As I was mentioning about post implementation analysis here's a good example in our first follow-up. So in May of this past year we implemented an edit that this board discussed and that was to implement

maximum daily dose limits on atypical antipsychotics for adult patients over the age of 18. Prior to this edit, we did have an edit in place for children with maximum daily dose of antipsychotics, but we did not have anything in place for adults.

So in May of this year we implemented that edit. So to try to look at a comparison we looked at January -- a three-month period from January to March of this past year. And you will see there in the left -- I don't have a pointer -- but in the far left column on both of the tables, did the dose that was -- the claim that was submitted, did it exceed the maximum daily doses? Yes it did, or no it didn't. Understand the tables?

So obviously the vast majority did not exceed the maximum daily dose when the claim was originally submitted.

And then how many -- on the other hand, how many of those did exceed the maximum daily dose? And so you can see there that prior to the edit -- and in the post edit period was immediately following when the edit was implemented for a three-month time

period.

Prior to that about 5 percent of the claims exceeded the maximum daily dose, afterwards about 2 1/2 percent of the claims exceeded the dose. It affected about 9 percent of the recipients versus 5 percent of the recipients.

And, you know, obviously you can see the totals there -- if you look at the totals at the bottom, you know, we had 7,821 recipients that received atypical antipsychotics. And I should say that this is just fee-for-service, by the way. 7,821 recipients in the pre-edit analysis and 7,409 in the post-edit analysis. So there's about a 5 percent difference there between number of recipients.

So again, you know, you have to keep in mind that this is not a perfect statistical comparison. So the number of recipients was slightly less. But I do think that probably the dollar impact is somewhat significant in that about 10 percent of the overall claims in fee-for-service were exceeding that maximum dose prior to this edit, and it's down to about 4 1/2 percent after.

Dr. Hayden?

THE CHAIRPERSON: The 2.5 percent that exceed the dose, was there a prior auth that was done by the psychiatrist, or how did they justify exceeding the maximum daily dose?

DR. BORGERT: Yes. At this point now that it stops for prior auth and it has to be submitted for a prior authorization.

THE CHAIRPERSON: And the reason -- the common reason was -- was it -- what was the --

DR. BORGERT: I'd have to check with our call center.

THE CHAIRPERSON: I'd just be interested.

DR. BORGERT: Yeah. I can take that back and ask our call center and look into the specifics of the prior authorizations.

DR. ALLEN: One other question, so just out of curiosity were any of these claims grandfathered? I just --

DR. BORGERT: No. We do not grandfather.

DR. ALLEN: So it's just the hard stop line you're looking at.

THE CHAIRPERSON: And they took into account the injectables as well or is it just

the orals? I'm just curious.

DR. BORGERT: I'll have to go back and look at the data we pulled. It was all.

THE CHAIRPERSON: It was all of them. Thank you.

DR. ALLEN: So, Dr. Hayden, just an assumption here. I think probably the majority of these yeses probably is what leads you to the members being grandfathered, they were probably already established on the atypical and maybe if they had it available for six months. It's just an assumption obviously --

DR. Borgert: Yeah. I'll take that back to our call center and ask them for the specifics on those.

THE CHAIRPERSON: I mean, is it drug-to-drug interaction with the levels of the medication were decreased? You know, that's the only other thing I'm thinking of. Well, that's good. That's good data in terms of, you know, rendering safe patient care.

DR. BORGERT: Right.

THE CHAIRPERSON: So I think it's really going in a positive direction.

DR. BORGERT: And so that's what I mean about, you know, trying to do some measurement, you know, of what we've done to get some idea.

And so here's another example of that exact same kind of thing in terms of a post implementation analysis. The dark blue columns there are the pre-period to the edit. And then the light blue columns are the post-period of data. So let me tell you a little bit about this.

So prior to the edit that -- the edits that went into place, our quantity limits on insulin vials were 10 vials per month, and in January of this past year we did lower that to a maximum quantity of allowing 7 vials of insulin per month. And in March -- excuse me, April of this past year, we decreased the quantity limit on our insulin pens down to two boxes -- a maximum of two boxes, so 10 pens per month.

And so in looking at that impact, you can see that really there was no impact whatsoever on the vials, it actually went up a slight amount. However, we did see, you

know, about a 13 percent decrease in our quantities dispensed with pens. And by quantities dispensed, that means the number of mls of insulin is what that quantity is. So if you're looking for units, you're going to have to multiply that by 100.

So the point was since -- I know there's a lot of representation now in the DUR Board from the MCOs. There was a discussion yesterday I think in that MCO meeting that 4 1/2 vials of insulin a month is a lot of insulin a month for a patient to be using.

Now, obviously, you know, insulin is not a set dose, it's a sliding scale, it's all over the board. So there's no, you know, this is the standard dose of insulin kind of thing.

And the question arose, you know, could this be an anomaly to fee-for-service population as opposed to maybe the recipients are in an MCO population. Really we can't tell, we don't know. It is possible that the patients that are in fee service are "sicker." It's hard to know.

But, you know, I'll just throw that out

there because it was brought up at the meeting if people are interested. I think, you know, the MCOs feel like that limit of 7 vials per month is still pretty high. We feel like if we lower the limit -- one of the recommendations from the MCOs was to limit the vials to 2 to 4 vials a month. But if we did that, we'd impact more than half of the patients based on this data, right? So that doesn't seem like a prudent thing to do.

I'll just throw that out there, not necessarily if the board has any comment about whether or not we would want to look at the MCO data as it relates to see if it's any different than the fee-for-service data.

THE CHAIRPERSON: Yeah. When I looked at this data, I looked at in terms of I know that under Medicaid they can pick up their prescriptions every 25 days.

DR. BORGERT: I think it's 27.

THE CHAIRPERSON: Is it 27 now or is it 25?

DR. MOORE: The edit actually stops at the 27th.

THE CHAIRPERSON: So every 27 days. So

it would be interesting to see when they next picked up their prescription, was it access just to walking to their pharmacy or getting a ride to their pharmacy they were picking it up in 40 days. And so I'm not sure if that data stratifies when their next pickup is. Because they could be stretching it out until they just run out and then they get their --

DR. ROMAY: I just wanted to say in terms of we can look up the refill to see how long it's really taking them to get through that supply. Because it strikes me odd that there's recipients out there using 7 vials of insulin, I find that hard to believe. I know there's a lot of demand for insulin, depending. But we need to do a better job educating those members in, you know, dietary and trying to scale them back. I know if they need insulin, that's one thing; but if we're just kind of like, you know, stockpiling at home just because they have to fill it every so often, that's what -- I mean, we can do a comparison data so see, you know, how long it's really taking them to get to the pharmacy.

THE CHAIRPERSON: The pickup dates. I'm not sure we can.

DR. BORGERT: Yeah. I would imagine we can look at that in terms of length of time between fills, we can probably look at that information.

THE CHAIRPERSON: And I'm not sure if we can differentiate a type 1 from a type 2, you know, some of these aren't pumped. If they pick up the vials and they -- yeah. So I'm not sure what the --

DR. MOORE: The only way we can possibly do that is maybe tie the diagnosis codes in with those listed that we've identified.

THE CHAIRPERSON: Right.

DR. MOORE: We probably can pull in that data.

THE CHAIRPERSON: You know, the dilemma that we face here is not to restrict anybody's coverage, but yet provide safe -- you know, making sure that the half-life dose, you know, those meds at home are still viable. You know, it's always a concern.

DR. OLSON: And I don't know if you can look into whether it's lost or damaged,

because you run into that a lot as well with broken vials. So that would be good to be looking into that too.

DR. BORGERT: Right. I'm trying to think of how we could capture that.

DR. OLSON: There's an override code, right, for a lost or not --

DR. BORGERT: Or even if they're getting it as an early refill?

DR. MOORE: Early refills are only approved for dosage changes in general. Yeah, they don't really do early refills for lost or stolen or vacation supplies.

THE CHAIRPERSON: And maybe look at the data on the patients that are using closer to the 7 vials or exceeding a higher dosage. Perhaps maybe looking at that population and seeing what's going on there. And seeing -- you know, look at better management of diabetes and those care coordinators or if something else is going on there or other options.

DR. BORGERT: Yeah, we can bring back some general information about who those recipients are; you know, age, diagnoses.

Some general types of -- maybe types of diagnoses, we can try to pull out some specific information about those.

THE CHAIRPERSON: I guess on the patients that are using more than 100 units per day, is that a fair -- I mean, that's kind of high still, but again -- I think --

Any comments, any opinions?

DR. MARTORANA: You can also just look -- just look at how many individuals say at 5, what percentage are more than 5. And the average, it's kind of diluted but you can have some very high utilizers with the overall is 3. So if you just look at the pure percentage that over 5 maybe it gives us an idea of what the 5 are off or 5 are above or something like that.

THE CHAIRPERSON: I guess we'd have to look at how many units per day. Because if they use the 5, but they pick it up at 35 days and not the 27 days. So I guess it would be -- I'm sure if we can -- if you can look at how many units per day total the high users instead of the vials pick up, because they could be picking up every 40 days

instead of every 27 days.

DR. BORGERT: We can use either mls or units. I mean, we can get that.

THE CHAIRPERSON: It's interesting.

DR. BORGERT: So what I heard was, we're going to take it back and try to drill down a little bit more looking at time between fills to see -- we're going try to get out some specific information on patients who are using more than 100 units per day and we're going to look at specifically patients that are getting 5 or more vials a month, what percentage of the overall utilized population does that represent.

I laugh because this is the thrid or the fourth meeting that we've had this -- it's a good topic, a really good topic, but we've struggled to get to the finish -- bring this one across the finish line.

So what we initially -- and this -- actually this recommendation actually came out of P&T. P&T asked the DUR Board to look at this. They asked the DUR Board specifically to look at codeine utilization under the age of 12.

So when we looked at our data what we found is that we did have some utilization. We had about 675 recipients and about 740 claims in patients less than -- under the age 12 or under who are receiving codeine.

Now I will say that none of these claims were for a single agent codeine, they were all or, you know, codeine acetaminophen or codeine guaifenesin.

And the reason -- the backup behind why the P&T Committee brought forth this topic was in 2013 the FDA added a contraindication and black box warning for the use of codeine in patients under the age of 12. Specifically those patients who were status post tonsillectomy and/or adenoidectomy.

But the issue here is that a small percentage of the population, probably less than 10 percent overall but higher in some ethnic groups, are ultra-rapid metabolizers of codeine. And to go back to the pharmacology, codeine is a pro drug. So it actually has to be converted in the body to morphine and that's where the analgesic properties come from.

So I think it's 592(D)(6), but don't quote me on that. If you are an ultra-rapid metabolizer, you're going to convert codeine to morphine more rapidly and, therefore, could be at a higher risk. And of course the converse is true as well; some patients get very, very ill because of the analgesic from codeine because they don't convert the codeine -- if you're a poor metabolizer, you don't convert it to morphine or hardly at all.

And then we look -- thought about the other things the codeine is used for pediatric patients; cough, general pain management. The American Academy of Pediatrics and the American College of Chest Physicians recommend against the use of codeine in pediatrics for cough. And we have a pediatrician on the board. That's awesome. And it's also not recommended for pain management for anyone by the World Health Organization, analgesics stepladder.

So on page 9 of the quarterly report that you received there is a proposed banner message. And we did look at this banner

message the last time and I'll bring you up to speed on that in a minute. But just a couple of highlights from that banner message is that codeine -- the DUR board lowered the age from 12 to 6, they felt like it was more appropriate to limit -- to require prior authorization only in those children under the age of 6 rather than using the age of 12 as a cutoff.

There's a link in the banner message to the FDA announcement for February of 2103. The banner message contains an alternate drug and dosing regimens that are reported in the literature for the use of children both post-tonsillectomy as well as bone fractures. And most of those supported the use of Ibuprofen and/or acetaminophen.

A link to the abstracts of those studies are in there. And then also on the banner message there is an equal analgesic opioid dosing conversion for children less than 50 kilos.

The thing that kind of stopped us last time was this alternate -- alternatives for pain management in these patients. And there

was a discussion on the board that they were concerned that if the alternatives were OTC, that that might pose a problem in terms of the children ultimately receiving those medications.

Would the caregivers, you know, go to the pharmacy, pay out-of-pocket for an OTC med, make sure that the child received the medication. There was some speculation that that might not happen.

So the board wanted to make sure that there was a prescription alternative that the caregiver could fill at the pharmacy and have it be reimbursed by Florida Medicaid and to make sure that the patient would receive the pain medication.

And so we took it back and did some research on it, and we do have Ibuprofen suspension 100 milligrams per 5 ml as an Rx product that is available on the PDL, so they will have -- Medicaid recipients will have access to that prescription product, that will be reimbursed under their Medicaid benefits.

I think that was the sticking point last

time, and now that we've got that cleared up -- actually I think we even voted on the banner message last time. I don't remember. But it's probably just for -- say we should probably revisit the banner message.

THE CHAIRPERSON: After further review of this banner message -- I always want access to patient care and I'm making sure they have adequate analgesic postop. Ibuprofen is good, but again the risk of bleeding, that's commonly known even in using an anti -- of that particular nature.

DR. BORGERT: I will say that the ENT Society actually came out and made a statement that Ibuprofen is safe for use post-tonsillectomy, they've looked at that, the risk of bleeding, and they feel that it's safe. The ENT -- I can find that.

THE CHAIRPERSON: That's fine. But the banner message, just look at it on -- looking at it as an antagonist, because codeine as an oral starting dose. Now we're putting this banner message out and here it says, "recommended starting doses of opioids in children weighing less than 50 kilograms,"

and yet codeine is listed on there.

DR. BORGERT: Well, yeah.

THE CHAIRPERSON: I mean, should we delegate that line as a --

DR. MOORE: Yeah.

THE CHAIRPERSON: -- consideration?

DR. MOORE: Yeah, I think the intent when it was put in there was as a comparison. You know, if you would have prescribed codeine at this, but I can see what you're saying.

DR. OLSON: I agree with Dr. Hayden. Why don't we just take it out of the chart and put it as a reference as a baseline as it exists but not in the chart for dosage.

DR. BORGERT: Okay.

DR. OLSON: The other question too is, so we're pushing -- you know, oxycodone is covered by Rx and that's fine. Why are we not allowing acetaminophen be covered by Rx? Because I mean, we alternate.

The other problem with some of the other combinations is the frequency of the opioid and getting large acetaminophen, so we recommend alternating, but most families don't buy the acetaminophen. So I recommend

we put acetaminophen on as available by Rx.

THE CHAIRPERSON: For those children under 6 years of age. I think that was our --

DR. OLSON: We brought that out.

THE CHAIRPERSON: We brought that out at the last meeting to have that. Do we have other generics like loratadine on our formulary that's generic? Ibuprofen is generic and over-the-counter as well, it's a liquid suspension. And I also made that recommendation that Dr. Olson is making about the acetaminophen.

DR. OLSON: It comes down to, you know, unfortunately the ibuprofen liquid, a lot of children don't like it. So acetaminophen is more palatable and you have the melt-away tablet and things like that. You have other options with acetaminophen. It's much better.

THE CHAIRPERSON: And the other concern I think I mentioned maybe two meetings ago regarding this banner message is putting this information out here and you're going from a schedule -- I think it's Schedule 4 drug or

Schedule 3 drug, these morphines and oxycodones are Schedule 2, so you kind of say "Well, let's do this."

That was my other concern as a recommendation. To put that ibuprofen or acetaminophen bolder or this is your option, you know, making it really easy for the prescriber to the see what their available options are.

DR. BORGERT: Yeah. I can't make the decision about acetaminophen, that has to be an Agency decision, so...

THE CHAIRPERSON: Acetaminophen is currently available on the preferred drug list, under arthritis dosage, I believe. So I'm sure why it would be -- you know, as a time limit postop, if it was for the six and under, it wasn't a long period of time. So as an available option If we're going to do this banner message to promote patient safety.

DR. BORGERT: I will take that back to the Agency. And --

THE CHAIRPERSON: And perhaps look at a fiscal analysis of it as well, maybe. If

that was the concern or --

DR. BORGERT: I don't think it's fiscal. I don't think that's the issue, but I certainly will take that back to the Agency about the acetaminophen.

THE CHAIRPERSON: Yeah. I don't think parents will buy the over-the-counter, even if they had those benefits with the added enhanced. They won't even buy the Refresh eyedrops, I mean, for dry eyes. It's just costs.

DR. BORGERT: Our next follow-up item has to do with methadone. And just some background that we discussed last time. Methadone is -- and specifically we were looking here at drug interactions with methadone. And we parsed out these -- just looking at the severe and major methadone drug interaction.

So we know that methadone has been associated with prolonged Q-T intervals and Torsades de Pointes. Methadone is metabolized by several of the CYP pathways. And concurrent use of drugs that block these pathways may increase methadone plasma

levels. It's also extensively protein bound, so that's another route of possible drug interaction.

And then, you know, another possible problem with drug interaction is that if you use multiple drugs that can prolong the Q-T interval, increase the risk there. And so consensus guidelines recommend the use of baseline ECGs to measure the Q-T intervals, as well as clinicians being aware of interactions between methadone and other drugs that might prolong the Q-T interval or slow the elimination of morphine -- or, excuse me, methadone.

So we looked at our data to see, you know, what we had going on in terms of these specific -- these very specific drug interactions, severe or major drug interactions with methadone. And we did have some claims there, as you can see, that got this message.

Now, what happens at this point in time with these drug interactions is what we call post and pay. So in other words, the message is sent back to the pharmacy, an alert on the

drug interaction -- and probably a lot of the pharmacy software has a drug interaction alert as well. But we do not stop the claim from paying based on that drug interaction, we still allow the claim to pay.

There were a few of them that were reversed. We have no idea why they were reversed. Some of it might be because of this reason or not, we don't really know. And so what the DUR Board had discussed was putting in a hard stop when -- anytime this type of drug, as severe or major drug interaction with methadone, was flagged at the pharmacy level. That would require the pharmacist to basically investigate the situation.

The pharmacy can then be able to enter some DUR service codes to allow the claim to pay if it were appropriate. But it would stop it to a point where some intervention needs to be taken.

However, in the interim, we met at the end of June and had this big discussion. And then I sent this letter out in pdf format with the packet. There was a letter to the

CMS acting administrator on July 20th, that was signed by eight U.S. Senators. And the gist of it was that they were very concerned that methadone was a preferred drug in many state Medicaid programs.

So some of those comments that they made is that they were deeply concerned about the inappropriate use and abuse of opioid prescription painkillers that has led to unprecedented numbers of overdose deaths across the United States. They estimated that 30 percent of opioid-related prescription drug overdoes deaths involve methadone. That most state Medicaid programs have designated methadone as a preferred drug for managing pain. And they feel that these state Medicaid policies may be inadvertently contributing to opioid overdose deaths. And they want to clean up the issue guidance to state Medicaid directors recommending the removal of methadone for pain from preferred drug lists.

So they pretty much just said "hum." So the plan was that the P&T Committee was going to discuss this yesterday and the

recommendation was going to be, I think -- well, the P&T Committee -- okay.

Since the P&T Committee did not meet yesterday, the P&T Committee did not discuss this issue. However, we didn't at the time that the P&T Committee was not going to meet. So we didn't proceed forward with this drug interaction edit, because we felt like that if something is going to change, then we -- you know, we don't need to do all that work.

So I think at this point what I would say about this is that it's pending. You know, I think it's pending the outcome of when the P&T Committee meets next. And we don't even know when the P&T Committee is going to meet next. So that's kind of the status at this point, just to bring you up to date that it's pending.

Anybody have any comments --

THE CHAIRPERSON: Well, the whole aspect of controlled substances is the Board of Pharmacy is going to be meeting again next month regarding their rule on controlled substance dispensing. I don't know if you all are aware of that. But the Board of

Osteo, Board of Medicine, FMA, all the state boards, CVS, Walgreens have been looking at -- you know, we talked about the paper that came out of the National Association of the Board of Pharmacy paper and all the states gave their recommendation.

So they're going to re -- updating their dispensing rules to reflect the consensus state guidelines in terms of the TMP and these red flags that are raised. And here's a perfect red flag in terms of safety for patient care. So that's another issue.

So anything that impacts patient care is to be reviewed. And I'm not sure -- this is the preferred drug list? The -- I'm just getting an update, they are looking at their -- updating their 64 -- I forget which one it is. They're somewhere in the process right now.

They have a committee that was meeting looking at the dispensing practices in terms of having the pharmacist asking the PDMP and making sure -- because sometimes the prescribers are not looking at it or writing a script because the server is down, the

password is reset, whatever. So many obstacles on behalf of patient practices -- private practices. So I'm just getting an update on that they're looking at that.

DR. SAEZ: I have a question. You know, I have -- you know, in the community I know that -- I'm not a psychiatrist, but I think methadone is also used for --

THE CHAIRPERSON: Detox.

DR. SAEZ: -- detox. So are we going to be able to differentiate these, you know, from pain? Because remember, methadone is also used for drug detox. So I mean, if you cut it from the preferred drug, all this -- we have a big drug issue in our community.

DR. BORGERT: Right. Actually that is not covered through the fee-for-service Medicaid benefit for methadone use for drug detox, only for -- right. It's kind of a separate issue. The 40 milligram dispersible tablet is not covered, because that's the one they use for detox. So that's a separate issue.

DR. SAEZ: What I see in the community is sometimes they just continue giving the

patient, not for the pain, but they just maintain them on a dose of methadone. I'm not sure if -- I think. You know, like --

DR. BORGERT: I mean, I think that -- I mean, what you're saying is you're kind of using it as medications just for treatment like similar to suboxone or something like that.

DR. SAEZ: Yes. That's what we see a lot in the community. And maybe they get away by saying that it's pain, but what we really see -- I don't know the standard of care. Again, I'm not a psychiatrist or, you know, a drug addiction doctor, but I see it used in this manner.

DR. BORGERT: Right. I think that's a valid point and I will say that I read recently that CMS is going to lessen the restrictions on suboxone prescribing. Because I think it's currently now there's a limit on the number of patients they need, a certified suboxone prescriber can prescribe and they are going to do away with that. Because they want to encourage medication-assisted treatment, and obviously I don't

think they want to encourage methadone in that role. So I think that we probably are going to see an increase in suboxone in that situation as opposed to the methadone.

THE CHAIRPERSON: I also wanted to comment in November the CDC is coming out with their revised guidelines or updated or new guidelines on chronic pain, and that will be coming out. There is a paper right now on there but it's not posted, I don't think, on the CDC website for chronic pain management.

Yes.

DR. MARTORANA: Question. Is it within the purview of this committee to make a recommendation to the P&T such like for removal of methadone?

THE CHAIRPERSON: Yes. You know, we have done it before. We did it with Soma years ago as well. And we also can put -- you know, the other recommendation we had done in the past, let's say for muscle relaxers, we put in like a time limit like for acute pain it's like 21 days or some -- or a certain number of refills per a calendar year. So we've looked at that as well.

Moses?

DR. ALLEN: And just to piggyback on both points. You know, certainly this is concerning the safety impact, but as a committee do we have -- will we be able to I guess have access to the impact that this would have if it were removed from the PDL?

So obviously it's currently a PDL medication and I would imagine, you know, there's a number of people that are on it. But, you know, have we had the ability to, you know, analyze those numbers, perhaps we could make the recommendation of removal or perhaps even put steps in place to just hypothetically try morphine or whatever first prior to going to the methadone, just to make it more difficult per se to get that medication.

MS. MOORE: Yes. This committee does have that -- it's in the purview of the committee to make that recommendation. What I will say is we do a pre-implementation impact analysis when I code the changes from the P&T Committee. However, we'll probably meet as a committee prior to this board

meeting again, so it would be kind of tough to get you guys that information. We can bring that information back once the P&T Committee votes.

Because we don't know which way the committee will go at that time. So if that drug does move to the non-preferred status, we will have that information that we can provide to you at that time. And if you all would like to -- at that time -- so it would be January at that point -- to discuss criteria, we can certainly discuss criteria for approval here and implement it after the January meeting.

So at this point I think that this edit is pretty much on hold until the P&T Committee reviews it.

DR. BORGERT: Okay. The next item for follow-up is regarding topical testosterone products. Just quickly some background. We know that Androgen prescriptions among men 48 years of age or older have increased threefold, and this is from 2001 to 2011. Now, this is not specifically to Medicaid, this is referring to in general.

There are four formulations of testosterone available; injectable, oral, transdermal, and topical gel. And of those four formulations the topical gel is the one that's really seen the most increase in utilization, it's increased more than fivefold. Again, not specific to Medicaid, just in the general population.

Another factor that caused us to want to look at this was the FDA in May, when they did labeling changes regarding possible increased risk of heart attack and strokes, there was a randomized trial in testosterone gels in older men that was halted due to these ongoing concerns about cardiovascular safety. And the FDA further made a statement that the benefit and safety of these medications have not been established solely for the treatment of low testosterone levels due to aging.

So what we did topical testosterone is on the preferred drug list for Florida Medicaid. We looked at our utilization. We did have -- during the one quarter -- the first quarter of this year 167 claims, 81 recipients, about

$82,000.

We tried to look a little bit about who these patients were. And some things that were a bit concerning were that, you know, we had a couple patients who had a diagnosis of prostate cancer or related to prostate cancer and theoretically testosterone should be contraindicated in anybody with that type of medical history.

And so what we did in the interim was to go back and explore what would be some reasonable diagnoses that we might be able to put in place to implement an AutoPA. So it is a preferred drug, so we're going -- it will continue to be a preferred drug as approved by the P&T Committee. But for preferred drugs it is acceptable for us to put a diagnosis look back on those to -- because that's in line with the FDA labeling of this drug.

And so these are the proposed ICD 9 -- and I know ICD 10 is literally around the corner -- but these are the proposed ICD 9 codes that the -- have thought to put in place where the system would just from back

automatically, look for this diagnosis in the patient's history, and if it found this diagnosis, then it would pay. And these are pretty raw. I mean, really pretty broad, you know, testicular dysfunction. Testicular dysfunction, really not otherwise classified, you know, pretty broad.

DR. ALLEN: Quick question. So No. 1, I really like this recommendation. But secondly, if this AutoPA were implemented, is there a look back, are all your edits hard stops from that point in time?

DR. BORGERT: I'm sorry, could you repeat the question?

THE CHAIRPERSON: What's the look-back time, I think.

DR. BORGERT: Oh, what's the duration time that we look back for diagnoses?

DR. MOORE: Generally it's two years.

DR. ALLEN: So --

THE CHAIRPERSON: What's the look back -- go head, I'm sorry, Moses.

DR. ALLEN: So just for clarity. So in the event, you know, that I was a patient that didn't have one of the three diagnoses

that you're looking for, and I had previously been on Androgel, when this AutoPA is put in place, it's going to reject it.

DR. BORGERT: That's correct.

DR. ROMAY: Have we researched the -- or perhaps we can -- or in addition maybe in place some AutoPA or actually PA the drug to request a baseline testosterone level? Have we looked at that? Because a lot of times --

DR. BORGERT: It's a preferred drug, so...

THE CHAIRPERSON: Or verfication of diagnosis I think he's asking for.

Also, are there other -- I believe there are other ICD 9 codes or a pituitary hypofunction. I mean, isn't there some other additional codes that should be on that list?

DR. ROMAY: Yes.

THE CHAIRPERSON: Do you have any other codes that were under any other -- besides pituitary hypofunction? I think there's -- any other suggestions in terms of other diseases that need testosterone? Because once these ICD 9 codes are used and if you don't have the other code are more broader.

DR. ALLEN: Right. So just out of curiosity, were these compendium? Were these four under compendium or I guess the PDI?

DR. MOORE: The Agency asks for suggestions from the plans to submit some ICD 9 codes that we would code for an AutoPA, and these are the ones that they had received feedback from the plan. And so we verified the ICD submitted it and that's where were this list came from.

THE CHAIRPERSON: Dr. Zitiello made a recommendation of adding --

DR. ZITIELLO: In the pediatric population we see it for Klinefelter Syndrome and I don't think a pediatrician in general would use ICD 9 codes.

DR. BORGERT: Right. And that's certainly on the list of medications.

THE CHAIRPERSON: Dr. Luis?

DR. SAEZ: You know, my population there's again a lot of transgender, so I guess gender as far as a new diagnosis are used by the psychiatric. I don't remember the diagnosis, but there may be a female that wants to transition into a male, you know.

So they may be using the injectable form of testosterone. So it's a valid ICD 9 code nowadays. It's gender coding or something.

THE CHAIRPERSON: Any other ICD 9 codes or suggestions from the board members? Moses?

DR. ALLEN: I'm sorry. I'm asking a ton of questions at the first meeting. I guess as a general rule of thumb, would this to be our advantage to have the ICD 9 codes mirror the PDI or compendium? I mean, just the reason I ask so -- I mean, I'm referring basically for suggestions right now, but without micromanaged or clinical pharmacology, I can't quote it right now, but I think we're at a disadvantage.

DR. MOORE: I actually have a pharmacology degree.

THE CHAIRPERSON: Go ahead. What does it say?

DR. MOORE: So for an indication -- they're really excited next door. So the only indications are delayed puberty, hypogonadism, and palliative treatment of breast cancer. There are a number of

off-label indications, but those are -- and I just looked up Androgel.

THE CHAIRPERSON: Okay. So I guess it will go through with those prior and then some other ones you just mentioned and then if they want to do a prior auth, they would have to submit their --

DR. MOORE: Right. It would be a manual PA at that point.

The CHAIRPERSON: So if the item -- and you may want to -- if an item is a non-preferred item, a patient can still have access to the medication, they would -- a prescriber would have to submit a prior authorization justifying medical use of any drug.

DR. MOORE: Right, right.

THE CHAIRPERSON: Just so you all know that.

DR. SAEZ: The other question is that there's a real controversy about how long should a person stay on this? You know, there's really no full guidelines as to how long. I know it's a preferred drug, but sometimes, for example, in the HIV

population, like they don't know what came first, either testosterone that was caused by the HME or the medications.

So sometimes what we do is we start the patient, we get them off for a year and then we do a trial where we see if they can be without it, and then we check the testosterone. Some, too, are able to be without it. So, you know, I don't know how long somebody should be on testosterone. I don't know if there's any indication. I know it's a preferred drug, but shouldn't there be some type of PA, maybe it's like a preferred for a year and then like -- I don't know.

THE CHAIRPERSON: Time limits you're talking about?

DR. SAEZ: Yes. I think --

THE CHAIRMAN: I don't think that's in the packaging insert. We've done that -- we've done time limits for oncology agents. For example, Tamoxifen has a 5-year time limit.

DR. OLSON: The prescription is only valid for a year so you would at least renew with the PA annually, but -- you know. I

don't know.

DR. SAEZ: But right now she says there's no PA because it's a preferred drug, so you just go through. So the question is like should we have some preferred. Should we have some type of PA? Because, you know, how long does somebody need to be on testosterone? Because the question is it's very hard to write right now with all these heart attacks and -- if we're talking about the safety of the patient, you know. Like there's studies that are coming out that -- you know, to answer these questions.

I mean, should there be -- I think everybody should be happy with the testosterone and everything, but I think we should also question ourselves because there's really no standard of care as to how long somebody should be on it. Some people would need to be on it forever, but there's no --

DR. BORGERT: Yeah. I'm just thinking about prorating it. I think we might have it -- we thought about doing a duration of therapy and I think we might have to tie that

to a specific ICD 9 code. For instance, you know, men who've had testicular cancer, who had a radiation or something like that, they -- my understanding is they're on lifelong, lifelong testosterone.

THE CHAIRPERSON: And also pituitary hypofunction --

DR. BORGERT: Right. So there are some occasions that lifelong therapy is clearly medically indicated. So we might need -- if we looked at duration of therapy, we might have to narrow that down in terms of diagnoses codes. We might just --

DR. ROMAY: I think to go back up to what we were mentioning before about the testosterone levels, I think we need to do a better job of getting that baseline level of testosterone. And then under renewal of that PA, they can submit, you know, the members -- you know, "they're therapeutic now, we're going to keep watching them, you know, we'll monitor them, you know, we're reassessing their condition to see if there's any cardiac complication or anything like that." And then moving forward and then they continue,

then we just monitor them on a yearly basis to make sure that they're on target.

THE CHAIRPERSON: Yeah. Then it voids the no-show part until the prescriber re-evaluates.

MS. MOORE: And my suggestion is because of the nature of the recommendation through the P&T. So because this is a preferred drug, we have limitation as to what we can do with this drug at this time. However, since we review P&T classes yearly, I think if we review those drugs through here before it goes to P&T, I think that's a great recommendation to take when that drug is up from review.

So since we get out ahead of the P&T classes, we're able to take everything that you all said here, which are valid and well points that we should take back to the P&T Committee. But it has to be before those classes are reviewed so that when provider synergies goes out to reach out to those manufacturers, they can layout our criteria that we want.

THE CHAIRPERSON: So you'll table that --

this item for -- because it's not in the January. I'm looking at the January. Well, it says January intergenic agents.

DR. MOORE. Yes.

THE CHAIRPERSON: So for January you'll have to put it on their agenda.

DR. MOORE: Right. So I think at this time it's a great time to discuss this, because before we meet again those discussions will happen with provider synergies and the Agency. So if we could summarize our talking points that we would like to propose for the next --

THE CHAIRPERSON: Dr. Luis made a motion for -- go ahead, make your motion.

DR. SAEZ: The motion to discuss the restrictions for --

DR. MOORE: Yes. So we should define those restrictions today.

THE CHAIRPERSON: So --

MS. BORGERT: Let me ask you a question, Dr. Luis. In your HIV population, the formulation that you're using in these patients, is it injectable or is it topical?

DR. SAEZ: We use both, but for some

reason or another, you know, or male population they like injectable form. So I have notice --

DR. BORGERT: Let me do this. We might be able to differentiate it a little out and look at it that way. I don't know.

THE CHAIRPERSON: I think the cost of the injection is less than the topicals.

DR. SAEZ: It is. Men tend to like the injection more because they feel like Superman, because they get the injection and they get like a big surge and then -- and I do notice that especially on my men patients, some of it I think is a little bit of abuse. You know, like -- so I don't know how -- I think getting the testosterone level and doing a trial without it to see, you know, I think it would be the one of the restrictions that I would put on it.

And getting a PSA every so often, because we do know that even though testosterone doesn't cause cancer -- you know, if a person, you know, is likely to get cancer, is just going to make it faster. So a testosterone PSA would be some of the things

that I would check.

DR. BORGERT: And when we looked at it, only 13 patients had a PSA or were ordered a PSA.

DR. ALLEN: So I have a question. I just want to make sure what we said -- we're on the right track here because it almost seems like we're veering off in two different directions. I think the original recommendation was for the AutoPA -- and please, I don't want to overstep my bounds here -- but maybe it's prudent for us to take a look at -- well, are we going to see if we're going to accept that recommendation and then take a look at the separate recommendation of the limit on the amount of time if we're in agreement?

DR. MOORE: I think, yes, the AutoPA was because it's in the preferred status and we can only look at certain items if it is in the preferred status, which, you know, the diagnosis is fine. If, you know, the inclining limits that are dictated in the prescribing information, we can implement those. Those are things that, you know, the

P&T Committee can look at the prescribing information.

But I think that the committee is trying to go a step further. And it seems to me that the recommendation might be to make this drug non-preferred to stop it so we could look at these lab values, take a PSA -- you know, monitor the PSA levels as well, and duration of therapy was something else that came up.

So if it's stopped as a non-preferred drug, that would allow us to do a better review of the appropriateness of this -- for those patients. So we could always look for the diagnosis when it stops as a non-preferred drug.

So to me it seems like our recommendation to P&T for January is to make these -- this product non-preferred and we're trying to draft some type of criteria here as to when it can be approved.

DR. ALLEN: That's what I'm saying on my part, yeah.

DR. OLSON: Can you bring back the diagnosis code data without that stop. Can

you get access to that information? Because my question to you, is how much -- what percent of these fall under the other category?

You know, if it's 50 percent, those are probably people that are kind of like -- I agree with you that even the ones that should be getting a baseline diagnosis and might be abused, that might be -- if that's 50 percent that's a category we might want to drill down, and say yes, you need a testosterone level. Yes, you need this or that.

DR. MOORE: It's really hard when it's non-preferred to tie the diagnosis to the actual recipient because they may fall in like in another -- like another category. But because it's -- it's not stopping for any reason at all, it's preferred. So they don't have to have a diagnosis. So they don't even have a diagnosis listed there in the first place. So it's kind of hard to tie that, make a correlation, a one-to-one, they're getting this drug because they have this indication, when it's non-preferred.

DR. BORGERT: I will say that when the

raw data was pulled -- yeah, when the raw data was pulled to these 81 recipients, 167 claims. The statistician when she pulls it, she usually gives me the raw data and just looking at it, just very unscientifically, the most common diagnosis was testing pituitary hypofunction.

THE CHAIRPERSON: So we have a motion on the floor. Luis, do you want to clearly state your motion again?

DR. SAEZ: The motion is to make testosterone products non-preferable and bring out a criteria for the P&T to review.

THE CHAIRPERSON: Do we have a second for the motion?

DR. ROMAY: Second.

THE CHAIRPERSON: Any further discussion?

DR. MARTORANA: The only would be to bring in the ICD 10 codes for us to review. Because I think that's going to allow us to more accurately and succinctly narrow that because they're going to be much more descriptive and much more specific than the general ICD 9s.

THE CHAIRPERSON: Moses?

DR. ALLEN: No. No questions.

THE CHAIRPERSON: The other item I think was to -- along with the ICD 9 code -- ICD 10 codes to review, the time limit was also, the one year, with lab values or the baseline PSA is to adhere to testosterone levels. And also adding transgender coding for the ICD 10 on there.

DR. SAEZ: And the other thing I see is like the amount people use. Do you have a limit on the amount? Because sometimes some people, they go crazy, they want more and more. So is like there a limit on the amount too, like how much --

THE CHAIRPERSON: It should be based on the levels of testosterone so that they're therapeutic and so everybody is individualized, I thought.

DR. SAEZ: Like just for the injection we try to keep it mostly I think 1 1/2 ccs per month -- a month at the most, you know, so... With the gel it's different because it's just like a set parameter I think 2.5 or 5. But with the testosterone sometimes they overdo it and they go 2 ccs. That is too much.

THE CHAIRPERSON: I think there should be a reassessment of the testosterone after your injection. I think that's what the --

DR. ROMAY: Yeah. I think it has to do a lot also based on weight also. I mean, if you have big body area and especially when you're applying the gel or the patch, you know, you need adequate blood level, so it's also really tied to the blood level of testosterone.

THE CHAIRPERSON: They recommend a lab value after injection to asses them, a fasting level, I believe.

DR. ROMAY: It has to be drawn usually in the morning, like an 8 a.m. draw. So we have to look at that as well. We have to make sure that the blood level drawing time is within, you know, standards.

THE CHAIRPERSON: And don't think we can set a limit on the dosing unless you have the lab values. Yeah, you need to know that they're therapeutic.

DR. SAEZ: I think the reason the package insert is like a limit of how much. So we have to be careful because then there's some

safety data that if you give too much, you may cause increased anxiety or other stuff that may be also -- I think there is a limit on how much you can give in order to be safe. So I think there should be --

DR. MOORE: It depends on the medication.

THE CHAIRPERSON: So you have a vote on that. We all voted or a final vote. All those in favor signify by saying "aye."

THE BOARD: Aye.

THE CHAIRPERSON: We have unanimous approval on that.

DR. MOORE: Just so I'm clear as to doing this. This is tabled until P&T votes on it in January. Our recommendation is to make that product non-preferred, so I'll take that back to them when I get back home. And the criteria for this is based on testosterone labs, we want that. Do we talk about duration of therapy? One year?

THE CHAIRPERSON: It would have to be a one year.

DR. MOORE: Right. PA's are generally a year, prescriptions are. PSA values, how often do we want those measured? Just

baseline and then subsequently every year or --

DR. ROMAY: Every six to one year depending on how often they're followed up. But I mean it's definitely warranted that they at least get a baseline and then that way we can monitor.

THE CHAIRPERSON: I think most plans cover it once a year.

DR. MOORE: Then we'll do once a year for that as well.

THE CHAIRPERSON: It has to be up to 365 days though.

DR. MOORE: Right. And then we're going to code, the ICD 10s. And the ICD 10s we are going to code are the prescribing information ICD 10 along with the --

THE CHAIRPERSON: Klinefelter, pituitary hypofunction, and transgenders.

DR. MOORE: Got it. Thank you. We'll get back to you for those ICD 10s.

DR. BORGERT: The next topic we're going to revisit is Synagis. Dr. Hayden, I just want to tell you that I did talk to Dr. Winterstein from the University of

Florida College of Pharmacy and who has done, you know, a lot of research and publications in this area. She wasn't able to make it to this meeting but she has committed to come to our January meeting and kind of give us an update on her research, which is what you had asked about regarding this topic.

THE CHAIRPERSON: So this is a hot topic we've been discussing for the last three years at our table. Three years, right, at least. And then when we went into the decision making as an advisory group here, our decisions were based on science with Dr. Winterstein and her group with all the research and most recently -- if you want to give the background to our new members so that they're up to par.

DR. BORGERT: Yes. That's what I have on the slide.

So in August of last year the American Academy of Pediatrics did update their guidance which they use very -- I don't know if it's on a regular basis. But they have certainly updated it multiple times.

And with when August 2014 update they

suggested a maximum of five total monthly doses in qualifying recipients. Prior to that it had been seven. The maximum recommended doses had been seven.

Now, just for background for those of you that don't necessarily do pediatrics, there is a geographic variability in RSV seasons. In most of the continental United States it's considered to be November to April. However, Florida is kind of an anomaly in that they have variations within the different regions of the state. And just FYI, this is the map of the different regions as it's classified for Synagis utilization. So we have northwest, north, central, southeast, and southeast, that's how it's broken down.

But, however, despite this -- and this is a direct quote there on the slide from the American Academy of Pediatrics, "Despite the varying onset and offset dates of the RSV season in different regions of Florida, a maximum of five monthly doses of palivizumab should be adequate for qualifying individuals for most RSV seasons in Florida."

So what we were proposing at that time

was to decrease the limits for the 2015-2016 RSV seasons done to a maximum of five doses to be in line with American Academy of Pediatrics recommendation.

So the data we looked at the last meeting was what happened in the 2014-2015 RSV season, which would have been July of 2014 through April of 2015, how many of our patients could we see that received more than five doses. And there was only about 25 percent of the recipients who did receive the maximum allowed at that time, which was seven doses.

And we broke it down by region and there was no difference amongst the different regions in terms of number of patients who received the seven doses. It was about 25 or 30 percent across the board regardless of the region. So that kind of brings you up to speed to where we left off with this topic at the last meeting.

So at the last meeting -- well, I guess I should say one less important thing. And that was the committee did vote, ultimately after quite a bit of discussion, to decrease

the maximum number of doses to five with the caveat that if a practitioner felt that a child needed the extra two doses, that they would be able to use the prior authorization process to obtain those extra two doses.

So I believe Dr. Olson was the one who brought up, you know, we're not really capturing inpatient utilization of Synagis and how does that change the picture or does that change the picture. So we did attempt to go back and capture our inpatient dosages of Synagis. However, looking at -- we were able to find some, but we really were not confident that we had a complete data set. Just based on coding and billing formats, we just didn't really feel like, you know, we got everything.

So we didn't want to present that as -- I mean, we included that data where we had it, but we just didn't really feel like it was a complete data set. But what we did do -- because we want to try to tie that to things that did have an RSV-related hospital admission.

So we looked at -- and we were able to

pretty clearly get that information. So we looked at Synagis recipients and these Synagis recipients either in the 2013-2014 RSV season or the 2014-2015 RSV season who had a RSV hospitalization in the 2014-2015 RSV Season. So do you follow me?

So they were hospitalized -- okay, so all these patients fit two criteria. They had a hospitalization for RSV that was the admitting diagnosis, the primary diagnoses or the secondary diagnosis. Somewhere between July of 2014 and April of 2015. Okay? But we needed to look at kids who got Synagis in the season before that, right? You know, in order to -- right. You understand? Do you follow me?

So then we look for back if you received Synagis in the two prior seasons and if you had a hospitalization in this past season. So everybody clear on the patient population? I will say, you know, again, you know, this is not -- you know, I'm not --

DR. OLSON: And can you define got Synagis? Did they complete the course or did they get a dose two, three, four --

DR. BORGERT: That's where I'm going with that. Thank you. Thank you for that beautiful segue. I will say that, you know, limitations that are very obvious to this is don't have -- we don't know -- we don't know the indication percentages. We don't know what their gestational age was, we don't know if they had a diagnosis of chronic lung disease. We don't know that information. And as I already said, we certainly believe that we had incomplete capture of inpatient doses of palivizumab.

With all those limitations in place let's look at what this population looked like. So not surprisingly most of the RSV-related hospitalization admissions were in the first year of life, which is what we would expect to see. So that is what we expected.

So this is being addressed -- this is your question, Dr. Olson. How many of these patients who had an RSV admission and received Synagis, how many of them got, you know, appropriate Synagis utilization? And by "appropriate" I mean they started within a

month or two of birth, assuming they were born in RSV season, and they received monthly doses. Or even maybe, you know, maybe they even skipped one month, but it was pretty close to textbook the way they were supposed to received Synagis.

About 50 percent of those patients who had the RSV admission did what were identified as having appropriate Synagis utilization based on their date of birth and the dates of service that we had for Synagis.

So that's the dark blue piece of the pie there.

DR. OLSON: I don't mean to interrupt. So where did you cut that? Is it they got four doses, they got three? Where did you cut that off because you have some of them at 50 percent.

DR. BORGERT: Well, I allowed them to have all the way up to seven, but I stopped at their hospitalization. So I'm talking about they received it within a month or two of being born and received it every month prior to their hospitalization.

DR. OLSON: Okay. I'm still not

following you, because it's like -- I mean, I get what you're saying of how they get it. But did they get at least the five doses or like you said they might have skipped a month. So do you have the data for how many doses the babies received total?

DR. BORGERT: Yes.

DR. OLSON: Because if you're just looking --really you're supposed to complete the whole series. That's the most effective way is to do the whole series.

DR. BORGERT: Yes, I do have the data. I don't have a graph on the data, unfortunately; but I do have that data, yes.

Just, you know, off the cuff I would say that the majority did not receive, you know, the seven doses prior to their hospitalization.

DR. OLSON: I bring that up because I think that -- I keep bringing up the hospital component because I think that's what's key here, is the dollars we're spending for patients to get doses. Some are getting it in the hospital, they're discharged, and the pediatricians do not follow up and complete

the series; some are getting hit and miss. So we're spending money on a drug that I think in reality very few patients are getting the whole series of the drug. So that's another thing I think we really have to consider.

DR. BORGERT: And I will go back and pull out those numbers. But like I said, just from my spending a couple of days with this data looking at it, most patients did not receive the seven doses.

But by "appropriate," I mean that prior to their hospitalization they were started in a timely manner and they pretty much received it on time, regardless of the number of doses they received prior to that hospitalization.

And then the purple piece of the pie there, the 20 percent, those were children who either had their doses delayed significantly. So, you know, maybe they were more born and then, you know, not -- nine months later they got their first dose of Synagis or something. Or they skipped multiple months in between there. That's mostly who those 20 percent of the patients

are.

And then what really intrigued me, was the 30 percent of the patients who only received Synagis after they had a RSV-related hospitalization. And pardon me while I read to you, but what the American Academy of Pediatrics has to say about that in their statement is that "if any instance or young child receiving monthly palivizumab prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued because of the extremely low likelihood of a second RSV hospitalization in the same season." And they quote the number as less than 0.5 percent.

So 30 percent of the children that had an RSV hospitalization only received Synagis after that RSV hospitalization. And to take that one step further of all the dose -- when you're looking at this population, they had an RSV admission, they had gotten Synagis in one of the two previous seasons, a full 63 percent of those doses were only given after the RSV admission. Only 37 percent were given prior to.

So when you think about what we're spending on this drug, as you said, this is -- we're 63 percent of the utilization in these RSV-hospitalized children was probably -- I mean, according to the American Academy of Pediatrics it's completely worthless.

And do you know what happens is, you know -- I don't know. I mean, I'm not sure what happens. But I guess the plan is we don't have -- you know, we don't get that inpatient -- you know, "oh, they were hospitalized," so it's not like we get some feed where we know that. It's only in retrospect when we look back at the data that we see this.

So I don't know. I don't really have a proposed solution, but I think it's very -- when we're looking at, you know, wise utilization of dollars this -- at least according to the guidelines, we're not doing a very good job.

THE CHAIRPERSON: It's interesting to note that recommendation from the American Academy of Pediatrics was not recommended

post hospitalization for RSV.

DR. BORGERT: That's correct.

THE CHAIRPERSON: And it's very quite different than the pneumonia admissions for the adults that we give our influenza and pneumococcal vaccination during any admission for any lung condition, pneumonia, or COPD exacerbation, or asthma exacerbation, so that's the standard. And it's interesting to note that new information.

So I'm not sure if there's anything that we can do as making a recommendation --

DR. MARTORANA: Could we put it under prior auth for Synagis? If there is a question on there, if there is a culture positive admission for RSV, then that would --

THE CHAIRPERSON: Well, a claim -- but again, if we don't get that data --

DR. MARTORANA: That's what I'm saying, claims lag, but the individual or the physician requesting if they can -- if they attest that there is a culture positive admission, they might know that. Maybe you might not catch them all, but you might catch

some to say not to go ahead and offer it.

THE CHAIRPERSON: Dr. Olson.

DR. OLSON: Is that part of the PA, is that not on there as an indication to non -- I thought it was.

THE CHAIRPERSON: I don't think it was.

DR. OLSON: No?

THE CHAIRPERSON: No, it's not.

DR. OLSON: Because we added all the other criteria.

THE CHAIRPERSON: Right, we did. But I think that we had discussed this like a few years ago, three years ago. I don't think we get that data RSV admission. I mean, it's never in their discharge diagnosis. I'm not sure -- it's not, right?

DR. OLSON: No. It's not on there, no.

THE CHAIRPERSON: And is it a culture that's transpositive admission or is it a viral -- Amy?

DR. ZITIELLO: It's usually a rapid -- you can do cultures for it, but they usually only do the rapid test.

DR. OLSON: The thing here, too, is, if you look at -- I mean, the criteria is pretty

clear. I don't know if this is appropriate that this Board to take this approach. But we keep looking at -- you know, there is an indication for it.

The other thing I think we're missing is the avenue to give it is not clear and it's not -- it's expensive. Most pediatricians do not want to take on the expense of that drug. So I think that's another -- I think we should look at it is where it's appropriate, how do we make that process simpler for the patients to get the medications.

Again, I'm not trying to say we're not going to use the drug, but use it appropriately, and to open up the guidelines. You know, Medicaid is -- I don't want to say it, but even contact specific specialty pharmacies. But it's that kind of methodology where you set up a system where you get it to the pediatrician's offices on behalf of the patient, they can still give it and bill for it. But it's just I think carrying the expense of the drug, a lot of them shy away from doing this. I think that's part of the reason compliance isn't

there.

THE CHAIRPERSON: Isn't there a care coordination program that -- like a home -- I'm not sure if that's done, but like a care coordination through a disease management or at least a premature pulmonary patient, or general abnormality? Is a therapy initiative at a bigger level? Do they have those kind of programs? I know we do it for mental health. Because stocking it in the office I guess it's cost prohibitive?

DR. MARTORANA: Yeah. And I know some practices -- because you need 1 1/2 vials, basically the other half vial is wasted unless you go ahead and schedule all of your Synagis kids in for a day, then you can go ahead, split vials. Because once it's reconstituted it has I think a four-hour or six-hour shelf life that you need to go ahead and administer. So that is one way that some large systems have looked to is go ahead and schedule those individuals in a certain date so that you can go ahead and use the multi-split vial.

THE CHAIRPERSON: The other -- what we've

done in our practice for another vaccine, adult shingles vaccine. It's very cost prohibitive to stock it internally. So what I do is I script it out. Unfortunately, this vaccine is not given to a pharmacist to administer at the pharmacy level at this point. That would be a legislative change I believe. But that's another consideration of doing it at the pharmacy level within -- or a walk-in facility or at a pharmacy -- I guess it would have to be legislative change for the pharmacist to admin -- or the nurse at the -- Dr. Olson.

DR. BORGERT: How does home care play a role in these kids -- to get these kids the Synagis?

DR. OLSON: And, again, I'm talking about making the drug available. I think home care can play a big part. I think it's a great opportunity. The argument there is that it's -- you know, the reimbursement for a nurse to go into a home and administer is not there. But my argument against that is the cost of a nurse is much less than the cost of giving a dose or missing a dose or giving it

in a hospital. That's where I'm going with this, is how do you either give it in the home, you know, or you at least get it to the pediatrician's office where they can give it. Those I think are two great avenues to accomplish this.

THE CHAIRPERSON: Or the other option is to prescription vial -- you know, but if you give your pediatrician a pulmonary -- a pediatric pulmonary and then give it at the pharmacy. But again that's another --

DR. OLSON: Well, we can administer in pediatrics in the state of Florida, we do it all the time.

THE CHAIRPERSON: At this point they would give it like they would give the pneumococcal vaccine or other vaccines. I mean, they've added several vaccines this year.

DR. OLSON: I think it's an -- and this is kind of off topic, but it's a debate between pharmacy and probably the pediatrician world; because, again, it's a source of revenue for them so it would be getting them to allow that. That's another

avenue that I'd like to approach too. But again, I just think, you know, we don't usually look at that as far as --

DR. BORGERT: Right. Yeah.

DR. OLSON: -- some type of care management for that.

DR. BORGERT: Yeah. That's certainly outside the Magellan purview. Outside the Agency, and I think it's probably outside the pharmacy policy which is where all our other representatives are here today. Maybe pharmacy equality or maybe some other avenue with the Agency. I don't know. I'll toss that over to you guys.

DR. OLSON: I think that we keep bringing that up. For three years now we keep discussing the issue of utilization. We've whittled it down to five doses which is great, but there's still a huge count of what we're missing and how we can bring the data back. And until we get compliance and come up with a process to do this appropriately, we'll just keep going back and forth.

THE CHAIRPERSON: Jeffrey, you're excused. Thank you for coming today. Thank

you.

MS. BORGERT: I think maybe what we'll do is just quickly run through the Hep C data and then maybe take a break.

THE CHAIRPERSON: We'll take a break for a few minutes. We'll take a break now, a bathroom break for 10 minutes. And we'll come back at 9:45. Thank you.

MR. HAMILTON: I'm sorry, folks. There's a motivational speaker next door, if you hadn't already guessed. There's nothing I can do about it. I've tried to calm them down, but it's hotel's perogative to put groups where they want to.

(WHEREUPON, the exhibit was marked.)

THE CHAIRPERSON: Good morning, everyone. It's 9:45, I would like to continue with meeting. Rebecca.

DR. BORGERT: For the last, I don't know, probably year and a half now this committee has just briefly -- for a while we've had lots of discussions about hepatitis C. For the last few meetings we basically just kind of kept abreast of the utilization data -- the committee had asked to be kind of kept

abreast of the utilization data. And in your quarterly report I did put some information about there were two new drugs approved in the past quarter, Technivie and Daklinza.

And I'll refer you to your quarterly report for more information about the specifics of those drugs.

But just in looking at our overall utilization in the fee-for-service population from January of this year up until September 1st of this year this is what the numbers look like. I will note that Viekira Pak was voted the preferred at the March 2015 P&T Committee meeting and all of the 20 recipients have been approved by CRS since that time.

And then this is just kind of some information about the prior authorization request and the outcomes that we have regarding the hep C drugs.

So now I will move on to new business. And as I said earlier, usually the first session of the new business has to do with upcoming P&T classes.

As I stated earlier I put in your

quarterly report all of the classes that will be reviewed in January and March. One of the classes that will be reviewed in January is the COPD agents, and I have it there for you on the screen the utilization data in the previous quarter for these medications.

And so just kind of looking at this and thinking about, you know, management, utilizing it -- utilization management, is there anything, you know, that we might be able to do. And we don't currently have quantity limits on Spiriva and the hand inhaler is one that's on the PDL and it is a once-a-day drug, so perhaps implementing some quantity limits of 30 capsules for 30 days might be appropriate for the Spiriva medication.

Any comments or thoughts about that?

THE CHAIRPERSON: I thought that's how it was dispensed.

DR. BORGERT: Yes, but we have people who are getting more.

THE CHAIRPERSON: But that's not in the FDA packaging, is it?

DR. BORGERT: Right.

THE CHAIRPERSON: So is there a medical justification for that or is there a reasoning behind that or is there a travel supply? I mean, I can't --

DR. BORGERT: Well, that can always be done through the PA.

THE CHAIRPERSON: What?

DR. BORGERT: If it were a travel supply we could do that through the PA's office.

THE CHAIRPERSON: Oh. I thought it just comes in --

DR. BORGERT: It does, but...

THE CHAIRPERSON: Have we looked at those claims or did you want to look at those claims?

DR. BORGERT: You mean in terms of people who are getting more than 30?

THE CHAIRPERSON: I'm just asking. I mean, is there a lot. It says here --

DR. BORGERT: No. Those are just -- that does not mean that those were recipients who got more than 30. This is overall utilization of that drug. It's not specific to people who receive more than the quantity.

THE CHAIRPERSON: Well, we don't know the

impact. If we can put a recommendation out there, is there a potential impact or are there a lot of patients that are getting more than 30 capsules a month?

DR. BORGERT: I don't know the answer to that. I could speculate, but it would be honestly just speculation. I don't know the answer. So I can go back and pull that data.

Any other questions or comments?

Before I go to the next slide I'll point out to you on the third row on the table Daliresp or roflumilast is also in this PDF category. We had 176 claims for 71 recipients for $46,000 in the previous quarter.

Daliresp, for those of you who are not familiar with it, it is phosphodiesterase-4 inhibitor. It has a very, very specific indication that was given to it by the FDA based on what they were able to show in the studies. And that is to reduce COPD exacerbations in patients with severe to very severe COPD associated with bronchitis and a history of exacerbations. And so these would be GOLD Class C or D patients with a high

risk of exacerbations.

So basically the FDA gave them that very specific wording of labeling because that's what they were able to show with this drug when they did the studies. It is not a bronchodilator and according to the 2015 GOLD guidelines -- the Global Initiative for chronic obstructive lung disease is the GOLD standard for those of you who aren't familiar. According to the 2015 GOLD guidelines roflumilast should always be used in combination with a long-acting bronchodilator.

So we have talked about this and one possible recommendation might be -- this is a preferred drug. If you go back to the table on the last column there's PDL status, so it is a preferred drug. And normally, as we've discussed early at this meeting today, we can do an AutoPA for diagnosis, so that wouldn't be a problem in terms of doing an AutoPA for COPD diagnosis.

But we might also even want to consider looking for a history of long activated beta-agonist in the claims history since that's --

according to the guidelines that's how this drug is supposed to be used.

Now, I will say, you know, that may cause some issues, but we feel like it's a reasonable recommendation to do that anyway.

THE CHAIRPERSON: Well, my recommendation is not only for beta-agonist, some patients could be intolerant of the beta-agonist and then we use the anticholinergic like Ipratropium as GOLD guidelines as first line.

Some patients cannot -- especially in the elderly they cannot even use an inhaler because of the coordinated efforts and they can't get a breath in. So those severe patients are doing quite well with an oral agent. This is one of the only oral agents we have on the market. But doing a prior look back on the ICD 9 codes, that's fine. But not only a beta-agonist but also the anticholinergic.

DR. BORGERT: Would you -- do you think short-acting anticholinergics or just long-acting? So in other words --

THE CHAIRPERSON: Both. I think the guidelines have long-acting steroid and --

depending on the level of COPD and then I think anticholinergics are the first line.

DR. BORGERT: When I looked specifically for this drug they recommended a long-acting beta-agonist. So I understand what you're saying that not all patients can tolerate it.

THE CHAIRPERSON: Yeah, not all patients can tolerate it.

DR. BORGERT: So if the Board is okay with that recommendation, then that would be something that we bring back to P&T in January when P&T meets to review those drugs. Okay? All right. That all is going to be a recommendation that we are going take to P&T. So the --

THE CHAIRPERSON: Do we need to vote on that or --

DR. MOORE: I believe so. I think this is an edit that we're trying to implement and so we need to get a unanimous decision then.

THE CHAIRPERSON: So I'll make the recommendation that we make a diagnosis look back along with the guidelines, because the GOLD guidelines recommend it for age 3 or 4 and just in concordance we'll get a

recommendation on the guidelines to make sure that we have either a long-acting bronchodilator, beta-agonist, or an anticholinergic on board. Do we have a second?

DR. ROMAY: Second.

THE CHAIRPERSON: Any further discussion? All those in favor signify by saying "aye."

THE BOARD: Aye.

THE CHAIRPERSON: Unanimous.

DR. OLSON: Are you looking for a motion to -- for Spiriva?

DR. BORGERT: Possibly. But since Dr. Hayden wanted to look specifically at how many patients we're going to impact, I thought maybe we ought to table that and we can look at that in terms of how many patients have been impacted. Thank you, though.

THE CHAIRPERSON: Next.

DR. BORGERT: Yes. So just quickly looking at some -- of one of the classes that will be reviewed in March, the topical acne agents are up for review in March. And I have the utilization for the past -- for the

second quarter of this year.

And really when you look at these things most of the them have FDA approval of age greater than or up to 12. However, we don't have any age limits on them in our formulary on the PDL, in our summary of limitations. So one thing we might be able to do is to put an age limit on there and possibly explore quantity limits, although we're sort of talking about that in a more general sense at this point, as opposed to specific quantity limits for specific occasions.

So I think maybe the most appropriate thing at this time would be to consider putting that age limit of 12 or older on these products.

THE CHAIRPERSON: 12 or older and no -- that's it?

DR. BORGERT: Yes. At this time I think the most appropriate thing would be to just do age limits.

DR. ALLEN: I would like to make the recommendation to accept that.

THE CHAIRPERSON: I'm sorry, can you speak into the microphone?

DR. ALLEN: I would like to make the recommendations -- Rebecca's recommendation to limit the use of age limit.

THE CHAIRPERSON: 12 and older. Do we have a second?

DR. ROMAY: Second.

THE CHAIRPERSON: Any further discussion? Do you think we use acne agents perhaps at 9 years? Do we ever -- you don't see it?

DR. ZITIELLO: Not that often.

THE CHAIRPERSON: So it won't impact our pediatric population. All those agree signify by saying "aye."

THE BOARD: Aye.

DR. SAEZ: I had a question on these agents. They're kind of expensive, you know, it's like very different. Are we using the cheapest, you know, version of a -- I mean, I think I don't think it's a disease, but I see that like we have -- it's very expensive, you know.

DR. BORGERT: All of them that I have listed on this slide are preferred. So you can you get them -- all Medicaid recipients can get them at this time.

DR. MOORE: But I will add this is not net-net. So this is -- meaning this isn't the actual cost that is actually paid. This is the cost at the pharmacy counter. So then you have, you know, federal rebates and supplemental rebates that are also realized and that is not the price here.

MS. ZITIELLO: I wanted to ask a question. Why is Retin-A preferred over Hepnol? For years and years and years we have prescribed Hepnol for our pediatric patients and all of a sudden Retin-A was switched over to the PDL. I mean, we do tons of denials on that. And, again, I know it's not a critical issue, but, you know, we're supposed to be -- the business is supposed to be helping these providers out and that change really made a lot of people angry.

DR. MOORE: It was a decision through the P&T committee. They weigh in clinical as well as financial side of the table to make a decision. You know, first what's safe for the patient, but also what's a benefit to the state, and so at that time that's why the recommendation was made.

DR. OLSON: Can I ask a question? I know this came up before and I don't know the answer. But, again, we're making decisions based on paid claims, but we're not making decisions on drugs spent, right? Are we privileged to that information on what the -- we're not? Okay.

DR. BORGERT: They discuss that in the closed session of P&T committee, but since this is an open meeting, I don't think that's -- yeah. All right.

We have reached the quarterly activities for this quarter. So the first quarterly activity that we wanted to take a look at was morphine equivalent daily doses. And one of the big reasons we wanted to look at this was basically CMS is really stressing the use of morphine equivalent daily doses. And they have made a statement that they believe morphine equivalent daily doses would be a useful tool for RetroDUR. They actually came out and said we think RetroDUR boards should be looking at morphine daily doses, to look at their opioid utilization. So to the best of my knowledge we have not done that in this

board, so we wanted to start taking a look at that.

Just a little background. Obviously we all know prescription opioid abuse is a huge problem. Medicaid participants are twice as likely to be prescribed opioids as privately insured patients. And Medicaid enrollees account for 45 percent of overdose deaths and are six times at the risk of dying from an overdose.

Calculating the morphine equivalent daily doses is basically just one tool that we might use to help us in looking at our opioid utilization. There are numerous morphine equivalent daily dose calculators that are available online. And in terms of what threshold to look at as a high dose is controversial, but usually some people will say somewhere between 100 to 120 milligrams of morphine a day would be the number that you would look at.

So just to bring everybody up to speed on what our current edits are with regard to controlled substances. We currently allow a patient a maximum of four controlled

substances -- that's just not opioids, that's any controlled substance. Four controlled substance prescriptions per month. There is an exception for patients with cancer or sickle cell disease where they are allowed six controlled substance prescriptions per month.

This board in the past year looked at opioid polypharmacy in Medicaid recipients, and as a result of that work we are in the process of coding edits that would deny overlapping long-acting opioids. So you wouldn't be able to get MS Contin and Oxycontin both basically is the edit that's currently being deployed.

So tracking the number of recipients who exceed this threshold of morphine equivalent daily dose can be used by us as a tool overall at looking at our opioid utilization. So it's timely in that we have not yet implemented in this overlapping long-acting opioid edit. So that might be something that we can use as a tool after that edit to look at it as one of the ways that we look at the data.

So just briefly approximate morphine equivalent daily dose and these can be somewhat -- depending on which calculator you use it can be slightly different -- but we're talking about patients who are getting 100 milligrams of hydrocodone in 24 hours or 27 milligrams of hydromorphone -- these are all oral except for the transdermal fentanyl. 27 grams of oral hydromorphone, 15 milligrams of oral methadone in 24 hours, 67 milligrams of oral oxycodone in 24 hours, or 50 micrograms per hour of a duragesic patch.

And so when we looked at how many patients we had in a quarter that were exceeding those limits that I just described, you can see there the number. So we have about 13 percent of our total patients -- about 12 percent of our total recipients and 13 percent of our total claims. So not a large number, which is good. But we -- the idea here I think is just that we keep looking at that and just sort of try to decide is this something that we see increasing, decreasing, staying the same, that sort of thing.

And how do the changes that occur impact that? For instance, if methadone changes status as we've discuss in this committee, you know, does that change anything? Do we see suddenly, you know, people using a lot more morphine or oxycodone. And then in terms of any edits that we implement. Like I said, the long-acting opioid polypharmacy.

So I think right now we're just kind of at a point where we're using this as a baseline. And we'll monitor this going forward to see how changes in opioids; either policy changes, or PDL changes, edits that this board thinks about doing, how this might impact with morphine equivalent daily dose.

THE CHAIRPERSON: Rebecca, that's good data. The 17 percent of 3,650 claims. I'd like to know if on those claims, was it one prescriber, or was it two prescribers, or three prescribers that that individual is receiving?

DR. BORGERT: I have the raw data so we can go back and pull those patients who fell into this chart and see how many prescribers accounted for that.

THE CHAIRPERSON: I know you can't look at ER or true care specialists. Yeah, that's the hardest part to extrapolate this data. But it's interesting to see that, you know, the proposed pharmacy rules going into changes. Maybe we'll see further changes down the road.

Any other comments, Board Members?

DR. ALLEN: Just a quick comment here. And, once again, Rebecca, I think this is good data. But I guess is there any consideration for us to make a recommendation to P&T to maybe add an abuse-deterrent product. Just my reason for bringing that up is because it seems like we may be going down the road that we went with methadone. And I can't remember the actual legislation that's out, but apparently -- I'll paraphrase. Essentially if a provider wants to write for an abuse-deterrent product, and, you know what the generic equivalent is on the PDL, it is my understanding that we can't deny a PDL product if they truly do want that abuse-deterrent product.

So I mean at the end of the day I think

our aim here is to prevent abuse in some safe form or fashion. So I just wanted to ask if that was anything you wanted to consider?

MS. HARRIS: Elboni, before you respond to that, I think some of us had a hard time hearing you, Moses. So would you mind repeating exactly what your recommendation is?

DR. ALLEN: Sure. I'll trade you microphones here. In summary my recommendation was to ask the Board to consider an abuse-deterrent product for opioid addiction. I mean, in summary -- I mean, we're looking at the MEDs but, you know, the whole focus of this is to reduce opioid abuse. And with P&T having a high likelihood of perhaps removing methadone, it just may be an opportunity here to place an opioid-deterrent product, you know, on the PDL.

And I was just referring to the legislation. I can't recall the actual house, you know, representative saying -- who actually said it now. But essentially the gist of the bill is to say, hey, look, if a

provider wants to write for an opioid-deterrent product, we can't deny it; therefore, an equivalent generic if that's what they really want. I mean, they -- they're evaluating the patient.

THE CHAIRPERSON: Is Naloxone on our formulary? I'm just asking.

MS. HARRIS: No, it's not.

THE CHAIRPERSON: There's some legislation on that also for --

DR. BORGERT: I don't know, Moses, about that. But that might be something I think that we could take a look at in terms of the overall formulary and the PDL. What we have on the PDL, what's an abuse-deterrent, what's not an abuse-deterrent. And that just might be a good topic even like a good quarterly topic at some point is to look at the abuse-deterrent products versus non and kind of where we sit with all of that.

MS. HARRIS: This is Shevaun Harris. I can tell you that we are looking at the abuse-deterrents within the Agency. It's not on the PDL. I believe there's a question of whether or not it's medically necessary. And

just because a prescriber chooses to do so, it is not prohibited by law from doing it. It doesn't necessarily mean that we have to actually pay for it as a PDL unless the P&T committee recommended and the Agency approved it. I think you're welcome to put it forward and we can look at that. But I can tell you we are looking at it as an Agency.

DR. BORGERT: Thank you, Shevaun.

DR. OLSON: This is combination products all of them?

DR. BORGERT: Yeah. This is long-acting and short-acting.

DR. OLSON: So did we also look at -- in relation to that too, the acetaminophen doses that are being taken with those. Because obviously that's a possibility --

DR. BORGERT: The hydrocodone is probably an issue. Yeah, maybe not so much with the other ones but with the hydrocodone, yeah.

DR. OLSON: Oxycodone.

DR. BORGERT: That's true, percocet. Okay. Yeah, I'll take that back and I'll look at it.

DR. ROMAY: I don't know if the Agency

has adopted this. I know we mentioned before where a combination would be long-acting and the combinations that we're capturing the acetaminophen dosage of 4 grams per day, that will also -- you know, that would be an aggregate to patient therapy and will be --

DR. MOORE: We just implemented an edit that caps off the max daily dose of acetaminophen. I think we did it in August, that you can't have more than 4 grams, and it did include combination products.

DR. BORGERT: And just FYI, too, for those of you who have been on the committee, you've heard me say this before, but I'll say it for the benefit of the new folks. Obviously when we look at diagnoses, you know, we can't say that, you know, this diagnosis and this claim go together, because there's no way to tie a prescription to a specific. All we can look at is of these claim recipients, what diagnoses did they have on file.

So when you look at that list of diagnoses that were on file for those recipients who were exceeding 100 milligrams

of morphine equivalent daily dose, this is in numerical order of the possible diagnoses, meaning opioids. So you can see that a lot of it is chronic pain rather than maybe say -- you know, there's obviously some malignancies, things on there, and that sort of thing. But a lot of it looks to be chronic pain.

One of the topics -- the next topic that was suggested for this quarter was to look at overall anticoagulant utilization in a fee-for-service population. So we looked at Warfarin, then novel oral anticoagulants, and low-molecular-weight heparins, all of which are represented on the PDL.

And what we found in overall anticoagulant utilization is about half of our claims are for Warfarin, but less than half of the recipients are getting Warfarin, and then -- so, you know, half of our claims are for Warfarin and then the others are split pretty evenly between the novel oral anticoagulants and low-molecular-weight heparins made up the other percentage of that. So that's kind of what the overall

utilization looks like.

And as we look at the data a little bit more carefully, we decided to look specifically at the novel oral anticoagulants agents. So just to refresh everybody's mind, we're talking about -- I'm going to use trade names here, they're easier to say -- Pradaxa, Eliquis, Savaysa, and Xarelto. There's four on the market now, so those are the four drugs we're talking about here.

And there are indications not every drug has exactly the same indications, but over -- from a broad scope there are indications are for nonvalvular afib, if somebody has an artificial, they're not recommended and they should use Warfarin. But nonvalvular afib, orthopedic surgery prophylaxis, treatment of DVT and PE. And you see there which ones are approved for that. And then the last approval category -- or indication category is to reduce the risk of recurrent DVT or PE after initial therapy.

So what's interesting is that two of these are kind of long-term therapy and two of them are somewhat short-term therapy. So

certainly the orthopedic surgery prophylaxis is really short-term therapy. For knees it's recommended -- knee replacement it's recommended for 12 days, and for hip replacement it's recommended for 35 days. So that's relatively a short utilization.

Certainly afib is a chronic indication for these medications for most patients. Treatment of DVT or PE is, you know, supposed to be a minimum of three months. And then reducing the risk of recurrent DVT or PE again can sort of be open-ended in terms of how long therapy is it supposed to last with those.

So what we did is we looked at how many patients were on these drugs for less than or equal to or more than 30 days. And I thought it was a bit surprising that over half of the utilization these patients were on therapy for less than 30 days.

Now, this was only a quarter that we looked at of utilization; so, you know, it was only a 90-day possible window, but 56 percent of the patients who got a claim for this drug in that 90-day window had 30 days

or less of therapy. Which I thought was surprising given the fact that only one of those indications is for short-term therapy with this drug -- with these types of medications.

THE CHAIRPERSON: The data, Rebecca, maybe fracture with immobility that was missing on there too. So maybe that can account for the short-term duration. A recent fracture with immobility, you know, pending surgery or pending --

DR. BORGERT: Okay.

THE CHAIRPERSON: So that was missing on that format.

DR. BORGERT: Maybe I can look at that other ortho surgery. Okay.

THE CHAIRPERSON: They have casts on or something and just waiting.

DR. BORGERT: Right, right, right. When I looked at that 44 percent who did receive more than 30 days, only 27 percent of that population had a diagnosis with afib. So, you know, I don't know, I think maybe what this warrants is looking a little more closely at these four drugs. I believe they

all four are PDL, and looking maybe at a broader length of time and just trying to see, you know, are patients who are supposed to be taking these drugs on a chronic basis, not taking these drugs on a chronic basis I think is the question.

I think they're being utilized because they are easier to manage than Warfarin, but if the patients aren't taking them, and you can't measure their PT and know that they're not taking them, maybe in some ways it's not a good thing, you know. There's no way, "Oh, yeah, I'm taking it," you know. But the claims data doesn't seem to bear that out that the adherence is there.

And I think maybe that my thought as I looked at this data was maybe we need to go back and look a little more closely at those four drugs in particular and with an emphasis on therapy and trying to figure out, you know, what's going on with that population.

Comments? Questions? I will do that and I will follow up on that data.

The next topic that was proposed for this quarter was to look at maximum daily dose of

antidepressants in recipients six years of age and older. And the reason we chose that is we already had maximum daily dose limits in place for children under the age of six, but we didn't have anything for the rest of our population.

So, again, similar to what we looked at in antipsychotics, did they or did they not exceed the maximum daily dose? Obviously the majority of them did not exceed the maximum daily dose, but we did have 1,740 claims for 1189 recipients where they did exceed the labeled maximum recommended dose for the antidepressants.

And this just kind of more minutia when I looked at the data which I thought was interesting, you know, which ones were culprits in terms if they were typically prescribed or typically received more than their recommended daily dose, and it was 34 percent of Trazadone prescriptions exceeded the FDA recommended max dose; 15 percent Venlafaxine prescriptions; 13 percent of Escitalopram prescriptions.

What I thought was really good was that

the really probably dangerous drugs over here, the Imipramine, Nortriptyline and Amitriptyline, very, very few of those which I think is really good information and helpful to know that -- you know, that one, you know, potentially could cause great patient harm, they're not exceeding the max daily dose. So that was I think a good thing.

But I think we would like to explore going forward with putting maximum daily doses on the rest of the population over the age of six if the board is in agreement with that.

THE CHAIRPERSON: Do we have to make a motion -- make a motion to look at following FDA package inserts on antidepressants for maximum daily dosage. Do we have a second?

DR. ROMAY: Second.

DR. ALLEN: Third.

THE CHAIRPERSON: Any discussion?

All those in favor signify by saying "aye."

THE BOARD: Aye.

THE CHAIRPERSON: There's a question for

Elboni and Rebecca. Would this go through a process like we do for pediatrics where a psychiatrist reviews any prior auths or they exceed or they can justify, you know a higher dose?

DR. MOORE: Yes, yes.

THE CHAIRPERSON: So the prescriber can still have access or patients can still have -- and there's a drug-to-drug interaction where another drug may decrease some drug level due to pharmacokinetics; or, you know, prescribers still can, you know, get a prior auth for access to the patient? You ask the psychiatrist to sign off on more?

MS. MOORE: Well, we partner with them for children less than six. But for children up to age 17, the clinical pharmacist in the call center would handle those requests. But USF is always available for us to consult with them if we need them.

THE CHAIRPERSON: So if there's any concern on the pharmacist who is signing the authorization, you can at least get another consult. Everyone wants to know the process.

The next part is best practices, correct?

We have in Florida -- and you may want to -- we have a best practices that was put out a few years ago. Maybe we should do a -- bring everyone else up to par here on the recommendations we've looked at over the last five years or more.

DR. MOORE: Can we do that next time?

THE CHAIRPERSON: Yes. The historical things so that, you know, in Florida we do have best practices for psychotropics with children and now we're probably going -- heading towards that direction as well.

DR. MOORE: They have a website that, you know, speaks about the best practices, but we can certainly include some of that information in our presentation for January. And bring to you guys some of the edits that we've done in relation to those best practices over the years. We'll be happy to do that.

DR. BORGERT: And I think there's websites like Medicaidmentalhealth.org, things like that. It's pretty easy to find. USF administration.

MS. WILLIAMS: And if you look on the

prior authorization forms, the website is also located on there and you can see all of our best practices, just go to one of our antidepressant or antipsychotic forms and click on it.

DR. BORGERT: Thank you, Susan.

So we have reached the point of the meeting where we talk about possible activities for next quarter. Now, obviously a lot of what we talked about today, there's some follow-up that needs to come back to this committee and that will all be done. And frankly, that's why follow-up usually takes longer than the usual quarterly activities. But all of that has been taken down and follow-up will be brought back on those questions for the January meeting.

But we also want to select some new fresh topics for the next quarter. Again, just to throw things out there but we really want to encourage the board to submit their suggestions.

One of the things that a lot of state DUR boards do is whenever the FDA administers a new safety alert or anything like that, you

know, and obviously it's subjective in terms of how severe it is or how prevalent it is. But that's a very common function of DUR boards in other state Medicaid is to basically look at those providers who have recipients who are receiving that drug and then basically just notify them of this FDA safety alert. It's almost just more of a, "Hey, I don't know if you saw this, but you're prescribing this, so we want to make you aware of that."

So, you know, one of those types of things that came out recently was about the joint pain with DPP-4 inhibitors. We have three DPP-4 inhibitors on the PDL. And the way I understand the FDAs thinking is that the joint pain can be severe and disabling and even require hospitalization for some patients, but was reversible within a month of stopping the drug and a lot of patients had -- when they were rechallenged, the joint pain -- the severe disabling joint pain returned.

So that's one thought for a possible DUR activity. I don't know if we want to talk

about those individually. Let me just say quickly about the other three. Metoclopramide maximum dosing and particularly in maybe people under the age 18 and the risk of tardive dyskinesia with -- related to duration of dose with metoclopramide. Antidepressants polypharmacy particularly using TCA metoclopramide. And then drug interactions antipsychotics and phenothiazine between.

So those last three there were recommendations that were brought to the Agency so those -- so we put those on the list of possible activities for the next quarter.

THE CHAIRPERSON: So with the metoclopramide maximum dose there's -- I thought we did a banner message a while ago.

DR. BORGERT: Not since my tenure, but...

THE CHAIRPERSON: Do we need a banner message for that one or many -- we can always update that.

DR. BORGERT: So we can look at that topic and see what we find. And then, yeah, we can decide at that point once we see

what's been going on in combination with that what we want to do, whether we want to do a banner message or whether we want to do an edit, or what we want to do. Okay.

DR. MOORE: One thing I do want to add is -- these are just suggestions that Magellan's seen. But if you all have anything that you would like to see for us to look at, we'd be happy to entertain those as well.

DR. ALLEN: It's a great point. I guess for the new members on the Board is it I guess possible -- and maybe it doesn't have to be done now -- but just educate us on the process. I mean, is there a quota -- I mean is there a minimum amount of suggestions that you can maybe submit; you know, we submit a few, what are the deadlines, things of that nature?

DR. MOORE: It's not really a submission process, we just bring them up at this meeting. We generally try to take about two to three into the next quarter to work on. That's the work that, you know, Becky and I work on to present to you all in January,

along with the follow-up items that have come about throughout the meeting.

So if you just would just jot them down and bring them to this meeting and suggest them to your colleagues here, you all vote on which ones you want, and we get to work on them.

DR. BORGERT: It's kind of an informal process, you know, just kind of throw it out there.

THE CHAIRPERSON: One of the things we had looked in the past was looking at the top expenditures and -- top 10 expenditures and the top 10 usage in our state and looking at that. And looking at ways of, you know, like we did the oncology drugs and we did the antipsychotic drugs.

DR. MOORE: Would it be helpful if we compiled a list of previous topics that we've looked at so that you all would know?

DR. OLSON: Right.

DR. MOORE: So you're not suggesting the same things that we've looked at. We've looked at a number of topics and some -- we began in 2008. So we'll be happy to compile

a list.

THE CHAIRPERSON: I'd like to see the top 10 again.

DR. OLSON: Yes. Can we get that list of top 10 in spending utilization? You don't have to give us a huge list, but if you can just narrow it down is all.

DR. MOORE: Right. So you'd like to by expenditure or claims or both?

DR. OLSON: Both.

THE CHAIRPERSON: Yeah, both would be good informational. Then we looked at HIV meds in terms of safety and in terms of edits that we've done -- you know, we've done over the years. Like, for example, DDI with AZT bag combo. So we've implemented that in terms of safety for our patients. And as new drugs come out make sure, you know, like the newer agents, you know, make sure that we talk -- if somebody's writing let's say for Prezcobix and you can show that Norbury is no longer on board.

DR. MOORE: We would do like therapeutic duplication on combination products, so patients can't take triple antibiotics.

THE CHAIRPERSON: Exactly. These are the DHSS guidelines, yeah. So make sure those are still -- so maybe look -- that's a top 10 item in our state.

DR. MOORE: Oh, yes, it is.

THE CHAIRPERSON: It's not?

DR. MOORE: Oh, yes, it is.

THE CHAIRPERSON: So let's look at that. I think that would be a good topic.

DR. SAEZ: I think that you should do the drugs utilization reviews that we talked about Daraprim yesterday and this would be good to see. Because then I talked to my pharmacist yesterday, and it turned out that the three new claims, they happened right after they increased the price. So I mean, I don't know if it was a coincidence. And I spoke to the CMO for the other plan and they also did the same. So it would be interesting to see what happens during these three months if there's an increase in utilization now and if there is fraud or something. Because I mean I'm assuming --

THE CHAIRPERSON: On which drug?

DR. SAEZ: Daraprim because it went from

$13 to $700, something that was generic before. So it just happened last week. So this would be a good utilization review to see. And how do we handle if something like that happens again? Because I mean, it's like as Magellan, the PDL has some type of -- you know, where they can bring like the price down from the manufacturer.

DR. BORGERT: In this case it hit the national media so we all knew about it. But, you know, in Magellan internally we have a way where we can -- in the past the problem has usually been generics that have just skyrocketed out of nowhere. So we do have a pulse on that, we look at that weekly, you know, in terms of what the percentage change is in pricing. But this one caught us completely off guard because it was a brand name drug, you know.

DR. SAEZ: And I guess the other drug that we can talk about next time is what's going to happen with utilization with the new drug Daklinza because it's a very tricky drug, it's like genotype 3. But you have to use all these other drugs in combination and

sometimes the cost can be very expensive. So I think it would be a good drug to look at to see for utilization. And I'm assuming that because this is the hepatitis C drug, you still have the same things, grade -- level, grade 3 or 4 to treat, right?

MS. WILLIAMS: Right.

DR. MOORE: Well, one thing that we do each quarter is we bring back after the utilization so Daklinza would fall in that.

DR. ZITIELLO: I'm a little concerned about underutilization of some of the asthma medication. I get a lot of requests for Budesonide and most pediatricians would write for generic upfront, but can only approve the Pulmicort in that population.

Doctors just don't seem to be aware that that's, you know, something they can replace. And I'm afraid that the members, you know, or the patients at the point of pharmacy just say, "Oh, well, not covered." And then those kids go on without their controller medication and end up in the hospital because they weren't controlled. Not in their benefit and I just for the life of me don't

understand why the generics aren't on the PDL? Obviously I said that before.

DR. MOORE: The same issues that we spoke of before, you know, is the clinical benefit versus the financial implication. What's available and the Agency and the provider synergies makes the decision on which agent to go with and those type of decisions are made.

DR. BORGERT: But I think this is good feedback in that, you know, I don't know off the top my head when those agents are reviewed, but because the Board talks about this, then we can provide that feedback to provider synergies during the contract negotiations and that can be a consideration as well for the P&T committee. Which until you spoke up and said that, you know, maybe we -- everybody wasn't aware that that's an issue of what adherence and compliance states.

DR. ZITIELLO: A general generic issue is huge. And cost and benefit state aside, these patients aren't getting the treatment they need. Potentially it could be very bad,

so...

DR. MOORE: I just wonder if it's a communication issue at the different plan levels, you know, providing that information out to the pharmacies, out to the providers, that, you know, these are preferred agents. If you get a script for, you know, Budesonide, Pulmicort is the PDL agent, so dispense that.

So I think it's just communication, training. You know, helping providers go out to the websites, see what's preferred before you write that prescription and maybe write that actual agent down so that the pharmacy isn't confused or having to try to figure that out while the patient is sitting at the counter.

DR. ROMAY: I think at the plan level we do it very rapidly, and unfortunately we rely on that pharmacist or pharmacy to call out to us. A lot of times that doesn't happen so there's a real problem with -- at the retail level that that pharmacy is not taking the time out to --

DR. MOORE: I get it.

DR. ROMAY: So that member, as she said, is walking away. And not only related to that one, but it's also related to all the ones that are in that category. Like, you know, Abilify, for example. We've had members who have been not being able to get their antipsychotics, and what happens they end up decompensated in the hospital with psych admission and that -- you know.

So I get your point. It's communication but, you know, there's so much control that you have with that retail pharmacy reaching out and doing their due diligence and make sure that that member gets what they need in a timely manner.

THE CHAIRPERSON: On the other end as a prescriber I have to keep up with about 50 different plans and their formularies. And I am like -- January is all the big change -- January is a big month in formularies for preferred drugs list changes, so... And there's a lot of changes. And you get notifications from the different plan carriers, you know, Medicare or it doesn't matter which payer source it is.

And, you know, this is the new preferred drug and then I have to implement a change and notify the patient of the changes and of the therapeutic equivalent now.

But as a prescriber with all these different plans, it is overwhelming, especially when they prefer -- you know, the plans have a different formulary than what the state has or what Medicare -- what particular Medicare. So I'm just overwhelmed.

And at one time I was downloading all the -- on my desktop all these different plans and just -- but it's very overwhelming as a prescriber.

DR. MOORE: Luckily we have the PDL right now.

THE CHAIRPERSON: I'm sorry?

DR. MOORE: Luckily we have the PDL right now.

THE CHAIRPERSON: No. But, you know, there's so many different ones. I mean you have no idea.

DR. MOORE: Right, right.

THE CHAIRPERSON: That Broward Health has

or Jackson or any institution has their own plan. Everybody has their own -- and just keeping up with all the -- it's very difficult. Especially January when they implement the change.

DR. SAEZ: Is there a way -- maybe an easy way when the patient and the mother takes the prescription to the pharmacy they automatically -- it just reverts to whatever is their preferred agent. So that way -- I mean, I don't know if that's a possibility to do that?

Because like she said, you know, imagine, you know, like seeing 25 patients per day and then trying to go on the PDL, you know, as a provider you cannot -- unfortunately you kind of have to spoon feed and make the process easy enough where like -- and so the only way I can see is that they take it to -- sometimes when I was in clinical practice I would put in the prescription "or whatever preferred," you know to make sure that would be a way, because after a while --

THE CHAIRPERSON: We have alerts -- actually there is a -- I signed up as a

provider under Medicaid. There are -- when the updates are sent out, there's a link for the -- but you have to sign up though. So I did sign up and you click on the link, but those are -- they change like every quarter I believe under Medicaid.

DR. ROMAY: After P&T meetings.

THE CHAIRPERSON: I'm sorry?

DR. ROMAY: After P&T meetings it's quarterly.

THE CHAIRPERSON: Yeah. That's what I said, but you have to keep and click on the whole list and the whole list is extensive, you know.

DR. MOORE: One other option -- and it's to program a message that says, you know, Pulmicort is the preferred agent if they're billing for the non-preferred product. That's one other way --

DR. ROMAY: I just think like we just talked about that yesterday that maybe like a second message maybe you can get exposure. I mean, maybe to the retail pharmacy when they're --

DR. MOORE: And maybe they're not

accessing it. That's a training issue again. Go and see if there's anything else, you know, what other messages are behind it.

DR. OLSON: The PAs come and go. Again, the plan of a pharmacy is too late, because you could be a day or two -- I mean, we need to look at ways that the physicians can be better informed so the prescriptions are written per -- I mean, when you get the pharmacy and now you can't use this. If the doctor doesn't want to switch, and now you got to go through a PA. I mean, there's a lot of these situations where you get a day to a week in delay in starting therapy or continuing therapy because of that.

THE CHAIRPERSON: Usually under Medicare, or the plan with Medicare it gives you 30 days before they implement their formulary change. I get a letter for like maybe December or January, the letter comes to me and it says "this item is no longer on your preferred" -- or "your patient's preferred drug list."

Sometimes, I would say 50 percent of the time, I'll get the preferred drug list

therapeutic exchange item. So I can at least make a change so I know what's on formulary. 50 percent of the time there is no therapeutic equivalent or option on the letter. And so I don't know what's on there. I mean, especially if it's an angiotensin receptor blocker.

Here Medi -- you know, signing up for the new updates is good. I am not sure -- and maybe at the point of sale the pharmacist can give it to the patient. The patient can at least have something available in their hand to bring back to our nurses in our office to inform me at that point that that would get rejected at the point of sale is a communication.

I don't think sending out a letter to these providers is overwhelming. I don't know how else to communicate broadly except for the prescriber would have to sign up.

The other option may be during credentialing, when we credential under Medicaid. This is how we try do it at the other states. Maybe at the time of credentialing, click on the website that you

sign up where we credential under Medicaid, maybe a link for the preferred drug list to make us aware that there is information there maybe.

MS. HARRIS: I'm sorry. Respectfully, I think we're of kind -- we're a little off topic here. I'm not sure how a lot of this relates to the purpose of the function of the Board. So would you mind if we --

THE CHAIRPERSON: Go back on top?

MS. HARRIS: Yeah.

MR. HAMILTON: Don't forget about our changes summary that comes out also quarterly that's on the website.

THE CHAIRPERSON: But to make sure subscribers click on that or are aware of that, how do we bring that out to our Medicaid community? That's what I'm trying to -- all of the actions that our P&T do, how do we -- besides having -- that's my concern, anyway.

DR. OLSON: Going back to the asthma, are we able to get -- I know we have a hard time with the medical claims, but are we able to get emergency rooms admissions for Medicaid

or no?

DR. BORGERT: If they're admitted -- well, if they have an ER visit.

DR. OLSON: ER visit.

DR. BORGERT: We know they have an ER visit and we know they were admitted and what those diagnoses type of admissions are, but I don't know.

DR. OLSON: That would be interesting to tie into too. If we're looking at that, that's another thing you want to avoid too.

Another drug that is kind of on the radar and I don't know what the spend is but we want to watch is for CF, Kalydeco. And I don't know if that's one we just want to kind of put on the radar watch and maybe get some data for the next meeting, preliminary data.

DR. BORGERT: Probably or can be --

THE CHAIRPERSON: Any other suggestions?

So you want to review that again?

DR. BORGERT: Yes, please. Just to make sure I've got this. So we talked about doing Metoclopramide and duration and dose-risk of tardive dyskinesia. We talked about bringing back out top 10 by spend in claims. We would

look at Daraprim utilization over the next quarter. We will include Daklinza in the hep C review in the next quarter.

And then this whole subject of asthma utilization and the Pulmicort needs to be Budesonide. I kind of was thinking about what you're saying, Dr. Olson, is like, you know, if they didn't fill -- I think where you're going with that is if they didn't fill the script, did they end up having an ER visit or an admission for acute exacerbation or something like that. But what we won't know is if they didn't fill, we don't know if there was a script. Do you know what I'm saying? That's where there's a link -- a missing link there is, we don't know were they supposed to have gotten it. All we know is -- does anybody have any thoughts on how to get around that?

THE CHAIRPERSON: Of the HIV drugs also.

DR. SAEZ: Just do a general, you know, to see what's the utilization of these drug agents.

DR. BORGERT: Yeah. We can certainly pull a general utilization of Pulmicort and

we can look for ER visits and try to tie that to the kinds of claims. You know, just look at that.

DR. OLSON: You can probably look at rejected claims as being what the --

DR. BORGERT: Yeah. Well, I think -- I mean, do you want me to pull --

DR. MOORE: Specifically Pulmicort or would you like at all like ICS or asthma medications just in general?

DR. OLSON: Asthma.

DR. MOORE: Just in general?

DR. OLSON: Yeah.

THE CHAIRPERSON: That's a lot.

DR. BORGERT: That's plenty.

DR. ALLEN: I just want to see if I can add one more to the Christmas list. I just wanted to see if there was any material impact on the PCSK 9s. I think these agents came on the market in the June, July time frame and there's widespread speculation that, you know, the economic impact was going to be huge. But, you know, just from an individual plan standpoint we haven't seen that take off. I just want to see if maybe

you know --

DR. BORGERT: Sure. That's a good suggestion. On the utilization we can bring you back information on that if we did or didn't.

DR. ROMAY: I have another one. I don't know if we can add it, but in terms of the IVIGs the current criteria that we have is not really specific to any one product, it's very broad based on communication and, you know, weights and all that stuff. Can we get a little bit more guidance as to the specific products that we might want to, you know, use over others -- preferred ones over others or --

THE CHAIRPERSON: Which drug?

DR. ROMAY: The IVIGs, Intravenous immunoglobulin, the gamunex --

THE CHAIRPERSON: Is that outpatient or inpatient?

DR. ROMAY: Usually -- well, depending. Now they have some that are actually given -- you know, self-administered, some of them have to be done at a infusion center.

THE CHAIRPERSON: Can you capture

infusion center data?

DR. BORGERT: I don't know.

DR. MOORE: I'm not sure on that one.

DR. ROMAY: That would on their medical claims.

DR. MOORE: It's not on the P&T, so we can -- I don't know if the Agency -- we'll take that suggestion back. I'll have to consult with the Agency on that one.

DR. ROMAY: Okay.

THE CHAIRPERSON: Another -- so we're done with the suggestions.

DR. BORGERT: It's feast or famine in this committee.

THE CHAIRPERSON: A copy guide to the Sunshine Laws will be sent out to all our board members here for follow-up.

Next on our agenda item is open discussion. Any --

DR. ALLEN: I have a -- sorry. I don't want to go over my quota.

THE CHAIRPERSON: That's okay.

DR. ALLEN: I just wanted to as far as, you know, the possibility of the date and the time of this meeting. When -- and it's just

been my own personal experience, I attend P&Ts on a Friday from 1:00 to 5:00 and, you know, the attendance is pretty large in comparison to this meeting. I just wanted to support a possibility to see if maybe a Thursday or I don't know maybe Friday morning would be a possibility for a change in the date?

THE CHAIRPERSON: Well, historically, you know, that involves taking personal leave and vacation hours for some individuals that volunteer their time. I don't have a lot of vacation days. I come home on weekends because I'm not working.

MS. HARRIS: If I may, I think that that's something that on behalf of the Agency we'd like to take that suggestion back and think a little bit about. We coordinate the travel for all of the DUR members and we just think that -- we try to accommodate the DUR Board meeting to be after the P&T since it is late in the afternoon on a Friday, we just need look at all of that logistically.

So the board is more than welcome to take that up as a motion and vote, but

respectfully we would like to go back as an Agency and talk about it.

DR. ALLEN: That's fair.

THE CHAIRPERSON: The other issue, Moses, as far as the time is 8:00 versus 9:00 versus any other time, we've looked at that over the years and most people would come in the night before; and then travel plans, we've had Board members that would leave and they've had to catch a plane to Pensacola or Jacksonville at certain times. I catch a plane to Fort Lauderdale. Just timing it with airlines, so most people come in the night before and then travel out on a noon or at an approximate time to catch their flight.

We're always open for suggestions if anyone has, you know, suggestions. But when you make your recommend -- when you think about it, you know, you think about hardship for work hours and taking off vacation hours, so -- you know. But I don't get administrative time or -- and then travel, for people that come from all areas in our state, not just from -- to Tampa Bay area; you know, some people come from Jacksonville,

Pensacola, I'm not sure all the regions we are all from but we have to consider that at the same time.

DR. ALLEN: That's fair.

MS. HARRIS: I think what we'll try to do is maybe look at the logistics and come back with some recommendations and the Board can look at them, and you can agree, disagree, come up with your own.

THE CHAIRPERSON: Thank you.

Next on our agenda are public comments from our audience. Yes, come on up to the podium and introduce yourself and --

MR. COLLINS: I expect the same round of applause they're getting in the other room. I just have to set this up and running here. It's up and running, I just have to get this -- one second.

My name is Scott Collins. I'm with VCG and Associates, it's now a Division of the Quintiles Company. And we represent a lot of different companies, so we're more or less a consulting firm. I'm here today speaking on behalf of one of the clients I represent for the state of Florida, and it's Pierre Fabre.

They're out of France, and they have a product called Hemangioma for infantile proliferating hemangioma. I'm trying to -- it's called Hemangeol, it's for infantile hemangioma.

Infantile hemagioma is -- I will refer to it as IH from this point forward -- is the most common tumor in infancy affecting approximately 4.5 percent of all infants born in the U.S. Female sex, low birth weight, prematurity, fair skin, multiple gestation, advanced paternal age, and placenta previa are common risk factors associated with IH development.

In the majority of the cases, about 88 percent, no treatment is required as the tumors spontaneously involutes over the time. In 12 percent of them, about 20,000 cases a year, IH can be potentially debilitating and associated with serious conditions like life-threatening airway obstruction, congestive heart failure, functional impairment such as vision, hearing, feeding, hypothyroidism, ulcerations with bleeding and pain, risk of permanent disfigurement. Thus these IHs can

have long lasting detrimental impact and also have impact on social, psychological, and emotional well-being in a patient for him and/or her and their immediate family.

For these severe forms of IH, systemic therapy is essential to initiate the involution process. Before 2008 these small babies were treated with corticosteroids, interferons, and other products associated with that which had some benefit but were also very serious side effects sometimes irreversible.

In 2008 propranolol was serendipitously discovered to induce rapid involution of the proliferating IH. Leaute Labreze reported the case of a four-month-old infant born with a nasal capillary hemangioma unresponsive to corticosteroid treatment who developed induced obstructive hypertrophic cardiomyopathy and was subsequently treated with propranolol.

Visible changes in the lesion from intense red to purple and palpable softening were observed within one day of initiation of propranolol. There was continued improvement

after the drug was tapered off.

Since its discovery propranolol's efficacy has been documented and numerous cases reported in case series and has led up to anti to first-line therapy for complicated IH.

As most of the published data suggests that IH require treatment of uniquely amenable to a non-surgical systemic therapy, Pierre Fabre Pharmaceuticals, Incorporated developed a specific oral solution of propranolol hydrochloride, Hemangeol, and obtained FDA approval for its use and treatment of the proliferating IH requiring systemic therapy.

Hemangeol was developed in compliance with existing guidelines for pediatric drugs ensuring safety, ease, and acceptability of use. It comes in the most appropriate formulation for younger pediatric patients.

On behalf of Pierre Fabre we sincerely thank the Florida P&T and DUR Board for making Hemangeol available for the babies from 5 weeks to 5 months old that need it through the traditional prior authorization

process.

However, because of potential delays of the PA process and since early detection and rapid treatment of IH using Hemangeol is so critical to the success rate and could potentially be cost-effective for insurers, while minimizing the impact on patients, respectfully ask the Florida Medicaid DUR to consider replacing the traditional PA process with a simple age edit AutoPA.

An age edit AutoPA would accomplish the same goal for Florida Medicaid providing Hemangeol to the appropriate patients; however, would potentially remove the approximately $25 to $30 PA cost, eliminating any possible delays in getting Hemangeol to the patients that needed it.

The following points highlight the reasons why we believe this is the best decision for the state of Florida and for the patients who are diagnosed with IH. Hemangeolis the only FDA approved treatment for IH and there is no other therapeutic equivalent generic available.

Hemangeol is the only drug that has been

evaluated by randomized placebo controlled double blind clinical trial in order to assess the ability to reduce or eliminate IH.

Studies reveal that 60 percent of enrolled infants treated with Hemangeol for a period of six months saw a complete or a nearly complete resolution of the targeted IH. This is in stark contrast to the placebo control which resulted in only 4 percent of patients seeing a complete or nearly complete resolution of IH.

Less than 2 percent of the infants who are enrolled in the clinical trial stopped treatment due to adverse experiences. There were no new side effects associated with Hemangeol treatment. Only the ones commonly associated with propranolol were observed; which is bronchitis, diarrhea, sleep disorders, and peripheral coldness.

Prudence must be taken when developing a drug for pediatric use since its population can be particularly sensitive. With this in mind Pierre Fabre formulated Hemangeol to be as safe and effective as possible with infants with IH.

In order to accomplish this Hemangeol was formulated with the following attributes; there's only one -- only available in one concentration to prevent the possibility of misdosing, and that's at 4.28 milligrams propranolol hydrochloride or a USDA equivalent of 3.75 milligrams of propranolol.

Every Hemangeol prescription comes with a specifically designed oral dosage syringe and syringe adaptor which is preinstalled in the bottle, together these accessories ensure the accurate dosing of Hemangeol and preventative spillage respectively.

Hemangeol is sugar free, alcohol free, pharament free, and does not contain the artificial sweetener Sorbitol or Xylos. These excipients were not used due to their potential harmful impact on development and the lack of established sets data.

Hemangeol comes in a strawberry flavored -- strawberry-vanilla flavor which we found variable tolerated by the infants. This flavor combination lead to a consistent accurate dose when administered to patients. It's dispensed with an FDA approved

medication guide and instructions for use. These documents ensure that caregivers are aware of the potential serious side effects associated with Hemangeol use and now to minimize such risks.

Hemangeol is available from a specialty pharmacy that ships directly to the patient. In addition, the specialty pharmacy has a dedicated information center that provides 24-hour support.

And in conclusion the American Academy of Pediatrics has recently advocated for appropriate benefits coverage and payment for children with infantile hemangiomas and vascular malformations. For the AAP early treatment of vascular anomalies like IH should be considered medically necessary for benefit plan coverage and payment due to the high risk of serious medical and psychological issues.

Therefore, the AAP has called upon public and private payers, including health plans to provide competence of benefit coverage and appropriate patient for evaluation of treatment of these conditions.

In the long run it will be more cost-effective for care to cover early intervention and treatment of these disorders. Children who are not treated properly at the earliest possible stage may not only require more reconstructive procedures down the road, but often requires psychological counseling to address living with these debilitating and disfiguring lesions.

Thank you very much.

THE CHAIRPERSON: Thank you, Scott. You mentioned something about a cost for a prior auth?

MR. COLLINS: Yeah. I think here in the state of Florida this was -- this was written in a general kind of a PA situation. And our understanding, just from my general knowledge is that PAs can cost about 25 or $30 apiece.

THE CHAIRPERSON: To whom?

MR. COLLINS: To the state for doing --

DR. MOORE: Not from Magellan.

THE CHAIRPERSON: I didn't think so. Just to clarify that. There's no cost.

MR. COLLINS: So I think here we're just

looking at maybe a more simple way of physicians being able to write this and the AutoPA was a possible suggestion.

THE CHAIRPERSON: Thank you, Scott.

Any other public comments? Very good.

Our next meeting, Vern, you want to give us an update?

MR. HAMILTON: Ladies and gentlemen, we're about 90 percent sure that we will be back here at this hotel on January 16th. I say that because I don't really have any contract in place yet, but we are working that out. And just please keep attuned to our website for any updates, but we're still focused on January 16th at this hotel.

THE CHAIRPERSON: That's Martin Luther King weekend.

MR. HAMILTON: That is correct.

THE CHAIRPERSON: Just letting you all know. So I would like to call for adjournment of the meeting. Thank you, everyone, for coming and safe travels back home.

(Proceedings concluded at 10:50 a.m.)

CERTIFICATE OF REPORTER

STATE OF FLORIDA :

COUNTY OF HILLSBOROUGH :

I, Jacqueline L. Reichert, Court Reporter, Notary Public in and for the State of Florida

DO HEREBY CERTIFY that I was present at the foregoing proceedings at the time and place set forth in the caption thereof; that I was authorized to and did stenographically report the foregoing proceedings; and that the foregoing pages constitute a true and complete computer-aided transcript of my original stenographic notes to the best of my knowledge, skill and ability.

IN WITNESS WHEREOF, I have hereunto set my hand at Tampa, Hillsborough County, Florida this 12th day of October 2015.

_____
JACQUELINE L. REICHERT
Notary Public, State of Florida
Commission No. EE 160968
Expires 3/27/2016

Florida Medicaid Retrospective Drug Utilization Review Program Quarterly Report

10/2015 – 12/2015

January 16, 2016

Pl. Trial Ex. 238

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Follow Up/Updates

Topic	Description	Action	Status as of 12/29/15
Skeletal Muscle Relaxants Utilization	Skeletal muscle relaxants may increase the risk of drowsiness, dizziness, and impaired coordination. In addition, certain muscle relaxants may increase the risk of liver injury when used for extended periods of time and/or in excessive dosages and may interact with other medications that primarily affect central nervous system function when taken concomitantly.	Implement maximum daily dose limits (excluding baclofen and tizanidine in patients with qualifying diagnosis)- complete -Implement duration of therapy edit for more than six consecutive months of therapy within the last 12 months; excluding baclofen and tizanidine in patients with qualifying diagnoses	An edit to limit the duration of therapy with skeletal muscle relaxants (excluding baclofen and tizanidine in recipients with qualifying diagnoses) deployed on March 25, 2015. -A problem was noted post-implementation where pharmacies were resubmitting denied claims for less than a 30-day supply to circumvent the edit; an analysis was conducted to determine how frequently this was occurring-see page 9 -Post implementation analysis of duration of therapy edit-see page 9
Duplicate Angiotensin Blockade	FDA Alert issued a safety alert in November 2012 regarding dual angiotensin blockade; DUR examined the use of overlapping prescriptions for dual angiotensin converting enzyme inhibitors (ACEs) or dual angiotensin receptor blockers (ARBs) or a combination of an ACE and an ARB; later clarified to include direct renin inhibitors (aliskiren and combinations)	Implement edit that denies first duplicate claim using ProDUR; allow pharmacist to enter appropriate intervention/ professional service code and outcome/result of service code once per six months; if another occurrence is encountered within the same six months, the claim denies for PA required	-Pre implementation analysis reviewed at Sept 2014 meeting -Edit went into production on 8/7/15 - post impact analysis will be presented at March 2016 DUR Board meeting to allow for the 6-month window to have elapsed after edit deployment
September 2014 P&T Top Therapeutic Classes	In an effort to create collaboration between the DUR Board and Pharmacy and Therapeutics Committee (P&T), the DUR Board agreed to discuss feedback and recommendations for certain upcoming therapeutic classes to be reviewed by the P&T Committee, to be presented as additional advisory information for the P&T Committee s consideration, if deemed necessary.	*Antipsychotics*- maximum daily dose limits for atypical antipsychotics in adults-	-Pre-implementation analysis reviewed at September 2014 meeting -Antipsychotic maximum daily dose limits in adults deployed on May 8, 2015 -post impact analysis was reviewed at September 2015 meeting -F/U regarding 381 recipients who exceeded MDD: Requests are sent back to provider by Call Center for justification of dosing

Topic	Description	Action	Status as of 12/29/15
January 2015 P & T Top Therapeutic Classes	In an effort to create collaboration between the DUR Board and Pharmacy and Therapeutics Committee (P&T), the DUR Board agreed to discuss feedback and recommendations for certain upcoming therapeutic classes to be reviewed by the P&T Committee, to be presented as additional advisory information for the P&T Committee s consideration, if deemed necessary.	*Insulins*-DUR Board approved a change in monthly quantity limits of 10 insulin vials to a quantity limit of seven insulin vials (7,000 units of insulin) DUR Board approved a change in monthly quantity limits of insulin pens, down to a maximum of 2 boxes. All pens come in boxes of 5 pens per box and all pens are 3mL each so 15 mL/box times two boxes = 30 mL(3,000 units)	The new quantity limits on the insulin vials deployed on 1/22/15 and the new quantity limits on the insulin pens deployed on 4/1/2015 - Overall post implementation analysis of insulin utilization was presented at September 2015 meeting -F/U regarding detail data on recipients receiving > 100 units/day and/or ≥ 5 vials per claim- see page 11
June 2015 P & T Classes	In an effort to create collaboration between the DUR Board and Pharmacy and Therapeutics Committee (P&T), the DUR Board agreed to discuss feedback and recommendations for certain upcoming therapeutic classes to be reviewed by the P&T Committee, to be presented as additional advisory information for the P&T Committee s consideration, if deemed necessary.	*ranolazine (Ranexa®)*- Implement diagnosis look back for chronic angina as a management strategy	Implementation pending
September 2015 P & T Classes	In an effort to create collaboration between the DUR Board and Pharmacy and Therapeutics Committee (P&T), the DUR Board agreed to discuss feedback and recommendations for certain upcoming therapeutic classes to be reviewed by the P&T Committee, to be presented as additional advisory information for the P&T Committee s consideration, if deemed necessary.	DUR Board voted in March to recommend to the P & T committee to make oral erythromycin products as non-preferred based on escalating costs and available alternatives such as azithromycin and clarithromycin.	P & T committee accepted recommendation but requested the DUR Board develop prior authorization criteria for oral erythromycin products. Proposed criteria will be presented at Spring DUR meeting
January 2016 P & T review classes	-Recommendation to institute a quantity limit of 30 capsules/ 30 days for Spiriva Handihaler (preferred) -Create AutoPA for roflumilast (Daliresp) to include diagnosis of COPD and concomitant therapy with a LABA and/or a LAMA -Add age limits of ≥ 12 years for all topical acne products	DUR Board requested further information regarding the number of Spiriva claims > 30 capsules/30 days	Spiriva follow-up information: There were 1,506 claims for 697 recipients ($454,401) from 3/1/15-6/30/15; of these there were 11 claims for 6 recipients ($6,304) that exceeded 30 capsules/30 days AutoPA for roflumilast is being coded and will deploy 1Q16 Age limits on acne products will deploy 1Q16

Topic	Description	Action	Status as of 12/29/15
Rheumatoid Arthritis Utilization Review	Review aspects of utilization regarding treatments for rheumatoid arthritis; break up the initiatives into three categories Concomitant use of more than one biologic agent Utilization without an appropriate diagnosis on file Use of a nonbiologic DMARD prior to use of a biologic	-Identified number of claims/recipients utilizing RA agents for off-label use -DUR Board approved an edit requiring FDA approved indication within the last two years prior to claim adjudication -Analysis of appropriate step therapy with a non-biologic DMARD conducted for recipients with TNF-inhibitor claim	An AutoPA combining all these elements is currently being drafted; a post implementation analysis will be presented approximately 3 months post deployment
Polypharmacy with PPIs	Proton pump inhibitors (PPIs) are a widely utilized class of drugs; omeprazole was the 4th most commonly filled prescription by number of claims for the Florida Medicaid FFS population during the 2nd quarter of 2014 (74,856 claims)	Implement edit for maximum daily dose limits for this class of medications; implement ProDUR edit to deny claim resulting in overlapping therapy with two PPIs; allow pharmacist to override first instance using service intervention/outcome codes	-Edits are currently being coded and will deploy 1Q16
Polypharmacy with Opioids	Opioids are a widely used class of medications and have the potential for abuse. There has been a rise in prescription drug overdose deaths in the U.S. in recent years and inappropriate use of opioids can lead to physical dependence as well as opiate addiction.	Analysis revealed recipients (excluding those with diagnoses of cancer or sickle cell disease) receiving overlapping opioid therapy; some overlap may be clinically appropriate such as utilization of a long-acting opioid and a short-acting opioid	-Educational banner message approved by DUR Board was posted on 3/2/15 -Edit to deny overlapping long-acting opioids: pre-implementation analysis presented at March 2015 DUR Board meeting; edit is being coded
Codeine Use in Pediatrics	Codeine is contraindicated in children following tonsillectomy and/or adenoidectomy. Other national guidelines recommend against the use of codeine as a cough suppressant in pediatric patients	Following a review of literature and the Medicaid FFS usage of codeine in pediatric patients at the January 2015 DUR Board meeting, the Board voted to restrict codeine to children below the age of six	AHCA has determined there are Rx-only ibuprofen suspension options that could serve as alternate therapy in these children; in addition acetaminophen solution products were added to the PDL for children under the age of six; banner message posted 12/3/15; edit deployed 12/17/15-see page 9

Topic	Description	Action	Status as of 12/29/15
Overlapping use of benzodiazepines and stimulants	Benzodiazepines and stimulants have opposing pharmacologic actions	Review utilization of recipients who received overlapping claims for a benzodiazepine and a stimulant medication to define patient population and to determine if the two medications were prescribed by the same prescriber	-Letters and patient profiles sent to affected prescribers -Create edit to deny stimulant claim only after two ProDUR pharmacist interventions when the two drugs are from different prescribers; this edit is being coded
Long acting stimulants (plus Strattera®) in children under the age of six	No long acting stimulants on the market for the treatment of ADHD are FDA approved for use in children under the age of six	Implement a prior authorization procedure for all long acting stimulant preparations as well as Strattera for children less than six years of age	Edit deployed 7/1/15: All long acting stimulants and Strattera require the provider to submit a prior authorization form for review before one of these products can be dispensed to a child under the age of six. Post implementation analysis- see page 14
High dose stimulants in children under the age of six	The Florida Medicaid Drug Therapy Management Program for Behavioral Health expert panel advised there is a concern with the use of high dose stimulants in preschoolers and suggested an appropriate prior authorization review be implemented	Any child under the age of six who is exceeding the expert panel s recommended dose limitations will require prior authorization review by the USF behavioral health program prior to dispensing.	Will deploy January 2016
Methadone Clinically Significant Drug Interactions	Methadone is a drug with a narrow therapeutic window between efficacy and toxicity; the pharmacokinetics and drug interaction associated with methadone can impact safety and efficacy	Due to the risk associated with severe and/or major methadone drug interactions and the fact that methadone is overrepresented in opioid related overdoses, the ProDUR edit for these interactions will be changed so that dispensing requires a pharmacist to review the interaction before the claim will pay	The P & T committee voted to make methadone products nonpreferred and will require a prior authorization effective November 2015; therefore no further edits will be initiated
Topical testosterone products utilization	There is increasing utilization of these products and the FDA has recently released a safety announcement regarding risks associated with these products as well as a lack of established evidence for use beyond the labeled indications	Implement prior authorization procedure for these products	Proposed PA criteria see page 11 below
Synagis® utilization	The August, 2014 updated guidance for the use of palivizumab (Synagis) by the American Academy of Pediatrics recommended a maximum of 5 doses for all qualifying infants	For the 2015/2016 RSV season, AHCA reduced the maximum number of doses per qualifying infant to five per season (providers will still be able to	Banner message posted regarding the decreased number of maximum doses. DUR Board requested information regarding how many children received a

Topic	Description	Action	Status as of 12/29/15
		request further doses through the PA process if necessary)	complete course of therapy for the 2014/2015 RSV season- see page 12
Morphine equivalent daily doses ≥ 100 mg	Determine the number of FFS recipients who are receiving ≥ 100 mg MEDD	Follow up requested on number of prescribers for excepted recipients as well as total APAP dosage in excepted recipients who were receiving combination products	See page 14 for follow up
Novel Oral Anticoagulants	Describe utilization patterns and length of use for the NOAC class	Utilize a longer window (6 months) to examine length of therapy and possible correlation with treatment indication	See page 14 for follow up
Maximum Daily Dose of Antidepressants in ≥ 6 years of age	DUR Board approved recommended maximum daily doses of antidepressants in recipients age six or older	Implement edit to deny claims exceeding recommended maximum daily dose on affected claims	Edit in process

Follow Up: Hepatitis C Virus (HCV) Treatment Management

Developments this quarter regarding the treatment of Hepatitis C:

- Simeprevir (Olysio®) indication expanded to include HCV genotype 4 (previously only G1)
- Ombitasvir, paritaprevir, ritonavir with dasabuvir (Viekira Pak®) and ombitasvir, paritaprevir, ritonavir (Technivie®) have been changed from not recommended in patients with Child-Pugh B liver dysfunction to contraindicated in patients with Child Pugh B cirrhosis.
- CMS issued a Medicaid Drug Rebate Program Notice regarding Medicaid beneficiary access to HCV drugs. Highlights include clarification of requirements for excluded drugs; a concern regarding limiting HCV drugs based on Metavir scores, specialist prescribing, or drug/alcohol abstinence; and CMS agreement with AASLD/IDSA/IAS guidelines. CMS acknowledges cost of newer HCV drugs may cause concern but states market competition may decrease costs and encourages states to negotiate pricing and supplemental rebates. Link: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf
- FDA approved expanded use of ledipasvir/sofosbuvir (Harvoni®) :
    - HCV genotypes 4, 5 and 6
    - Patients with HIV co-infection
    - Harvoni + ribavirin (RBV) for 12 weeks as an alternative to Harvoni monotherapy for 24 weeks for treatment experienced, cirrhotic patients with genotype 1 infection, who have failed prior therapy with a Peg-IFN + RBV regimen followed by a treatment failure with a Peg-IFN + RBV + HCV protease inhibitor regimen.
    - Wyden-Grassley investigation releases report regarding Gilead s pricing strategy for Sovaldi. Findings state marketing strategy was designed to maximize revenue with minimal concern for

impact on access or affordability . Link: http://www.finance.senate.gov/newsroom/ranking/release/?id=3f693c73-0fc2-4a4c-ba92-562723ba5255

Current Utilization:

Hepatitis C Treatment Utilization- FFS Medicaid Recipients 1/1/15 to 12/1/15			
	Claims	**Recipients**	**Total Paid**
ledipasvir/sofosbuvir (Harvoni)	70	23	$2,141,452
simeprevir (Olysio®)	2	1	$44,911
sofosbuvir (Sovaldi®)	25	9	$710,593
Viekira Pak®	39	22	$1,099,539
Technivie®	-	-	-
Daklinza®	-	-	-
peginterferon	8	3	$24,762
ribavirin	63	34	$33,269

*Note: Viekira Pak was voted as the preferred agent at the March 2015 P & T meeting and was effective April 1, 2015

Follow Up: Skeletal Muscle Relaxants- Duration of Therapy

The DUR Board voted at the June 2014 meeting to implement a duration of therapy edit for the skeletal muscle relaxants. The Board was interested in reducing inappropriate chronic daily use of these medications which are generally intended for short-term treatment of acute musculoskeletal pain. This edit looks back for claims filled for at least a 30-day supply within a rolling one-year period. Once the patient has received six claims (≥ 30 day supply) within a rolling 365 day period, future claims for ≥ 30 day supply will deny. This edit excludes all claims for baclofen and tizanidine for any patient with a qualifying diagnosis on file within the past two years.

Skeletal Muscle Relaxants- Qualifying Diagnoses	
ICD-9	**Description**
335.2	Upper motor neuron syndrome
343*	Infantile cerebral palsy
342*	Hemiplegia and hemiparesis
334*	Spinocerebellar disease
438.2	Late effects of cerebrovascular (CVA) disease, hemiplegia/hemiparesis
438.3	Late effects of CVA disease, monoplegia of upper limb
438.4	Late effects of CVA disease, monoplegia of lower limb
438.5	Late effects of CVA disease, other paralytic syndrome
438.9	Late effects of CVA disease, unspecified

340*	Multiple Sclerosis
341*	Other demyelinating disorders of the CNS
781.7	Tetany
952*	Spinal cord injury

The duration of therapy edit deployed on March 25, 2015. Therefore, impacted claims would have begun in late September 2015 (6 months post edit deployment).

Post Edit Impact Analysis: Skeletal Muscle Relaxants

Time Frame	Claims Count	Recipient Count	Quantity	Amount Paid
Pre-Edit (12/24/14-3/24/15)	12,464	7,264	823,779	$222,796
Post-Edit (9/25/15-12/15/15)	7,288 *(41%↓)*	5,085 *(30 % ↓)*	469,739 *(43% ↓)*	$139,611 *(37%↓)*

Follow Up: Codeine Use in Pediatric Patients

- On July 1, 2015 the FDA published a Drug Safety Communication stating they were evaluating the potential risks of codeine cough-and-cold medicines in children http://www.fda.gov/Drugs/DrugSafety/ucm453125.htm
- On December 12, 2015 the FDA s Pulmonary-Allergy and Drug-Safety and Risk Management advisory committee voted to expand codeine contraindication for pain management in anyone under the age of 18 years and also voted to recommend contraindication of codeine for the treatment of cough in anyone under the age of 18 years. FDA action regarding these recommendations is pending.
- DUR review of FFS Medicaid revealed 740 claims for 675 children ages 12 or under during time frame 8/1/14 to 10/31/14; all of these claims were for codeine combination products (acetaminophen, guaifenesin) rather than single agent codeine
- DUR Board voted to implement an edit restricting the use of codeine to children ages six and older
- DUR Board was concerned about Rx versus OTC availability of alternative agents such as ibuprofen suspension
- Ibuprofen suspension 100 mg/5mL is available on the Florida Medicaid PDL as an Rx product; APAP liquid product alternatives are now available for children less than 6 years on PDL
- Educational banner message was posted on December 3, 2015
- Edit deployed December 17, 2015

Follow Up: Insulin Quantity Limits

Due to the wide range of dosing requirements, quantity limits for insulin products are difficult to establish. Effective 1/22/15 the quantity limit for insulin vials was reduced to 7 vials (70 mL) per month and effective 4/1/15; the quantity limit for insulin pens was reduced to 30 mL (2 boxes of 5 pens each) per month. Prior to these edits, quantity limits were 100 mL of insulin across all products.

Despite these new quantity limits, the quantities of insulin being dispensed still remains quite high.

Insulin- New Quantity Limits (4/1/15 to 6/30/15)						
Insulin Dosage Form	**Claims**	**Recipients**	**Total Paid**	**Total Days Supply**	**Total Quantity Dispensed**	**Dispensed Per Recipient**
Cartridges	218	103	$78,195	6,251	3,066	29.8
Insulin Pens	6,229	2,320	$2,338,772	175,426	94,425	40.7
Vials	7,001	2,694	$2,343,189	194,749	119,652	44.4

The DUR Board requested further analysis of the data, specifically looking into how many recipients were receiving 5 or more vials per claim and also how many recipients had claims indicating they were using > 100 units of insulin per day.

(4/1/15-6/30/15)	Claims count	Recipients	Amount Paid
>100 units/day AND/OR ≥ 5 vials/day	5,931 (45%)	2,367 (47 %)	$2,666,137 (57%)
Totals	13,230	5,014	$4,681,961

Of the 2,367 recipients who received > 100 units/day of insulin (based on quantity dispensed and days supply), or received 5 or more vials of insulin per Rx, 1,620 (68.4%) of those patients had a diagnosis of Type 1 diabetes on file.

Follow Up: Topical Testosterone Product Utilization

In the U.S., androgen prescriptions among men 40 years of age or older increased more than 3-fold from 2001 to 2011. Of the four formulations available (injectable, oral, transdermal, topical gel), topical gel demonstrated the highest rate of overall use and highest rate of increase- more than 5-fold.

In March 2015, the FDA released a Safety Announcement concerning the use of prescription testosterone products. The FDA noted that testosterone is FDA-approved as replacement therapy only for men who have low testosterone levels due disorders of the testicles, pituitary gland or brain that result in medical hypogonadism. However, the FDA has become aware that testosterone is being used extensively in attempts to relieve symptoms in men who have low testosterone for no apparent reason other than aging. The benefits and safety of this use have not been established. The FDA has concluded there is a possible increased cardiovascular risk associated with testosterone use. Based on these findings, the FDA is requiring labeling changes for all prescription testosterone products to reflect the possible increased risk of heart attacks and strokes associated with testosterone use.

Topical testosterone is currently on the Florida Medicaid PDL with only age and gender restrictions. A recent review determined approximately 75% of Florida Medicaid FFS recipients had a history of a serum testosterone level measurement while 70% had a diagnosis of testicular hypofunction on file.

DUR Board recommended that the P & T committee consider moving all topical testosterone products to non-preferred and to institute prior authorization criteria for topical testosterone products. Further, the DUR Board recommends requiring a baseline PSA concentration as well as serum testosterone concentration (measured in the morning on at least two separate days) indicating a serum testosterone value below the normal range for all diagnoses except gender identity disorder.

The following are the proposed ICD-10 codes that would satisfy the prior authorization diagnosis criteria:

- ICD-10-CM-E89.5- postprocedural testicular hypofunction
- ICD-10-CM-E29.1- testicular hypofunction
- ICD-10-CM-29.8-Other testicular dysfunction
- ICD-10-CM Code Q98.0-Klinefelter syndrome karyotype 47, XXY
- ICD-10-CM Code Q98.1-Klinefelter syndrome, male with more than 2 X chromosomes
- ICD-10-CM Code 98.4-Klinefelter syndrome, unspecified
- ICD-10-CM Code E23-Hypofunction and other disorders of the pituitary gland
- ICD-10-CM Code F64-Gender identity disorders

Follow Up: Synagis Utilization

According to the most recent update of the American Academy of Pediatrics guidelines regarding the use of palivizumab (Synagis®), which were published in August, 2014, the benefit resulting from this drug is limited; palivizumab prophylaxis has limited effect on RSV hospitalizations on a population basis, no measurable effect on mortality and a minimal effect on subsequent wheezing. Current guidelines recommend the use of a maximum of 3 to 5 doses depending on the infant s age and risk factors. There is geographic variability in the onset and offset of RSV season. Generally it runs from November through April in the continental United States; however Florida has variations within different regions of the state. According to the AAP guidelines, despite the varying onset and offset dates of the RSV season in different regions of Florida, a maximum of 5 monthly doses of palivizumab should be adequate for qualifying infants for most RSV seasons in Florida .

After reviewing the Synagis utilization data for the 2014-2015 Florida RSV season, The DUR Board voted at the June 2015 meeting to decrease the maximum number of monthly doses from seven to five for Florida Medicaid recipients during the 2015-2016 Florida RSV season.

The DUR Board requested further information regarding the total number of doses recipients were receiving:

Synagis DOS Count	Recipient Count
1	445
2	341
3	299
4	273
5	269
6	240
7	278

During the review of the Synagis utilization, it appears there are some recipients who received Synagis only AFTER an RSV-related hospitalization. There were 40 recipients identified who had a Synagis claim as well as an RSV-related inpatient admission during the 2014-2015 Florida RSV season. Of those 40 recipients, there were 15 recipients with only post-admission Synagis claims on file. The patient s ages may have been a contributing factor as the medical claims capture is likely incomplete in the analysis.

Recipients with RSV-related admission and only post-admission Synagis claims

Date of Birth	Hospital Admit Date (Age at time of admission)	First DOS Synagis claim	Last DOS Synagis Claim
2/6/13	7/24/14 (17 months)	9/11/14	10/13/14
1/2/14	10/17/14 (9 months)	10/28/14	2/10/15
12/9/13	7/27/14 (7 months)	10/8/14	2/10/15
3/4/14	9/14/14 (6 months)	10/8/14	3/23/15
5/20/14	8/30/14 (3 months)	10/7/14	4/8/15

7/3/14	11/13/14 (4 months)	1/12/15	1/12/15
12/28/13	8/6/14 (7 months)	9/29/14	4/6/15
8/7/14	11/15/14 (3 months)	12/9/14	3/9/15
9/2/14	11/16/14 (2 months)	3/23/15	4/22/15
8/26/14	10/7/14 (1 month)	10/29/14	1/7/15
9/9/14	11/24/14 (2 months)	1/5/15	4/7/15
9/9/14	11/23/14 (2 months)	1/5/15	4/7/15
9/6/14	11/27/14 (2 months)	12/15/14	1/12/15
9/6/14	11/26/14 (2 months)	12/15/14	1/12/15
9/19/14	11/11/14 (1 month)	12/3/14	3/23/15

Follow Up: Long-Acting Stimulants (and Strattera) in Children Under 6 Years of Age:

Prior to the implementation of this edit (7/1/15), there were no age restrictions on any long acting stimulant or atomoxetine (Strattera). None of the long-acting stimulants are FDA-approved for use in children under the age of six years. In consultation with the USF Behavioral Health program, a prior authorization form for children under the age of six was developed and is now required prior to approval of one of these agents in these children.

Long Acting Stimulants and Strattera in Children Under 6 Years of Age (FFS):

Time Period	Claims Count	Recipient Count	Amount Paid
Pre edit (4/1/15 to 6/30/15)	477	253	$109,384
Post edit (7/1/15 to 9/30/15)	95 *(80% ↓)*	55 *(78% ↓)*	$21,362 *(80% ↓)*

Follow Up: Morphine Equivalent Daily Dose (MEDD)

A total of 1,510 recipients were identified during the time frame April 1, 2015 through June 30, 2015 who received opiate doses that were greater than or equal to a 100 mg MEDD. The DUR committee requested further information regarding the identified recipients including the number of prescribers associated with these opioid claims and the acetaminophen daily dose for those recipients who were receiving opioid/acetaminophen combination products.

Prescriber Count	Recipient Count
1	1,007
2	347
3	109
4	30
5	9
6	7
9	1
Total	1,510

Acetaminophen Dose:

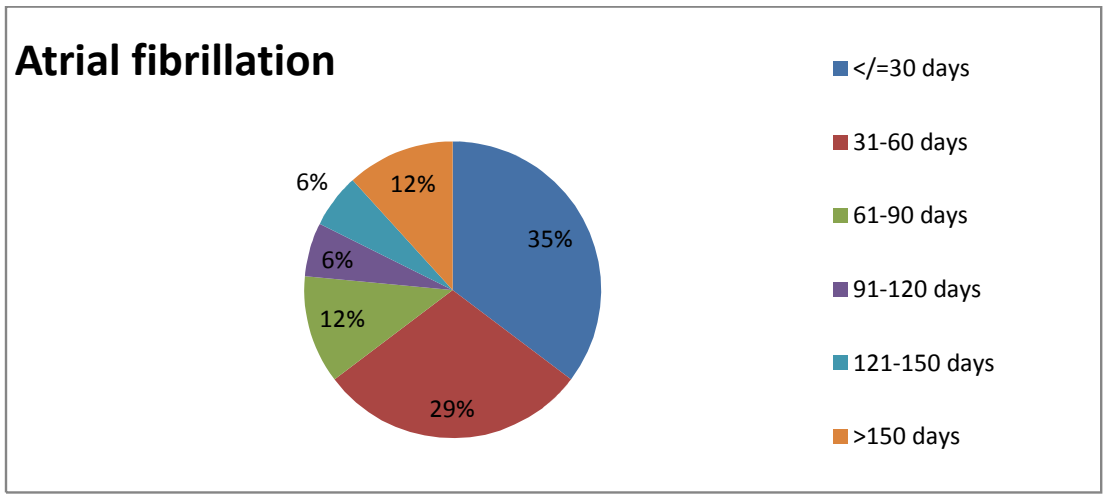
There were a total of 686 recipients who received a combination opioid/acetaminophen product in the same time frame. Based on quantity dispensed and days supply submitted on the claim, 230 recipients may have received greater than 4 grams of acetaminophen on at least one day of the examined period.

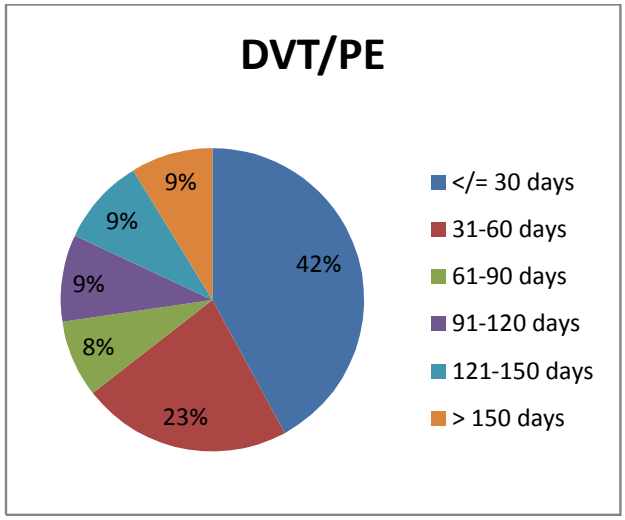
Follow Up: Novel Oral Anticoagulant Utilization

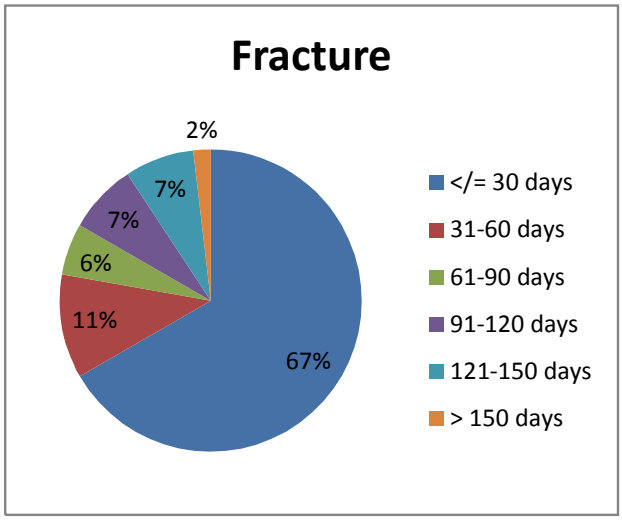
Preferred novel oral anticoagulants include dabigatran (Pradaxa), apixaban (Eliquis), edoxaban (Savaysa) and rivaroxaban (Xarelto). The indications for these products vary slightly from one another but generally include deep vein thrombosis (DVT) prophylaxis following orthopedic surgery, the treatment of DVT, prophylaxis for patients at risk for venous thromboembolic (VTE) complications due to a transient cause, prophylaxis or treatment of various types of myocardial infarction and to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (NVAF). The length of therapy may vary according to indication. VTE prophylaxis is generally short term, 10-14 days postoperatively or until the reversal of a transient risk factor such as immobility. For the treatment of VTE, the American College of Chest Physicians guidelines recommend anticoagulation for a minimum of three months. Adherence with NOAC therapy may be a concern for long term

treatment or prophylaxis and these agents are not routinely monitored with blood levels in the same way that INR is utilized in patients receiving warfarin for these same indications.

During a six month time frame (June 1, 2015 through December 1, 2015); there were a total of 689 unique FFS recipients who received a claim for one of the preferred novel oral anticoagulants. The majority of these recipients (62 %) did not have an indicated diagnosis on file; some of these may represent short-term DVT prophylaxis indications. For those patients with a diagnosis on file, the most common diagnosis was DVT (169) followed by fracture (54), pulmonary embolism (25) and atrial fibrillation (17).







New Business

June 2016 Pharmacy and Therapeutics Committee Therapeutic Classes

June Therapeutic Classes

Antibiotics, vaginal
Antidepressants, other
Antidepressants, SSRIs
Antiemetics/Antivertigo agents
Beta-blockers
Cephalosporins and related antibiotics
Cytokine and CAM antagonists
Epinephrine, self injected
Erythropoiesis stimulating proteins
Hepatitis B agents
Hypoglycemics, TZDs
Immunosuppressants, oral
Intranasal rhinitis agents
Lipotropics, other
Otic antibiotics
Pancreatic enzymes
Platelet aggregation inhibitors
Stimulants and related agents
June Mass Review
Acne agents, oral
Analgesics, non-sal/1st gen antihistamines
Analgesics, non-sal/barbiturate
Analgesics, non-sal/barbiturate/xanthine
Analgesics, sal/barbiturate/xanthine
Analgesics, salicylates
Anti-alcoholic preparations
Antifungals, vaginal
Antihypertensives, sympatholytics
Anxiolytics
Estrogen agents, combinations
Estrogen agents, injectable
Estrogen agents, oral/transdermal
Glucocorticoids, injectable
Glucocorticoids, oral
Histamine II receptor blockers
Iron, parenteral
PAH agents, injectable
Rosacea agents, topical

Mucolytics

Drug	Claims	Recipients	Total Paid	PDL Status
Acetylcysteine nebulizer soln 10%	10	6	$680.66	preferred
Acetylcysteine nebulizer soln 20%	10	6	$724.92	preferred
Pulmozyme (dornase alfa) 1 mg/mL	839	357	$2,737,599	preferred

The only FDA-approved indication for Pulmozyme is mucolysis in patients with cystic fibrosis, given in conjunction with standard therapies to improve pulmonary function.
Recommendation: Establish AutoPA with diagnosis look back for cystic fibrosis

Glucocorticoids, Oral

Label Name	Users	Claims Count	Total Amt Paid
BUDESONIDE EC 3 MG CAPSULE	46	66	$49,134.55
METHYLPREDNISOLONE 4 MG DOSEPK	1,462	1,551	$40,431.94
PREDNISOLONE 15 MG/5 ML SOLN	2,501	2,817	$24,391.29
PREDNISONE 20 MG TABLET	2,383	2,647	$17,311.35
PREDNISONE 10 MG TABLET	1,029	1,260	$11,772.53
PREDNISOLONE 15 MG/5 ML SOLN	1,693	1,883	$11,639.00
HYDROCORTISONE 5 MG TABLET	175	368	$9,726.32
PREDNISONE 5 MG TABLET	424	640	$6,798.85
METHYLPREDNISOLONE 4 MG TABLET	52	79	$5,060.16
HYDROCORTISONE 10 MG TABLET	60	123	$4,786.55
PREDNISOLONE 5 MG/5 ML SOLN	67	77	$3,639.50
ORAPRED ODT 10 MG TABLET	8	9	$2,604.89
DEXAMETHASONE 4 MG TABLET	294	374	$2,548.36
ORAPRED ODT 15 MG TABLET	8	10	$1,909.00
PREDNISONE 50 MG TABLET	285	302	$1,810.72
DEXAMETHASONE INTENSOL 1MG/1ML	19	27	$1,583.31
DEXAMETHASONE 2 MG TABLET	58	72	$1,366.13
PREDNISONE 1 MG TABLET	47	94	$1,342.82
PREDNISONE 5 MG/5 ML SOLUTION	39	48	$1,310.11

Budesonide EC tablets are indicated for the treatment of mild to moderate Crohn s disease dosed at 9 mg once daily for up to 8 weeks. Repeated 8 week courses can be given for recurring episodes of active disease. Budesonide EC tablets are also indicated for the maintenance of clinical remission of mild to moderate Crohn s disease at a dose of 6 mg for up to 3 months. Continued treatment with budesonide EC tablets for more than 3 months has not been shown to provide substantial clinical benefit.
Recommendation: Require clinical prior authorization of budesonide 6 mg for any patient who has exceeded 3 months of consecutive therapy.

Quarterly Activities

Metoclopramide Dosing /Risk of Tardive Dyskinesia

Purpose:	To determine the number of Medicaid FFS recipients who are receiving doses exceeding the recommended maximum daily dose of metoclopramide (60 mg/day for adults and 40 mg/day for patients < 18 years old) or who are receiving more than 12 weeks of continuous therapy	
Why Issue was Selected:	Metoclopramide carries a black box warning stating the risk of developing tardive dyskinesia is directly related to the length of therapy and recommends against use for durations lon ger than 3 months. Extrapyramidal reactions are dose dependent and also occur more frequently in younger patients.	
Program Specific Information:	Performance Indicators	Exceptions
	FFS adult recipients receiving > 60 mg/day	16
	FFS recipients < 18 years old receiving > 40 mg/day	2
	Any recipient receiving more than 84 days (12 weeks) of therapy	255
Setting and Population:	All FFS recipients who received a claim for metoclopramide between July 1, 2015 through October 31, 2015	
Main Outcome Measures:	Determine the number of recipients exceeding recommended dose limits	
Anticipated Results:	Consider implementing dosing limits	

There were a total of 1,813 claims for 1,178 recipients ($12,363) for metoclopramide in the studied date range. There were only 18 patients (1.5% of recipients) who exceeded the recommended daily dose. However, there were 255 recipients (22%) who received 84 or more days supply of metoclopramide. Of the 1,178 recipients examined, one patient had a diagnosis of tardive dyskinesia on file.

Recommendation: Consider implementation of duration of therapy edit to ensure therapy does not exceed recommended maximum of 12 weeks.

Budesonide Suspension for Inhalation/Brand versus Generic

Purpose:	To determine if denials of generic budesonide suspension for inhalation prescriptions are being appropriately redirected to preferred brand name Pulmicort Respules	
Why Issue was Selected:	The DUR Board is concerned that asthma patients are not receiving optimal therapy due to rejected claims for generic budesonide suspension for inhalation not being appropriately redirected to preferred Pulmicort Respules	
Program Specific Information:	Performance Indicators	Exceptions
	Percent of recipients with rejected claims for generic budesonide suspension for inhalation who subsequently had a paid claim for Pulmicort Respules within 7 days of the denied generic claim	49%
Setting and Population:	All Medicaid FFS recipients between August 1, 2015 and October 31, 2015	
Main Outcome Measures:	Determine the relative percentage of recipients that are appropriately redirected to the preferred drug	
Anticipated Results:	Patients are being appropriately redirected to preferred agent	

Recommendation: Consider educational letter campaign or other means of contacting pharmacy providers to educate regarding preferred status of Pulmicort Respules.

Celecoxib (Celebrex) Quantity Limits

Purpose:	To determine the incidence of recipients who are receiving celecoxib (Celebrex) doses of 800 mg/day	
Why Issue was Selected:	The P & T committee requested at the November 2015 meeting that the DUR Board review and consider implementing quantity limits for celecoxib	
Program Specific Information:	**Performance Indicators**	**Exceptions**
	Number of recipients who are receiving celecoxib doses greater than or equal to 800 mg/day	3
Setting and Population:	All celecoxib claims for FFS recipients between DOS 5/1/2015 to 10/31/2015	
Main Outcome Measures:	Describe the incidence of celecoxib use equal to exceeding 800 mg/day	
Anticipated Results:	Determine need for maximum daily dosing and quantity limits for celecoxib	

Current FDA approved indications for the use of celecoxib include:

- Osteoarthritis
- Rheumatoid Arthritis
- Juvenile Rheumatoid Arthritis
- Ankylosing Spondylitis
- Acute Pain
- Primary Dysmenorrhea

The normal dose of celecoxib for these currently FDA-approved indications ranges from 100 mg/day to 200 mg twice daily. In December 1999, the FDA approved celecoxib as an adjuvant treatment for patients with familial adenomatous polyposis (FAP). This approval was based on data showing that 200 mg BID or 400 mg BID for up to 3 years led to fewer patients with an adenoma at years one and three compared to placebo recipients. However, in February 2011, the FDA withdrew the approval of celecoxib for FAP following analysis of two long-term safety studies which revealed an increased incidence of serious cardiovascular events in patients with long-term celecoxib as compared to placebo, the risks associated with this therapy were determined to outweigh the potential benefits for patients with FAP. Therefore, there are no current FDA approved indications with a recommended dose of 800 mg/day.

Recommendation: Implement celecoxib 400 mg/day maximum daily dose limitation.

Further Information Requested by the DUR Board:

Daraprim Utilization:

On August 11, 2015, Turing Pharmaceuticals increased the price of Daraprim 25 mg from $13.55/tablet to $750/tablet (based on Wholesale Acquisition Cost). On October 8, 2015 AHCA implemented clinical prior authorization criteria for the use of pyrimethamine (Daraprim).

Daraprim Utilization:

Date Range	Claims	Recipients	Total Paid
4/10/15 to 8/10/15	26	15	$21,548
8/11/15 to 12/11/15	12	6	$335,574

Top Therapeutic Classes by Claims Count (9/1/15 to 11/30/15)

Therapeutic Class	Claim Count	Total Amount Paid	Paid/Claim
Anticonvulsants	36,986	$4,961,574	$134.15
Antipsychotics, Atypical, Dopamine & Serotonin Antagonists	14,725	$2,545,818	$172.89
Analgesics, Narcotics	12,646	$341,281	$26.99
SSRIs	11,034	$73,352	$6.65
Beta-Adrenergic Agents	9,626	$413,335	$42.94
NSAIDS, Cyclooxygenase Inhibitor	8,900	$75,522	$8.49
Penicillins	8,568	$108,023	$12.61
Anti- Anxiety	7,235	$53,552	$7.40
Antihistamines-Second generation	6,204	$36,239	$5.84

Top Therapeutic Classes by Total Paid (9/1/15 to 11/30/15):

Therapeutic Class	Claim Count	Total Paid	Paid/Claim
Antihemophilic Factors	529	$11,236,394	$21,241
Anticonvulsants	36,986	$4,961,574	$134.15
Antipsychotics, Atypical, D2 Partial Agonist/Serotonin Mixed	2, 896	$2,744,831	$947.80
Antipsychotics, Atypical, Dopamine & Serotonin Antagonist	14,725	$2,545,818	$172.89
Insulins	3,202	$923,485	$288.41
Glucocorticoids, Orally Inhaled	2,458	$705,341	$286.96
Adrenergic, Aromatic, Non-Catecholamine	4,651	$631,008	$135.67
Attention Deficit-Hyperactivity Disorder/Narcolepsy	3,408	$504,030	$147.90
Antineoplastic Systemic Enzyme Inhibitors	56	$479,088	$8,555.15

Prior Authorization Requests/Outcome Statistics for the following drugs will be presented at the January 16, 2016 DUR Board Meeting:

- Alirocumab (Praluent)
- Evolocumab (Repatha)
- Ivacaftor (Kalydeco)
- Lumacaftor/Ivacaftor (Orkambi)

DRUG UTILIZATION REVIEW BOARD

Agency for Health Care Administration

Tampa Marriott Westshore

Saturday, January 16, 2016

8 a.m - 10:55 a.m.

REPORTED BY: JACQUELINE L. REICHERT
Integra Reporting Group
Court Reporter
Notary Public
Commission No. EE 160968
Expires 3/27/16

Pl. Trial Ex. 238

PRESENT:

BOARD MEMBERS:

Anna Hayden (Chair)
Jeffrey Martorana (Vice-Chair)
Allen Moses
Diane Fagan
Vanessa Goodnow (Absent)
Larry Field (Absent)
Kevin Olson
Alfred Romay
Luis Saez
Amy Zitiello

AHCA STAFF:

Beverly H. Smith, Esquire, Medicaid Counsel
Vern Hamilton, AHCA Liaison
Arlene Elliott, RPh, Operations Administrator
Susan Williams, PharmD

MAGELLAN MEDICAID ADMINISTRATION

Rebecca Borgert, PharmD

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P R O C E E D I N G S

THE CHAIRPERSON: Good morning. I call this meeting to order. I'd like to welcome everyone for taking the opportunity to come here this morning and provide services for the State of Florida.

Vern, do you want us to do role call, just go around the room and -- we'll just go around the room and start off with Dr. Moses there, Allen. And then, you know, just a word or two about your practice and what you do full time.

DR. ALLEN: Sure. Good morning everyone. Moses Allen. Currently I'm Director of Specialty Distribution with Lemire Health, previously with Prestige Health Choice as Director of Pharmacy.

DR. FAGAN: Good morning. I am Diane Fagan. I'm Director of Pharmacy with WellCare.

DR. OLSON: Kevin Olson, Manager in the Pharmacy at All Children's.

DR. SAENZ: Good morning. I'm Luis Saenz, I'm Director from PHC.

DR. ROMAY: Good morning. Alfred Romay,

Director of Pharmacy over at Molina Healthcare Florida.

DR. ZITTELLO: I am Amy Zittello, Medical Director for Amerigroup.

DR. MARTORANA: Dr. Jeff Mortorana, Chief Medical Officer Sunshine Health.

THE CHAIRPERSON: My name is Anna Hayden. I'm your Chair of this Board -- of the Drug Utilization Review Board. I'm a family practice physician. I work in Downtown Fort Lauderdale for Broward Health.

MS. SMITH: I'm Beverly Smith. I'm the Medicaid Counsel for the DUR Board.

MS. ELLIOTT: Arlene Elliott, Pharmacy Policy Administrator at AHCA.

DR. WILLIAMS: Susan Williams. I'm a Senior Pharmacist with AHCA.

MR. HAMILTON: And I'm Vern Hamilton, the Agency liaison for these meetings.

DR. BORGERT: And I'm Becky Borgert. I'm a Pharmacist with Magellan Healthcare.

THE CHAIRPERSON: And we have two members that are excused due to travel issues. Dr. Vanessa Goodnow could not be here due to a grounding of her plane in Fort Lauderdale

due to bad weather. And Dr. Field could not be here this morning, he's also excused due to issues as well.

Next on our agenda we have opening remarks from Arlene Elliott, she our AHCA Administrator.

MS. ELLIOTT: Good morning. Welcome everybody. Thank you for being here early on this beautiful morning. I failed to mention yesterday, so you guys can spread the word, the Agency has not made a decision yet whether the plans need to follow or not the PDL. So at this point currently all the plans should be following the Agency's PDL, the decision has not been made to change that or continue it. Thank you.

THE CHAIRPERSON: Thank you very much.

Next on our agenda is the review of the Drug Utilization Review minute from our September 26th, 2015 meeting. I make a motion to approve. Do we have a second?

DR. ZITTELLO: Second.

THE CHAIRPERSON: Any discussion?

MR. HAMILTON: Well, Dr. Hayden, I corrected the spelling of your name I believe

on page 3.

THE CHAIRPERSON: That's the editorial.

MR. HAMILTON: Thank you for pointing that out. And if there are any other corrections, let me know.

THE CHAIRPERSON: Very good. Thank you. Any other discussion? So for the final count, all those in favor of approving the Drug Utilization Review minutes with the minor editorial comment, signify by saying "aye"?

THE BOARD: Aye.

THE CHAIRPERSON: We have unanimous approval of the minutes. Thank you.

Next on our agenda we have information from the review of the P&T minutes from the November 9th, that is informational. And Rebecca will be giving us a short report of yesterday's P&T as a conduit of --

DR. BORGERT: Sure. So the P&T Committee did meet yesterday. I'm going to refer in the DUR presentation so this is here now. Now, we know that P&T normally meets the day before DUR and they did yesterday. But if you'll recall back in the fall, they had to

postpone the meeting, so P&T actually met in November. So there's one thing that came out of that November meeting that they requested that the DUR Board look into, and that was dosing of Celebrex. So we're going to talk about that today. I have that in the quarterly topics because it was requested at the November P&T Meeting. So it's just a little strange because of the timing of the last meeting.

She the P&T Committee did meet yesterday and they reviewed several classes, just things that might have an impact on the DUR Board that I'll mention.

They did review Androgenic Agents, and as you know we're going to talk about testosterone today. And they basically endorsed the DUR Board putting a ClinicalPA on the class and the DUR Board determining the criteria. So the P&T Committee did endorse the DUR doing that and we'll finalize that today.

They added Entresto which is a new -- sacubitril/valsartan, a new -- it's in the ACE inhibitor class, although not technically

an ACE -- you know, it's one of the entities that's an ACE inhibitor. Let's see, what else. For inhaled antibiotics, both Tobi and Kitabis Pak are now -- will now be preferred.

All of the -- again, we're going to talking about the novel Oral Anticoagulants today. And they -- the P&T Board voted to keep all four of the currently available commercial products on the PDL.

One thing that was referred to DUR was Xopenex because they reviewed the Beta Agonist Bronchodilators. And one member of the P&T Committee felt like the utilization was really higher then you would expect it to be, and asked us -- and referred that to the DUR Board. So that just happened yesterday, so we'll look at that in April when we meet again.

Let's see. You know, we talked in the past we looked at our P&T class, we had talked about Daliresp, and they basically were in favor of having the DUR put some criteria around that to try to tighten utilization.

I don't think there's anything else that

had -- we're going to talk today about the PCSK-9 inhibitors because you guys asked about that of the last meeting. Those were actually single product reviews yesterday, and they're both non-preferred at this time. We're talking about alirocumab which is Praluent, and evolocumab which is Repatha.

And I think that was pretty much the highlights of things that might have to do with the DUR Board from P&T yesterday.

THE CHAIRPERSON: Thank you very much.

And then other item that was on our agenda originally was Dr. Winterstein's presentation, but that's been postponed until more data is available on the Synagis vaccine and impact on our Floridians with access to that medication. So the data is not available so she's been postponed until either April or September meeting just as a follow up --

DR. BORGERT: We'll probably wait at least until the end of this RSV season so we have at least one full year of RSV data, so that won't be until the end of April, right.

THE CHAIRPERSON: And then that data may

not be available probably until our September meeting. And the main impact was reducing from 7 to 5 vaccines to see if there was any impact at all, those were questions we had. So she's been postponed. Very good.

Next, Ms. Rebecca again on quarterly DUR activity reports.

DR. BORGERT: All right. So as must of you are familiar now that you've been to at least one meeting. We typically start this meeting with -- sorry. We normally start this meeting with follow-up or updates. So during this section we talk about anything that had previously come to the Board where maybe there were additional questions by the Board about the data that was presented, so we try and follow-up with those questions.

The other thing that's presented in this section of the presentation is any post intervention analysis. So any time we do an intervention or an edit, we try to measure the impact of that. And so typically we're looking at a three-month period of time and so we always bring that back to the DUR Board in terms of looking at the impact of any

interventions that the Board has recommended. So that's what's going to be in this section.

And this first topic is one of those things. It's a follow-up on an intervention. So we wanted to look at limit the duration of therapy of skeletal muscle relaxants. We felt like patients were getting on skeletal muscle relaxants and sort of being on them indefinitely, when most of really the indications are for short term musculoskeletal type of conditions.

So what we did is we put a limit on it where patients were allowed to have six consecutive claims for -- six claims for a 30-day supply, and after that time then it would stop requiring a prior authorization.

Now, we did exempt any patients with chronic -- some diagnoses and it was diagnosed. So basically they were chronic spacticity-type conditions for baclofen and tizanidine, because those patients, it would be appropriate for them to be on long term skeletal muscle relaxant therapy.

So the edit was deployed in March. So since the way this edit worked was it allowed

six months worth of therapy, we wouldn't start having impacted claims until September. Does that make sense? The edit went in in March, but we wouldn't have had had impacted claims until September because they were allowed six months before the edit would go into place.

So when we looked at the post edit, we looked from September 25th, which would have been six months post implementation, through December 15th which was the day we did the analysis, so that was all the data that we had.

And as you can see it was a pretty substantial decrease. We had 41 percent decrease in claims, 30 percent decrease in recipients, and an overall 43 percent decrease in the number of dosage units that were dispensed, and a 37 percent decrease in the amount paid.

Now, I will have to add a caveat here. And that's I don't know the answer to this either, but, you know, back in the day when everybody was Fee-for-service and it was much a more stable population, I think maybe it

was more apples to apples. I think now maybe when we look at these numbers, I don't know, nobody knows really, on how much of an apples to apples comparison it is, because Fee-for-services are a more fluctuating population than it used to be in the past. So all we can do is take a snapshot, you know, before and after. And from what it looks like, it looks like certainly there was some effect of that edit.

So any questions?

THE CHAIRPERSON: Was there any other prior authorizations requested on any of the --

DR. BORGERT: I don't know.

THE CHAIRPERSON: Maybe we should look at that.

DR. BORGERT: I'll look.

THE CHAIRPERSON: I know that's a good point you're making about the fluctuations of the recipients.

DR. BORGERT: Right.

THE CHAIRPERSON: And the other one is, you know, the impact you can look up prior auths if it was a medical necessity or if

there was a --

DR. BORGERT: Right, right.

DR. MARTORANA: And is there any ballpark figures as far as the number of members in the Fee-for-service world that this would indicate?

DR. BORGERT: Arlene, do you know the number?

MS. ELLIOTT: Yeah. It's approximately 400,000.

DR. MARTORANA: Okay.

DR. BORGERT: And I mean the whole number is not so much this fluctuating as the individual recipient is fluctuating is what I mean when I say that.

THE CHAIRPERSON: Oh, I got it.

DR. BORGERT: Yeah. Because you might come in Fee-for-service and then go out to an MCO. So, you know, not so much the aggregate number as individuals.

This is a follow-up item from a topic that we discussed in the past. This is just a short recap. Prior to this edit we had an overall limit of 100 mls of insulin per 30-day limit, and last year the DUR Board

decreased that to a limit of seven vials of insulin and two boxes of insulin pens. Some people felt at that time that that was still a very high limit. However, when we looked at the data, it looked like the majority of patients that was kind of where the cutoff fell for the majority of patients so that's why those numbers were picked.

So not surprisingly, I don't think, when he look -- this is the slide that looked at last time -- the new dosing limits didn't really have much of an impact on the quantities that were being dispensed. Pens went down a little bit because we didn't have any real limit on pens before, so that did decrease about 13 percent.

Vials basically stayed the same, which again, is pretty much what we expected because we knew kind of that's where the cutoff was for what was being utilized.

So the Board had asked -- you know, we had some discussion last time as you recall about the fact that that seems like an awful lot of insulin for people to be using. And was it just an anomaly of the fact that that

amount was being dispensed and called it a 30-day supply and it really wasn't a 30-day supply. And so the Board wanted to look into that a little bit closer.

So what we did in -- and this was -- you know, with the DUR Board slides, kind of that's a high blood. Somebody that was getting more than 100 -- greater than or equal to 100 units per day of insulin or five or more vials per claim.

So of that same data set that we looked at originally from April to June, we looked -- and this was just strictly based on what was submitted on the claim in terms of quantity dispensed and day supply.

So if you just take that at face value, if you just take what's submitted on the claim as quantity dispensed and days supplied, then almost half the patients were exceeding 100 units of insulin per day, which seems like a lot. I think that's what the point the Board was trying to make.

I will note because one of the other questions was about the type of diabetes these patients might have. And of those high

utilizers almost 70 percent did have a diagnosis of Type 1 diabetes on file -- so at that was good -- whereas, only 28 percent had Type 2 diabetes. And 4 percent we could find neither of the diagnosis on file. Maybe some of those were gestational, I don't know, but 4 percent we couldn't find a diagnosis, so...

So in order to try to gain a better understanding of these high utilizers, we took those same recipients but we expanded the time range out to nine months so that we could look at subsequent fills.

So we had that the same utilizers, those ones that were identified in the past slide, and we looked at a nine-month period of time. And we tried to calculate a true day's supply based on time, actual time to the next time they filled the insulin prescription.

Now, several of the utilizers only had one claim in that nine-month period of time, actually 38 percent. I know. So I think that might speak to, again, the coming in and out of Fee-for-service. Like, you know, maybe they were Fee-for-service for a very short time, got one fill, and then moved on

to an MCO or something like that. I have a feeling that's probably the explanation for that. I don't know why there was --

So we, in terms of this analysis, we discarded those 38 because there would be no way to look at when their next fill was. In Fee-for-service we didn't have that information.

So of the remaining 1475 high blood recipients, when we looked at actual days elapsed between fills, the true average day supply was 36 days. So it was about a week longer than a true 30-day supply. I was kind of surprised it wasn't even more than, but that's what the number was.

It was when we looked at -- you know, there's always going to be a last claim, so we only could carry the data out so far. But in that nine-month period of time looking at the fills that they received in the quantities that they were dispensed, the average day supply was 36.3.

However, when we did that same type of thing, the number of patients who were receiving more than 100 units a day dropped

down all the way from 2,367 to only 270 recipients. So that seems a lot more likely, that there were 270 recipients who were truly getting 100 units if insulin or more a day.

So that's the information back to the Board. You know, I think Magellan and the State are, you know, still trying to get our mind around what's the best way to handle insulin utilization because it's really hard to know what an average dose is. And then we've also got the complicating factor of, you know, vials obviously can't be broken, they're dispensed as one size. Pens are usually -- the boxes are usually not broken, they're usually dispensed as an entire box. So somewhat of the -- you know, just the nature of the product, I think, makes it harder as well to, you know, really tighten down that quantity dispensed in day's supply.

So does anybody have any question questions or comments about that? That was just the follow-up information from the questions we discussed last time.

Okay. This is a post impact analysis. If you'll recall we looked at putting in a PA

on long-acting stimulants in children that were under six years of age. And we did this because none of the long-acting stimulants are currently FDA approved in this age group. And prior to the edit we had no age limits on this group of medications. And this list of medications that were involved in the edit are on this screen.

And, again, it seems like this impact did have a very large impact. So we looked at three months pre-edit and three months post-edit. The edit was implemented on July 1st of 2015. There was an 80 percent decrease in claims, and 78 percent decrease in the recipients, and then 80 percent overall in total spend on long-acting stimulants in that population. So that was an effective edit. I thought that was -- and maybe you were the first one to bring up that idea, so that was a good thing. And the PA for that is, of course, on the AHCA website. Questions? All right.

As I mentioned yesterday -- as mentioned earlier, excuse me, the P&T Committee yesterday did enforce putting a ClinicalPA on

this class and going with the DUR Board recommendations. The only update -- this was a slide that we went through that last time in terms of background. The only update to this slide would be the hours we met in September, the American Association of Clinical Endocrinologists issued a position statement that was actually somewhat contrary to the FDA warning about cardiovascular safety.

And what the American Association of Clinical Endocrinologists said was there is no compelling evidence that testosterone therapy either increases or decreases cardiovascular risk. And they encourage large scale clinical trials to assess that. So there's been a little bit of push back in terms of the FDA warnings on cardiovascular use.

Again, we saw this last time and we had some concerns about the fact that we had some patients who had some diagnosis of prostate cancer, very few had orders for PSAs, and that, you know, there probably needed to be tighter utilization around this class.

So this is just a summary of what was discussed last time. The ClinicalPA will require a baseline serum testosterone level, require a diagnosis verification, and we will require baseline PSAs. So that's what we will be doing and implementing in the next quarter for the top testosterone products as endorsed by the P&T Committee.

THE CHAIRPERSON: There's another online packet here for the ICD-10 codes. I'm not sure if F64 encompasses all the transgender codes as well -- you're seeing that as well -- is it something else to consider adding as a different ICD-10 code.

MS. ELLIOTT: If I may comment on that?

THE CHAIRPERSON: Yes.

MS. ELLIOTT: Yes. The Agency is going to discuss that internally and then we'll bring it to the Committee or to the members to the meeting -- next meeting. Because we don't have -- Medicaid doesn't pay for gender identity disorders, so this is a discussion that will be discussed internally and then we'll figure it out and bring it to the Board next time.

THE CHAIRPERSON: Thank you.

DR. BORGERT: Okay. Just a follow-up about Synagis. You probably hope this is the last time we'll talk about this for a while. Dr. Olson, I believe had -- he had expressed some concern that he felt like patients were not receiving their full schedule of Synagis doses. And so he asked for how many doses were these patients were receiving. So that's what this graph is trying to indicate.

So there were 445 recipients but we could only identify one Synagis claim. Out to 278 recipients that we could identify that got seven Synagis claims. The only caveat here is, like I said at the last meeting, we don't really feel like -- and this includes both Fee-for-service and encounter data, and we didn't feel like we probably were able to capture all of the medical claims.

So all of the hospital -- you know, the hospital administered doses, just really hard for us the way that billing is to capture that. I mean, If it's a claim at point of sale, super easy, we have that, that's all solid data.

But, you know, with a drug like this, it's administered sometimes in the inpatient setting, we're not 100 percent certain that we, you know, documented all the doses that were received on the inpatient side.

But I think the point is that you're right that, you know, it does look like that probably the majority of the patients fall between two and five doses, which is -- you know, five doses is now the current recommendation.

But certainly there is a significant population who looks like they've received only one or two doses and then don't go on to receive the following doses. Unless these were doses that they received late. You know, that one dose that we had is the dose that they received late after they've been hospitalized for many months or something and gotten it in-house. Kind of hard to know, but that's what the data looked like.

Another follow-up in -- and we saw this last time -- is talking about the use of morphine equivalent daily doses as a quality indicator tool. This is something that is

really a lot in the quality literature now about use this measure as a way of managing opioid strategies.

So we saw this last time. We looked at how many of our recipients were exceeding 100 milligrams of morphine daily dose. And the question that was asked about that data was how many prescribers were associated with those opioid claims.

And so the pie chart here represents, thankfully, the vast majority 1,007 of the recipients only had one prescriber that was responsible for all of their opioid claims that put them into that greater than 100 milligrams of morphine equivalent daily doses per day. So that was good.

You know, the 30 patients who had four -- no, wait. Yeah. There were 30 patients at four prescribers. And I don't think there were any that had five. That six -- seven patients had six prescribers and one patient had nine prescribers. So, you know, this again would be an additional way that we would look at this.

And, you know, certainly the recipients

who had only one prescriber would much less of a concern than patients who had three or more -- or four or more basically prescribers. And that might be a way that we identify recipients where we want to look into that utilization. And, you know, maybe even contact prescribers and say, you know, "Are you aware that, you know, these claims are -- there additional claims for your patient from different prescribers for these drugs?"

THE CHAIRPERSON: As a follow-up to that, when the Board of Pharmacy updated their Pharmacy Rules, 64B16, regarding dispensing of controlled substances, that was in just last month. So those poly prescribers or the pharmacist, before they issue that prescription, has to check that red flag at the point of sale because the pharmacist now has the ability to go to the PTMP. They have to take two extra hours of continuing medical education of controlled substance prescribing. They have to consult with the patient and collaborate with the prescribers writing the order. Those are recent updates.

So I think that number -- prescriber counts when you get into that high multiple prescribers for those patients, especially four and three, that's still 109 and 30 --

DR. BORGERT: Right.

THE CHAIRPERSON: -- almost 150 patients, they'll have to answer to that.

DR. BORGERT: Right.

THE CHAIRPERSON: So I think we'll see less of those numbers in terms of safety for our Floridians.

DR. BORGERT: Right. I mean, that's the ultimate solution is to have it stopped right there, and have the prescriber contacted at that point to be informed that, you know, there are other prescribers for those patients.

DR. ALLEN: I have a question as well. Is there any correlation to the Lock-In Program with this state? I guess just a high level thought, the patient who has nine prescribers or even six prescribers, I'm assuming those prescribers are probably prescribing different opioids. So if yes, are they being controlled in the Lock-In

Program?

DR. BORGERT: Arlene, I don't know if you want to address this or not, but currently the Lock-In Program did Sunset --

DR. ALLEN: Oh, Fee-for-service. Okay.

DR. BORGERT: -- I don't know -- a year or so ago. So there is currently absolutely no active Lock-In Program. But I think the Agency is looking into --

MS. ELLIOTT: Well, it's Sunset for Fee-for-service patients. The plans -- the criteria are our guidance. So, yes, they would follow them. And we're still reviewing and updating the criteria for the Lock-In Program for the plans. We have put in so many edits for Fee-for-service, that nobody felt -- it wasn't appropriate, or because all the edits that we put in quantity limits, age limits, a maximum of four or three. So that -- when we looked at the patients, there were no patients that we would be able to log in. So that was a good thing.

THE CHAIRPERSON: What about looking at -- we're looking at morphine equivalent doses, but looking at doses for our

intermediate- or shorter-acting controlled substances in terms of maximum daily dosages on the package insert and how many patients are exceeding that? If they're outside of that recommended package insert, could we put an edit at that also?

DR. BORGERT: I don't know with opioids if they actually have a maximum recommend dose on --

THE CHAIRPERSON: It's two tablets every four to six hours.

DR. BORGERT: Oh, because of the acetaminophen limit. Is that the product you're talking about or are you talking about just --

THE CHAIRPERSON: Just put the package insert -- I see the date on some of them. I'm looking at the shorter- or intermediate-acting as a possible mechanism of providing for patient care of those patients that are -- or prescribers that are exceeding the maximum daily dosage as in the package insert.

DR. BORGERT: I will look into that.

THE CHAIRPERSON: So that would be like

hydrocodone with the Tylenol.

DR. BORGERT: Right. Certainly the products that have acetaminophen.

THE CHAIRPERSON: Like oxycodones with Tylenol.

DR. BORGERT: Right, right. And that's the next piece of this down here in the bottom, which I don't if you can read or not. But that question came up last time as well about the amount of acetaminophen these patients would be receiving.

So of those recipients that we identified, 1500 of them that were receiving more than 100 milligrams of morphine equivalent daily dose, 42 of them did exceed the 4 grams of acetaminophen a day.

If you'll recall this time frame that we looked at was April 1st to June 30th. And an edit did go in on Fee-for-service on November 16th that would stop any -- that does an acetaminophen accumulation. So hopefully those 42 patients would get caught with that edit that was deployed in November.

THE CHAIRPERSON: Didn't we -- I think we talked about this before, Rebecca, as far as

the dose of the acetaminophen has been modified to 3 grams, I believe?

DR. BORGERT: You know, we talked about that and then we went back and looked at it and I think across the board it's still 4 grams. I mean, certainly at-risk patients, you know, liver disease or some things like that, it has been reduced to 3. But the last time --

THE CHAIRPERSON: I was thinking more of the older adults.

DR. BORGERT: Maybe there's an age with the 3 grams?

THE CHAIRPERSON: Yes, there is.

DR. BORGERT: Maybe the 3 grams is age-related, that could be. Because when we looked at it, it was still, you know, 4 grams. But we can go back and look at that.

THE CHAIRPERSON: And is it possible to do an edit on that as well? Can we can look at that?

DR. BORGERT: We can certainly look that, uh-huh. We'll look at age as it relates to acetaminophen dose.

THE CHAIRPERSON: I think it's -- I'm not

sure if it's 65 and how many Medicaid recipients are duly enrolled and are receiving that.

DR. BORGERT: Right.

THE CHAIRPERSON: I'm not sure if it's 65.

DR. BORGERT: Okay. Well, we can look it up, that's fine. No, big deal.

THE CHAIRPERSON: I know we sent out banner messages on that as well in the past.

DR. BORGERT: Okay. That was probably before my time.

Out last follow-up item for today, as I mentioned, the P&T Committee did look at this class of drugs, and we had looked at this last time. We were looking at adherence with therapy. And this is just -- we saw this last time. This is just quick reminder of the indications and the recommended duration of therapy.

When we looked at, you know, what types of diagnosis these patients were -- we carried it out for a six-month period of time and tried to look at diagnosis. Unfortunately, most of them we couldn't

identify a diagnose -- they didn't have any of those diagnoses on file. So I don't know if that really tells us anything.

But, you know, one thing we did kind of focus in on was the afibulizers. Now, it's a relatively small percentage of the utilizers because, you know, that age demographic tends to be, you know, less representative in Medicaid because of Medicare.

However, when we looked at a six-month period of time a lot of patients really were not receiving therapy on a continuous basis. And there's been some stuff in the literature about, you know, real world adherence data to these drugs.

And, you know, unlike warfarin, which -- I mean, these drugs haven't had any advantages over warfarin, but the flip side is, you know, they're not coming in for PT monitoring. So there's no way that sort of it's being monitored. And some people speculate because there's that less interaction between healthcare provider and patient with the monitoring of the warfarin, that adherence is actually lower with these

medications than with warfarin because of the follow-up involved.

So, you know, one of the things that we thought we might do is just pull out those recipients who had gaps in their care. So, you know, maybe they get a fill and then they don't fill it again for three months and then they fill it.

It's a small number of patients, so we could probably just letter those providers that were involved with those patients in terms of saying, "Hey, we've identified that, you know, over a period of time your patient, you know, only had, you know, adequate anticoagulation based on their claim's data for, you know, a third of that period of time," or something like that. So just kind of a heads-up to those prescribers about adherence with these medications, because obviously patients need to be anticoagulated. And adherence seems to be an issue that is coming to light with these -- with this class of medications.

THE CHAIRPERSON: You know, I think perhaps if the diagnosis was paroxysmal

atrial fib and they didn't have a test for the novel anticoagulant with warfarin, some of them are just offered Aspirin. So I'm not sure.

DR. BORGERT: Right. But these are patients who have had a fill for one of these drugs. So the concept is they filled it and then they didn't fill it, didn't fill it, didn't fill it. And then they fill it again. You know, so it's just very sporadic in terms of -- that's what I mean about the gap in care in terms of, you know, it looks like they were supposed to be taking it all the time, but based on the amount of times they're filling it, it doesn't look like they are really adequately taking the medication.

THE CHAIRPERSON: And these are continuous with the recipients?

DR. BORGERT: Uh-huh.

THE CHAIRPERSON: Okay.

DR. BORGERT: So what we'll do is we'll try to pull out those individual recipients and bring that back next time just with a letter so that you guys can see it.

And then just to follow-up -- to finish

up this section. This is a standing agenda item regarding Hepatitis C and our utilization. So as you can see there we have about equal number of recipients for Viekira Pak, which is preferred, and Harvoni. And that might be a reflection of the fact that Viekira only became preferred at the March 2015 meeting. And certainly the Viekira Pak numbers have gone up since that time.

The P&T Committee did make Daklinza and Technivie preferred yesterday as well as Viekira Pak. And this is the prior authorization information. And you can kind of just see there the number approved, the number denied, and the total numbers of requests that we received for the Hepatitis C therapies.

DR. ALLEN: A quick question for you.

DR. BORGERT: Yes.

DR. ALLEN: Is there any indication since the implementation of -- well, I guess that's making Viekira Pak preferred is the -- are the other agents -- are their uses trending downward or is the uses still similar?

DR. BORGERT: I think just relatively

speaking, yes. Because certainly the amount of Viekira Pak that we're dispense -- that we're approving has gone way up compared to what it was before March. We still see a lot of requests for Harvoni and we still get -- you know, we still really -- because Viekira Pak is a preferred agent we really try to -- and Elboni and I -- Elboni obviously is not here today. But she and I were talking about his, and, you know, I think we're going to go ahead and pull all of those PAs on Harvoni that have occurred since March and just look at them. And just, you know, kind of see what is going on with why are we still approving Harvoni in patients -- you know, there are some valid reasons sometimes.

DR. ALLEN: Sure.

DR. BORGERT: But we want to just kind of really dig a little bit deeper into that, just because of the sensitivity of this class and that sort of thing, and make sure that it's being approved appropriately.

DR. MARTORANA: I had a question. Are you seeing an uptake in requests for those individuals that don't have stage 3 or higher

disease?

DR. BORGERT: Yes. The state of Florida we maintained it at stage -- no, we have some that are F2. Which ones are F2 now? Are there any of them that are F2? I don't know. Susan will look for us.

But I will tell you that some Magellan states went down to F2 across the board. But Florida by and large stayed at F3.

DR. ALLEN: Yeah, F3 and F4.

THE CHAIRPERSON: Wasn't there a letter from CMS that we received?

DR. BORGERT: Yes, we did. And I had a link to that in your quarterly report. CMS did send out a letter encouraging Medicaid programs to broaden their approval criteria while at the same time sort of try to lean on manufactures to do their part to work with Medicaid to make this a more affordable therapy.

MS. ELLIOTT: Right. And if I could comment on that. The letter from CMS was guidance, and an e-mail was sent to all the states. And we received -- you know, it's a group -- the DEHP Group -- I don't know if

you're familiar with it. Pharmacy directors or pharmacy representatives for each state. And most of the states are just taking it as that. They're saying, "It's a guidance, we're not going to change anything at this time."

THE CHAIRPERSON: Thank you.

DR. SAENZ: I have a question on Daklinza for the -- you know. How cost effective is it? I know that it's approved -- it has a better chance for stage 3, but you still need to use sofosbuvir.

DR. BORGERT: Right.

DR. SAENZ: And it only works if they don't have cirrhosis. So if you have cirrhosis, then you have to add Ribavirin.

DR. BORGERT: Right.

DR. SAENZ: So cost effective, instead of using Harvoni, how -- you know, I understand that for a grade 3 they have no cirrhosis --

DR. BORGERT: Is Harvoni approved for Genotype 3? I think it's 1, 4, 6 -- 1, 4, 5, 6.

DR. SAENZ: They still use it. Well, they use it for 24 weeks, you know, for like

Genotype 3 it has less percentage of cure. But once it gets to cirrhosis, like they don't do as well with Daklinza. You know, it's like -- so in terms of cost Daklinza and Harvoni with stage 3 with cirrhosis, I don't know, the price.

DR. BORGERT: The Agency has made a decision more to go -- to base their approval guidelines more on FDA approved indications as opposed to the ASLD guidelines. So I'm -- can somebody look for me -- because I don't want to pull off the slides -- is Harvoni approved in Genotype 3?

DR. SAENZ: Yes. It's 24 weeks, if I recall.

DR. BORGERT: All right. I will --

DR. SAENZ: I'm just looking in the cirrhosis stage.

DR. BORGERT: Right. I know. So you're taking about Genotype 3 patients --

DR. SAENZ: Yeah. Because those with cirrhosis don't seem to do as well.

DR. BORGERT: Right.

DR. SAENZ: So it's about the same percentage as Harvoni. And I don't know how

much they cost because you have to have Daklinza, sofosbuvir, plus Ribavirin.

DR. BORGERT: Right, right, right.

DR. SAENZ: So the three. And I think you still need to do it for 24 weeks.

DR. BORGERT: Right. So I guess the question would be --

DR. SAENZ: Like for cirrhosis maybe most cost effective maybe to use Harvoni --

DR. BORGERT: Right.

DR. SAENZ: If they have cirrhosis because there may be the same chance.

DR. BORGERT: Right. I mean, obviously we only had one approval and three denials for Daklinza. Obviously this was approved later in year and this is year to date data. But, yeah, we can look at that in terms of, you know, cirrhotic versus non-cirrhotic, and what's the optimal regimen.

DR. SAENZ: And the other question I have is like now we're going to get some of -- very unlikely, but there's like very likely that people are going to get reinfected. You know, so if I look at the FDA guidelines, I think they never said this is used for

infection. So how do we handle -- I guess, in a case by case basis. How do we handle an appeal like that? How do we handle a patient that -- very few, but it's a little money.

DR. BORGERT: Currently I believe the State still has the once in a lifetime --

DR. ALLEN: Yeah. Criteria is once in a lifetime.

DR. BORGERT: -- on the therapy. I don't know that that will always remain there, but at this time that's still the situation. I have not heard of any request that we've had for retreatment but -- we've had some requests for retreatment for patients who haven't achieved an SVR, but not patients who achieved an SVR and then were reinfected. I haven't heard of that situation coming up yet. But you're right, it will eventually come up.

DR. SAENZ: It will come. But the data is showing that it's less likely for there's that -- they say it's as high as 1 to 10 percent that they may -- very unlikely, but it may happen.

DR. ALLEN: One additional question. I

also notice that there were some Peg-Intron and Ribavirin claims.

DR. BORGERT: Right.

DR. ALLEN: And I guess my question is, I guess now with the new generation Hep C agents, I really couldn't imagine a provider utilizing those agents. Are those old claims prior to the PA going into place or --

DR. BORGERT: Yeah. The date range was year to date for 2015.

DR. ALLEN: So those will just adjudicate it down.

DR. BORGERT: Yeah. I mean, the Ribavirin we'll probably continue to see because we use that still in combination --

DR. ALLEN: Sure.

DR. BORGERT: -- with several other recommended regimens. Ribavirin is still recommended. But the Peg-Intron I think will fall away to almost nothing.

DR. ALLEN: Okay.

DR. BORGERT: All right. Well, we are on to our new business section. And sometimes we take a break here, but it's only 8:45, so do you want plow on? Do you want to go on?

THE CHAIRPERSON: You want to take a break -- a 10-minute break and then we'll reconvene?

DR. BORGERT: It's up to you guys.

THE CHAIRPERSON: Yeah, we'll take a break. 10 minutes and then we'll start again at 9:00 -- or 8:50 -- 8:55.

(WHEREUPON, a brief recess was taken.)

THE CHAIRPERSON: Good morning, everyone. I'd like to reconvene the Drug Utilization Review Broad. It's 8:56. And Ms. Rebecca again.

DR. BORGERT: Okay. Just a couple things that we followed up on in the break that wanted to clarify for the minutes. We do actually -- Dr. Allen, pointed out that on the summary of limitations we do have quantity limits on products like hydrocodone A pap, we have a tablet per day limit on those things already. So those are on the summary of limitations. So we had talked about that.

THE CHAIRPERSON: So how many are the tablet limits?

DR. BORGERT: Does Dr. Allen or Susan do

you have them pulled up?

DR. ALLEN: Sure. I have them up.

THE CHAIRPERSON: I didn't think we had that. I thought we had the maximum number of scripts per month, but I don't remember tablet --

DR. BORGERT: It might be a fairly new edit in that I think the MCOs encourage that when they, you know, sort of think it's going to --

DR. ROMAY: Yeah. I think we suggested that we have a cumulative edit that takes all -- if a person is on several formations with the Tylenol, it will look cumulative and then after that it will reject it.

DR. BORGERT: Right. And that's the edit that went in in November though that I was referring to. But I think also in addition to that there are individual product tablet limits and that's what Susan is going to look it up right now and is going to tell us.

DR. WILLIAMS: For instance, Vicodin we have eight tablets per day for the 5/300. For the 7.5 we have six tablets. For Vicodin HP we have six a day. So we have them on

various products on our summary of limitations and you can find them on our website.

THE CHAIRPERSON: So for the Vicodin 5 we have the 5/300 you have eight per day? Is that what you said?

DR. WILLIAMS: It was eight per day, yes.

THE CHAIRPERSON: And the one for the 5/325 also I believe?

DR. WILLIAMS: For which one?

THE CHAIRPERSON: The hydrocodone again.

DR. WILLIAMS: The hydrocodone 7.5?

THE CHAIRPERSON: 7.5.

DR. WILLIAMS: Six per day. And the 10 milligram is six per day also. Was there another one you were interested in that I can see if we have it?

THE CHAIRPERSON: No. I didn't realize we had those edits in place already. Thank you.

DR. ALLEN: Right. And it's also the same for Percocet as well. It's also the same for Percocet as well, they have limits on them as well, yeah.

THE CHAIRPERSON: Aspirin-related products?

DR. ALLEN: Yes.

THE CHAIRPERSON: Any other limits we have? Do we have any on --

DR. BORGERT: On like single opioid agents? Is that what you mean?

THE CHAIRPERSON: Uh-huh. For the short-acting or intermediate-acting.

DR. BORGERT: Oxycodone would be the most likely one.

DR. WILLIAMS: Which one?

DR. BORGERT: Just single agent oxycodone.

THE CHAIRPERSON: And tramadol.

DR. WILLIAMS: Yeah, we have it on tramadol.

DR. BORGERT: We definitely have it on tramadol.

THE CHAIRPERSON: How many per day on the tramadol to 400 milligrams per day?

DR. WILLIAMS: On the oxy IR we have 12 tablets per day.

THE CHAIRPERSON: Is that per package insert or is that for all doses or for --

DR. WILLIAMS: That is for 5 milligram it's 12 tablet per day. For the 7.5

milligrams it's eight tablets per day. For the 10, 15, and 30 milligrams it's six tablets per day. And for the 20 milligrams it's nine tablets per day.

THE CHAIRPERSON: Thank you.

DR. WILLIAMS: And then the tramadol.

DR. ALLEN: One per day.

DR. WILLIAMS: One per day. I'm sorry.

THE CHAIRPERSON: How many again?

DR. WILLIAMS: One per day for the tramadol. That's the extended release.

THE CHAIRPERSON: Oh, extended. But the short-acting?

DR. WILLIAMS: Eight per day.

THE CHAIRPERSON: And the 50 milligram dosage?

DR. WILLIAMS: That is eight per day.

THE CHAIRPERSON: And these edits went into place --

DR. BORGERT: I can't tell you exactly when the individual product limits went into the place. They've sort have been put in over time. Some of them I think have been in for quite a long time. The one that was the most recent is the one that Dr. Romay was

talking about with the cumulative across different product lines. If you were getting, you know, prn hydrocodone; prn oxycodone, you know, Percocet, Vicodin, cumulative.

THE CHAIRPERSON: So if the recipient had to exceed this dose there would be a prior authorization?

DR. WILLIAMS: Right.

DR. ALLEN: Correct.

THE CHAIRPERSON: And have we looked at data on this? Because we looked at morphine total. Have we looked at --

DR. WILLIAMS: The short-acting?

THE CHAIRPERSON: Yeah.

DR. WILLIAMS: No, I don't think we've ever done that.

THE CHAIRPERSON: We haven't had an issue with that.

DR. BORGERT: Not that I'm aware, yeah. I think we kind of -- you know, I think that's what the quantity limits do for us is kind of try to keep that under control.

THE CHAIRPERSON: Okay. Very good. Thank you so much.

DR. WILLIAMS: No problem.

DR. BORGERT: And just for the minutes also just to note that Harvoni is not approved for Genotype 3 for -- FDA. It is recommended in the AASLD guidelines but it's not FDA approved for Genotype 3 for Harvoni.

THE CHAIRPERSON: Thank you, Rebecca, so much.

DR. BORGERT: All right. Moving on to new business. The first thing we usually do in new business is we look at upcoming P&T classes. And just see if there's anything that the DUR wants to have input with regard to that.

A class that's coming up in June for review is Mucolytics. There's really only two drugs in that class, acetylcysteine both as the 10 percent and 20 percent, and then Pulmozyme. And as you can see there, there's a huge cost factor associated with Pulmozyme. And, of course, it is only approved for -- the FDA indication is for Cystic Fibrosis, it is non-approved for other types of general Mucolytic therapy.

And so one thing that we might

potentially recommend to the P&T Committee was to create a very easy AutoPA that would look back for a diagnosis of Cystic Fibrosis to ensure that it was being limited to patients with Cystic Fibrosis.

THE CHAIRPERSON: Do you want us to vote on that?

DR. BORGERT: Yes.

THE CHAIRPERSON: So the motion would be to have --

DR. OLSON: Motion.

THE CHAIRPERSON: The motion is for easy PA for Cystic Fibrosis look back for a time period of --

DR. BORGERT: Well, I mean, typically with our diagnosis look back, I typically -- think we actually typically look back two years.

THE CHAIRPERSON: 24 months? Do we have a second.

DR. ROMAY: Yeah, second.

THE CHAIRPERSON: Any discussion. All those in favor signify by saying "aye"?

THE BOARD: Aye.

THE CHAIRPERSON: That's a unanimous

approval.

DR. BORGERT: That we can -- what's the word I want to say? Told to the P&T Committee. I forgot what I wanted to say.

Another class that will be reviewed in June are the Oral Glucocorticoids. And, again, here I think the thing that kind of jumps out at you a little bit is the Budesonide EC in 3 milligram capsules. So look a little bit more closely, we broke down the utilization.

And just as a background, the indication for that product is mild to moderate Crohn's Disease. And the way it's dosed it is a 3 milligram capsule. And the way it's dosed is patients take 9 milligrams once daily for up to eight weeks. And then they can repeat that eight-week course if they have recurring episodes for active disease. And so that's the active disease dosing regimen.

And then maintenance of clinical remission. So, you know, with steroids or however they've achieved remission, for maintenance of clinical remission the dosing is 6 milligrams once daily for up to three

months.

And the important part here is that continued treatment with Budesonide EC tablets for more than three months has not been shown to provide a substantial clinical benefit. There was actually a trial that looked at this in patients who were on -- who continued on therapy did not receive any additional clinical benefit. So that's where that recommendation comes from.

So we pulled the data and there were 46 recipients of this product from September through November of this past year. And so -- obviously that's only three months, so we expanded it to a six-month time frame to look at those 46 recipients claims. And there were on only six of those patients who did receive more than three consecutive months of therapy.

So it doesn't seem to be a huge problem. But we thought, you know, maybe one thing we would do is -- since it's just six patients, is maybe letter those prescribers regarding, you know, these guidelines and the study that supports that data and that sort of thing.

So that's what we looked at with Budesonide EC. Because, you know, initially we talked about maybe doing a length of therapy edit of three months. But when we looked at, you know, what was actually going on, at least in Fee-for-service, it was a very small number of recipients who were being prescribed outside of what's recommended. So probably not worth, you know, creating a whole edit just for the small number of patients.

THE CHAIRPERSON: So you want to vote on the letter or --

DR. BORGERT: Sure. I mean, actually we can write the letter and bring that back for the next time so you don't have to vote on it, because you'll be voting on the letter at the next meeting.

THE CHAIRPERSON: Is there an age cutoff for this? I'm not quite familiar with it because I don't use it for -- so a letter is fine.

DR. BORGERT: Okay. Like I said, when we initially started going down this path, we were thinking we would do an edit, but we

just saw that it was so few. Now, if the MCOs are seeing something different in their data set, then, you know, we might reconsider it, but that is what we saw in Fee-for-service.

DR. MARTORANA: And I guess going back to my original question is, what are the numbers that we're dealing with as the Fee-for-service numbers continue to come down, this is not really indicative of what we're seeing out there --

DR. BORGERT: Right.

DR. MARTORANA: -- in the market place because there's, you know, another million and a half --

DR. BORGERT: Right.

DR. MARTORANA: -- recipients out of the managed care arena. So we maybe have to look at is there something that we're going to have to do to bridge, or when we're bringing these classes to maybe have a template to have the MCOs bring some of their utilization --

DR. BORGERT: That would really -- yeah, that would be --

DR. MARTORANA: -- of those products so that we get a better picture --

DR. BORGERT: Right, right. I mean, we have --

DR. MARTORANA: -- of what's happening across the state.

DR. BORGERT: -- encounter data, but --

DR. MARTORANA: It's tough to sort that out.

DR. BORGERT: Right. Exactly. Yeah. I mean, that's another thing we can do -- not to give you all homework, but, you know, if you guys wan to go back to your plans and those of you that are affiliated with MCOs and look at your utilization and then you can bring that feedback back to the next meeting. And then we can certainly say if you guys are seeing that it is a problem, we could reconsider an edit.

MS. ELLIOTT: Just to piggyback on that, for the next P&T Meeting we have been requested to run data from the plans to -- for the next recommendations from now on is to include utilization from the plan. So we have our data analytics group already warned

that we're going to give them the Agency numbers and that we're going to include that utilization from the plans for the next future meetings.

DR. MARTORANA: Yeah. I think if we just -- both for P&T and DUR if we just have -- you know, if the request, then obviously with three months is probably ample time for the plans.

I mean, I don't think I'm speaking out of turn, but anyone can throw something at me if they think otherwise, that we very happily would -- you know. So we just need to go ahead and get that published. Say, "Okay, this is what we're looking for." And then everyone can kind of bring it in that same format so that we can compare apples to apples.

DR. BORGERT: Right. Exactly. I mean, I think this is all new territory for all of us. So we're trying to figure out what works best.

For the quarterly activities for this quarter. The first one was looking at metoclpramide dosing. And specifically

focusing on the risk of Tardive Dyskinesia. Metoclopramide does have a black box warning that it can cause Tardive Dyskinesia. The risk of developing Tardive Dyskinesia increase with the duration of therapy and the total cumulative dose.

And specifically in the black box warning they say that treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risk of developing Tardive Dyskinesia.

So since this is associated with both high dose and duration therapy, we decided to look at both dose and duration of therapy. And it appears that we're not having a big problem with patients receiving high doses. Only 16 adult recipients and two pediatric recipients who exceeded the recommended dose -- or we did have 255 recipients who got more than 12 weeks of therapy.

So, you know, we went from July -- so July, August, September, October. So we looked at four months worth of -- and there were -- 255 in that four months who got more

than 12 weeks of therapy. So it was a pretty substantial number.

So I think maybe the recommendation here would be to implement, you know, a 12-week or 84-day continuous supply maximum duration of therapy and then require a prior auth once they exceed that just for safety purposes based on the black box warning.

DR. ZITTELLO: Did you look at diagnosis at all?

DR. BORGERT: We did not. We did not. Are you thinking about like --

THE CHAIRPERSON: Gastroparesis.

DR. ZITTELLO: Exactly.

THE CHAIRPERSON: Because sometimes we may have to. So I would exclude -- consider --

DR. BORGERT: You want to go back and look at it and exclude the gastroparesis?

THE CHAIRPERSON: Yeah. I think so.

DR. BORGERT: Okay.

THE CHAIRPERSON: You know, I think --

DR. BORGERT: Because those patients are on continuous never ending therapy.

THE CHAIRPERSON: At the lowest possible

dose --

DR. BORGERT: Right.

THE CHAIRPERSON: -- while monitoring. I think we sent out a banner message a while back.

DR. BORGERT: Again, it must have been before my time.

THE CHAIRPERSON: Yes, we did. Because it was a concern then.

DR. BORGERT: Okay. I will go back and I will exclude those patients and then I will bring that information back.

THE CHAIRPERSON: And then we'll look at creating an edit then?

DR. BORGERT: Yeah. Right.

THE CHAIRPERSON: Because I think it is a good idea, definitely. Do you want to vote on that also or --

DR. BORGERT: I mean, since we're going to have to follow-up next time, I don't think we really need to take a vote right now because we're going to bring it back up next time.

THE CHAIRPERSON: Very good.

DR. BORGERT: The next thing that the

Board expressed an interest in -- and I think this was good that the Board brought this to our attention -- was about the brand preferred. And specifically we decided to look at Pulmicort Respules.

And so just for background so that we're all understanding about the generic drug life cycle. In certain cases -- and it depends what the FDA awards. But they can award a generic manufacture a 180-day exclusivity for their generic product. It's basically there to incentivize generic companies to challenge weak patents or whatever and to reward them for doing so.

So sometimes when a generic comes on the market there's only one. And when it comes on the market, it's typically -- that first generic is typically priced at about 90 percent of brand. Basically pretty -- I think legally it can't be more than 90 percent, so it is 90 percent. All right. So it's at 90 percent of the brand name.

And so if they have -- especially if they have that 180 days exclusivity, it's at least six months before more players come into the

market. And in those situations it generally takes about a year for the price of the generic to drop. So that's the market forces that are in play there.

And with Medicaid, based on the federal rebate and supplemental rebate, oftentimes the brand product is still net-net cheaper to the State then the generic product. Based on the rebate contracts. Federal and supplemental rebates that the State is collecting back, because, again, those generics are priced almost as much as the brand name and the rebates aren't in place.

So that's what creates this dynamic of why the State brand prefer things at a certain time. So the Committee was concerned that patients -- you know, (a) that lots of calls were coming back into the practitioners, so it was, you know, a workload issue in terms of the pharmacist having to call the prescribers. And ultimately the concern was that patients weren't just getting their meds. Because it would reach out to the pharmacy and they would just leave.

So for this particular product multiple generics only become available about mid-2015 and there are currently three generic manufacturers of Pulmicort or generic budesonide inhalation on the market. And currently the net-net cost still is lower for the branded Pulmicort Respules than for the generic.

The class review of this class is due in the March P&T meeting, so it's possible that it will switch at that time. It might switch from brand preferred to generic at that time. But I can't see in the future, so I don't know if that will happen or not.

Arlene, do you have a comment?

MS. ELLIOTT: Just to clarify. The meeting is in April. It's April 1st.

DR. BORGERT: I'm sorry, I keep saying that. She tells me, "Don't say March. Don't say March."

MS. ELLIOTT: P&T is April 1st and DUR is April 2nd. But just to clarify one point is we -- or Magellan -- Celemonzel (phonetic) rebate factor, which used to be provider Synergis, you're familiar with that name

better. They give us an update every month when it's time to switch.

So, for example, if Pulmicort was to be the generic cheaper in June, we would be able to switch it before, you know, the next P&T or whatever. So every month they give us a list of it's time to switch or not.

THE CHAIRPERSON: It happened also for nimodipine and valsartan a while back. And the claims were being denied at the pharmacy because it went brand one month and it went generic. Same situation again. So I think -- I'm not sure if it's the providers that need the letter. I think it's the pharmacists, because they'll enter the data there and it stops it at the point of sale.

DR. BORGERT: Right. And so we looked at it and you guys were right. We looked at there were -- we looked at denied nebulizer suspension for inhalation claims. We had 2,000 claims in a three-month period for 1700 recipients, and only 841 of those subsequently had a paid claim for Pulmicort Respules within a seven-day period. So we think some more of them might have gotten it

farther on down the road. But we wanted to look at, you know, a time in a period of time. So we looked at seven days.

And that played, you know, half or less received the Pulmicort suspended. So I think that's true that what is happening is that claims are being denied at the pharmacy and then the patients just aren't receiving the drug.

So based on this data -- and I don't want to get into the nuts and bolts of coding because that's not the role of this Committee. But we have some limitations because of other legislatively required messaging that has to go back to the pharmacies. We had some limitations because I mean the thing -- the easy solution would be to say to the pharmacy dispense -- you know, reprocess or dispense brand name Pulmicort. Because if the pharmacy saw that message, then that would be fine.

We've had some challenges with that just based on other requirements that we have. But we did sit down and put our heads together and we think we've come up with a

solution. I won't get into the nitty-gritty of the solution by using a State class code. But we're going to try to implement a solution for this that we think will work, that we think will get the message to pharmacies at that exact time so that they will know what they need to do.

And so what we'll do is we'll work on implementing that solution and then we'll go back -- you know, if Pulmicort Respules have become preferred by that time, then we'll pick a different, you know, brand preferred, and we'll go back and we'll measure -- try to measure if this new solution that we're still in the works, still being vetted, will solve this problem basically.

THE CHAIRPERSON: Logistically is it possible -- I'm not quite sure about the logistics behind this -- but for the electronic prescribing system for people that are using electronic health records, will that alert the prescriber at that point also? Can that also be done, or is that beyond the --

DR. BORGERT: Yeah. The solution --

THE CHAIRPERSON: -- capability? I know you have preferred drugs. Sometimes in my prescribing it says "preferred." I'm not sure if it's up to date, but it will give me my preferred on the patient's profile based on their plan.

DR. OLSON: How is this handled in Prev -- the same issue was Prevacid a few years ago, how did we handle that? I mean, that didn't seem to be an issue at that time of the denied claims. Brand Prevacid was --

MS. ELLIOTT: Was it preferred?

DR. OLSON: -- rebated, so -- yeah, preferred.

MS. ELLIOTT: What we did -- and I don't know if this will answer your question because I don't know if this is what really resolved it. But we did have both, brand and generic, paid for like maybe two, three months, either one. But an alert was sent like four months in advance to allow pharmacists to get used to buying the generic so -- and then they could use their brand that was in stock.

So that was -- because we had

30-something thousand patients on prevacid. I don't know if this is as many patients. But that was a big one. And that we never had -- because we overlapped the coding, you know, the reimbursement, that was not an issue after they switched. So it was a well thought process because it was so big.

DR. BORGERT: We also do big letter campaigns for every single drug that we do this for. I'm not sure -- you know, we might be on information overload it we tried to. But, like I said, we do -- we have a solution that we think is going to work and we're in the process of sort of working through that process.

And then we will go back and if at that branded Pulmicort Respules are still preferred, we will do a post impact analysis once we get that solution implemented and we'll see if we've improved this number here.

DR. ZITTELLO: I appreciate you coming back to the Committee with that information.

DR. BORGERT: Sure.

DR. ZITTELLO: And hopefully it help a lot of kids in the state of Florida.

DR. BORGERT: Right.

DR. SAENZ: I have a question and I talked to Kevin about it. You know there is going to be a new class of drugs called Biosimilars.

DR. BORGERT: Right.

DR. SAENZ: So how is the Agency going to handle -- I guess based on the price, you know, because it's going to be an in between price, between the brand and the generics. Generics are now becoming expensive, they're not as cheap anymore.

DR. BORGERT: Yeah. We could spend hours talking about drug pricing issues. But there actually is already one Biosimilar on the market, Zarxio, the generic filgrastim, Biosimilar filgrastim. And that actually was looked at by P&T yesterday because the Colony Stimulating Factors were one of the classes that were looked at yesterday.

DR. SAENZ: And what happened?

DR. BORGERT: And based on pricing, Neupogen is still the more favorable for the State. So I think we're going to handle it just like any other generics on this market

because Zarxio was talked about at P&T yesterday.

MS. ELLIOTT: But to clarify on that, Zarxio as of now the ACA, you know, the Affordable Care Act, we are not -- the pharmacists are not allowed to substitute.

So if you get a prescription for Neupogen, you have to dispense Neupogen. If you get one for Zarxio, you have to -- so they are all -- even the Zarxio is still more expensive, they're all PA. So they'll have ClinicalPA.

So if we get a prescription for Zarxio, we would have to -- the reviewers would have to look at the criteria and approve it or not, depending, you know, if they meet criteria. But they could not tell them, "No, dispense Neupogen." At this point they cannot do that.

DR. BORGERT: Yeah. And just to expand a little bit more one that, not to get too far off on a tangent. It kind of depends on the way the FDA approves it. If they approve that they are interchangeable -- because they have the option to approve Biosimilars as

interchangeable, Zarxio is not approved as interchangeable. I think not because it's not interchangeable, but just because they weren't ready to go there yet, and they're still, you know, working through all their process.

But, you know, how the FDA designates it, if they designate it as interchangeable or not. And all of the individual states are looking at this legislatively as substitution. You know, what could be substituted and what can't.

So, yeah, we're still kind of in the process of figuring all that out. But that's what happened with Zarxio yesterday.

MS. ELLIOTT: And one more thing, if I may add for Dr. Hayden's comment about the electronic prescribing. That's a different vendor, that's not the Agency, but they have our PDL, so -- you know. And the other PDLs also from the other plans.

THE CHAIRPERSON: It gets updated elec -

MS. ELLIOTT: Yes. When we update the PDL, the electronic vendor will update it.

THE CHAIRPERSON: I see it come up.

MS. ELLIOTT: Yes.

THE CHAIRPERSON: Sometimes I see patients every 90 days and then the prescription is already written. So then the concern is bridging that change in the PDL to the patient's timing of the prescription.

DR. SAENZ: It's basically your vendor for the EMR also. So like if it's cloud-based, it would do it. But if it's like an EMR that's not cloud-based, sometimes there might be a delay of a week, a month. It depends when they update that. It's not automatically, sometimes there's a delay. And it has nothing to do with them, it's just the vendor that your company is using for the EMR.

THE CHAIRPERSON: That would be interesting. Thank you. Thank you.

DR. BORGERT: So we'll continue to keep you guys abreast of what's going on with this.

As I mentioned at the top of the meeting, the P&T Committee that met in November specifically asked the DUR Board to look at maximum daily dose limits of Celebrex based

on the available efficacy and safety data.

And their concern was that the current quantity limit that we had on Celebrex was two capsules per day. And Celebrex is available at 50, 100, 200, and 400. So since there was a two capsule per day limit, that would in essence allow people to get 800 milligrams of Celebrex a day. So that was the concern.

So we went back and looked at it. And those are the currently approved FDA indications for celecoxib; osteoarthritis, rheumatoid arthritis, JRA, and spondylitis, acute pain, and primary dysmenorrhea.

I think what has happened here is that the current approved FDA dosing ranges from 100 milligrams per day up to 200 milligrams a day. So the current approved indications their recommended dose is anywhere from 100 milligrams a day to 400 milligrams a day.

And the history of that in December of 1999 it was actually approved as adjuvant treatment of familial adenomatous polyposis, FAP, at a dose of 200 milligrams BID or 400 milligrams BID.

And then, 12 years later, the FDA actually came back and rescinded the approval of celecoxib for FAP based on two long term safety studies which revealed an increased incidents of cardiovascular events in patients on long-term celecoxib as compared to placebo.

So at that time the FDA determined that the risks outweighed the benefits for patients with FAP.

And there is no currently FDA approved indication for celecoxib at 800 milligrams a day. So we would recommend implementing the 400 milligram per day maximum daily dose.

And P&T just didn't have time to dig into all these details. You know, that's why they refer this type of thing to the DUR Board so we can look at it more closely and say, "Well, you know, why is this?" So that's why.

It seems a little bit straightforward but, you know, that's why P&T referred it to us because they were like, "Well, we think that, you know, the risks are higher with higher doses and we're allowing patients to

get 800 milligrams a day, so let's refer that to DUR and see what they want to do with it."

THE CHAIRPERSON: So there are three exceptions there. So the impact would be --

DR. BORGERT: I'm sorry?

THE CHAIRPERSON: On the data that's presented in our -- I have three.

DR. BORGERT: Okay. I didn't even realize I had put that in the quarterly report. So there weren't -- the bottom line is there weren't many patients who were receiving that, so thankfully, but there were a few. So probably the thing to do at this point, since there are no FDA approved indications for 800 milligrams a day, is to put a limit -- change that two capsule per day limit to a 400 milligram per day limit.

THE CHAIRPERSON: So do you want to put an edit in place?

DR. BORGERT: Yeah. Change the edit from two capsules per day of any dose of celecoxib to a maximum of 400 milligrams of celecoxib.

THE CHAIRPERSON: So we'll make a motion for that?

DR. BORGERT: Correct.

DR. MARTORANA: So moved.

THE CHAIRPERSON: Second.

DR. ZITTELLO: Second.

DR. SAENZ: Second.

THE CHAIRPERSON: Any other -- the other interesting thing is for these drugs are, you know, the guidelines and the FDA indications and dosing changes, we probably should look at all that in our --

DR. BORGERT: Yeah. There's a lot of that stuff that comes through. We get like --

THE CHAIRPERSON: There's a lot.

DR. BORGERT: At Magellan we do a weekly summary of basically all those type of FDA updates and that sort of thing. But I can -- so I get that report every week so I can look at that more closely and see if there are things that probably should come to DUR. I haven't really looked at that report with the thought of DUR in mind, so I can try to do that.

THE CHAIRPERSON: And also other drugs on our preferred drug list if there are high outside of those limits. I'm not sure

if we can look at that and bring it back. I mean, just for safety, I mean that is the purpose of this Committee.

DR. BORGERT: Right.

THE CHAIRPERSON: And when drugs are added to our PDL if there are limits on dosage, I'm not sure if there's an edit. I mean, do you look at that in terms of --

DR. BORGERT: Yeah. It's probably sort of on a case by case basis. You know, like when new drugs are added. When we're going about programing to be preferred, you know.

THE CHAIRPERSON: When we looked at HIV drugs I mean in terms of contraindications with certain things, I mean, we had those edits in place. But as new agents come out and drug to drug interactions.

DR. BORGERT: Right, right.

THE CHAIRPERSON: Okay. So that's unanimous.

DR. BORGERT: The next few items that we're going to look at are really just more -- as opposed to analysis, are just more data that the Committee requested at the last meeting to be brought.

So one of the things that the Committee asked -- or the DUR Board asked about was Daraprim utilization. And I think we're all familiar with the story, but just as a recap, on August 11th of this past year the manufacturer of -- the only manufacturer of Daraprim increased the price of 25 milligram tablet from $13.55 a tablet to $750 a tablet. That's based on wholesale acquisition. So that happened in August.

On October 8th, so you know, pretty much as fast as we can move as a governmental agency, we did implement a ClinicalPA program for Daraprim, instead of -- because before you could get it, anybody could get it.

And can see there the dramatic increase in spend that happened with Daraprim. We went from spending $21,548 for 15 recipients to less than half of the same number of recipients cost us $335,574.

And, you know, there was some pressure on the manufacturer at the beginning, and they had stated that they were going to re-evaluate the price. They have since stated they are not going to change the

price. So $750 a tablet is here to stay.

There are some -- I will tell you that some PBMs, some large PBMs in the country are looking at compounding pharmacies who are compounding this in combination with Leucovorin. And some of the PBMs in the country are going that route in getting the compounding product from a pharmacy I think in California who is offering it as opposed to, you know, going with this scenario.

DR. ALLEN: Question.

DR. BORGERT: Yes.

DR. ALLEN: So this story, to your point, was sensationalized. I mean, I think everyone knew about it. But is there any way that the Committee can be notified in the event that there's subtle price increases? So every manufacturer is probably going to increase their drug, you know, to some extent, you know, at the end of the year.

But for things that are anomalies, for example, doxycycline on the generic side, that was one. You know, I don't know. If we just pick a number and just say, "Hey, if a drug increased by 50 percent," or something

of that nature, can we just be notified so we could, you know, keep an eye with it?

DR. BORGERT: The thing about that and -- yes. The answer is yes. But we actually at Magellan -- since this kind of has starting to be -- we have a process where we actually get a weekly report of generic price increases that have increased more than -- there's a cutoff. I think it's 10 percent or something.

But what typically happens is there's multiple NDCs for generics, and only some of the manufacturers have increased their price dramatically. But there are still other NDCs on the market that haven't increased so dramatically. And so we look at what percent of our utilization was the product that -- product increase and spend a lot or the others to know whether or not we need to take some action.

So I think the thing that made this situation so unique was there was only one manufacturer. But I agree that we can -- because we are already doing it. We're already monitor -- Magellan's already

monitoring that in terms of across the board if there is very few manufacturers or if all the manufacturers of a product or both, let's say. Most manufacturers have had a similar increase, then that would be something that we could bring. Would that be okay?

DR. ALLEN: Yeah. I think that would be great.

DR. BORGERT: Because I think there a lot that do have these dramatic price increases, but in most cases what we're finding is that there are other manufacturers, other NDCs that are available that haven't increased their price. So as an aggregate the price of that drug hasn't bumped up so much.

Dr. Olson, were you going to say something? Okay. So I will -- I took down that 50 percent and I will make a note about that and we'll bring that back if we find that. Okay.

The Committee also asked us to look at top therapeutic classes by claims count and by total spend. And so, again, this is Fee-for-service. I think it's probably -- the numbers are probably different, but I

think overall similar in terms of placement with claims count; anticonvulsants, antipsychotics, narcotic analgesics, SSRIs, beta-androgenics, NSAIDs, Penicillins, anti-anxiety, and second generation antihistamines.

So the Committee hasn't done a lot with anticonvulsants, but certainly we've done a lot with antipsychotics, and certainly we've done a lot with narcotic analgesics. But in terms of number -- just sheer number of claims, this is what the top ten basically looks like.

THE CHAIRPERSON: Do we have any edits in place for maximum daily dosage of anticonvulsants? Have we looked at that data --

DR. BORGERT: Susan -- I don't know.

THE CHAIRPERSON: -- for package inserts, can we do that?

DR. BORGERT: Not off the top of my head if we have a limitation on anticonvulsants. I don't know. Let's pick one.

DR. WILLIAMS: Yes, we do.

THE CHAIRPERSON: Can you talk into the

mic?

DR. ALLEN: Yeah. We have one Lamictal. I don't know if it's across the board. But there's a few on fee.

DR. BORGERT: We can look at that. I mean, we can look at PDL preferred anticonvulsants and we can look at all of them and see --

THE CHAIRPERSON: Maximum daily dosage.

DR. BORGERT: -- how many of them have maximum daily dosages on them. We can do that, yeah.

DR. ZITTELLO: I'd also be curious to the diagnoses here.

THE CHAIRPERSON: Yeah. Because we use it for neuropathic pain.

DR. BORGERT: Right. Progesic is used for, you know, all different kind of psychiatric.

THE CHAIRPERSON: Migraines. We use it a lot of them.

DR. BORGERT: So it is hard to them pin down how many of them have --

DR. ZITTELLO: And they might be on it for long term and it might not make any

difference and things like that.

DR. BORGERT: So maybe look at how many of them we can actually find a diagnosis of epilepsy on file for, or just look at what the diagnosis is.

THE CHAIRPERSON: I'm not even sure if it would make -- I mean, just look at what -- those are important things. I mean, we use anticonvulsants. But I think it's -- I mean, in terms of protecting the safety making sure that the maximum daily dose doesn't exceed the number that it's indicated for, package inserting. I think that would be -- because we have so many uses of anticonvulsants.

So bring back the data on the multiple uses is one thing, but I think it's the safety issue and poly -- I don't know if we can do polypharmacy or a drug -- you know, the paid for interactions, that's rejected at the point of sale. We had an edit in there at one point on that.

Any other ideas?

DR. ROMAY: Currently anticonvulsants are on AutoPA, correct, so it looks back for a diagnosis?

DR. BORGERT: That's correct. For the branded products. The generics I think they go through --

THE CHAIRPERSON: They're preferred.

DR. BORGERT: Yeah, they're preferred and they go through the AutoPA.

DR. ROMAY: Because I mean I'm concerned like topiramate, for example, that's being used for obesity, for weight loss. So that would be something to look at to see if those people are truly have the right diagnosis because we don't cover it.

THE CHAIRPERSON: Which drug was used --

DR. ROMAY: Topiramate, Topamax. Yeah, it's also in combination with another -- with phentermine as well. So, I mean, when it comes in like that, I mean obviously it doesn't get paid, but...

DR. BORGERT: I'm aware of that. So is there an edit on the combination of topiramate and phentermine?

DR. ROMAY: I'm not sure about that.

MS. ELLIOTT: Well, if the indication is weight-loss, it's not --

DR. BORGERT: Well, I don't think it's an

FDA approved indication. But I don't think we're looking for the -- I'm not aware if we looked at the combo, but...

THE CHAIRPERSON: I don't think it's mentioned on our preferred drug list.

DR. BORGERT: No, it's not. No, no, no.

THE CHAIRPERSON: But if they filled a claim, you could look at that. But it wouldn't have been filled --

DR. BORGERT: We wouldn't have.

THE CHAIRPERSON: -- so how can you do it?

DR. BORGERT: Yeah.

THE CHAIRPERSON: And then looking at the SSRIs, do we have maximum daily doses for adults as well? You knows we have --

DR. BORGERT: Yes. Yes, we did maximum daily doses of antidepressants for adults I think within the past calendar year we might have done that.

THE CHAIRPERSON: I think it was children.

DR. BORGERT: We've had children for a long time. But we did adults just this past year, uh-huh.

THE CHAIRPERSON: All right.

DR. BORGERT: And then the other way to look at the data is by total paid out. The antihemophiliac factors are not going to be an issue for the MCOs because those are carved out to Fee-for-service. But, again, you can see it kind of mirrors the number of claims in terms of anticonvulsants, antipsychotics. Insulins, which we're actively working on. Orally inhaled glucocorticoids. Attention deficit disorder drugs, which we we've worked a lot on in this Committee and has some new edits in place on those.

THE CHAIRPERSON: We don't use them. It's not approved for adults over -- Medicaid doesn't cover it for adults over 18?

DR. BORGERT: No. We do. We do. We just have -- but we did put in those maximum daily dose limits on the adults for the ADHD drugs. But we do cover it.

THE CHAIRPERSON: And then the last one is antineoplastic systemic enzyme inhibitors.

DR. BORGERT: I think that's like Gleevec type of thing in that -- for CNL.

THE CHAIRPERSON: We had an edit or a safety --

DR. BORGERT: Yeah. We have it across the board on all oral oncology -- anytime you have a new oral oncology agent that comes on -- I mean, they're not preferred, but we still put quantity limits on them based on the fact --

THE CHAIRPERSON: Yes.

DR. BORGERT: -- it's right when they hit the market.

THE CHAIRPERSON: Yeah, we did last year and it worked out fine.

DR. BORGERT: Yes. And we continually update that. We had like seven new oral oncology drugs in 2015, and we added all those to that edit.

THE CHAIRPERSON: And I don't see in terms of the HIV drugs in here.

DR. BORGERT: Yeah. Interestingly or not. I guess it's the era of generics. I don't know. More of the HIV drugs are available generically. So from a total cost standpoint, they're not --

DR. ROMAY: I'm curious to know about the

human growth factor, the human growth hormones, did that make the list, because that was -- I think that was -- last time it was up for review.

DR. BORGERT: It was up for review yesterday. No. When I'll pulled the data, it didn't show up. But I'll go back and look at where it falls.

DR. ROMAY: But I think that would probably make the list because that's their -- it's up for utilization.

THE CHAIRPERSON: Yeah. That had a prior auth on that.

DR. ROMAY: Well, it has an AutoPA on it just to check the diagnosis, but...

THE CHAIRPERSON: Right.

MS. ELLIOTT: Which --

DR. BORGERT: I'll pull it and I'll find out where it falls in the scheme.

MS. ELLIOTT: Yeah. Just to follow-up in P&T on the human growth hormone, it was voted to keep Genotropin and Saizen as preferred, but it's going to be a ClinicalPA for all.

DR. ROMAY: Okay.

MS. ELLIOTT: And -- are you going to

bring that up?

DR. BORGERT: Yeah. You're right. I skipped that. I somehow missed that on P&T review. They did -- P&T did request that DUR look specifically at idiopathic short stature syndrome. And it's really -- it's kind of going to be difficult because one of the preferred products has an FDA approved indication for that. And we're pretty much mandated to cover FDA approved indications, so if that's going to be a preferred product.

And the point that was made at P&T is well there are other drugs that are preferred and had an FDA approved indication that -- so, for instance, they mentioned, you know, like the PAH drugs, but we don't cover them for erectile disfunction.

So they were looking at -- you know, the question to the DUR -- that they wanted to bring to the DUR Board was, you know, is that -- is idiopathic short stature, does it fall sort of into that box? And, you know, it's sort of an Agency decision as well.

But, you know, I don't know, it's gray. I'm not even sure how we'll tackle it, but

I'm certainly open to thoughts and ideas of the DUR Board surrounding that issue.

DR. ROMAY: I mean, I think personally -- not personally. I think from a standpoint of, you know, making sure that that person has proper -- you know, initial work up for a growth hormone to see to make sure that they really do meet -- because a lot of little patients we have a short stature obviously fail their stimulation test.

I mean, they way are over the 10 mark. So we need to look to see to make sure that they didn't get an adequate follow up. Because I know for a fact a lot of members are just seeking these drugs for -- you know, because they want to be at a particular parental or maternal height. And obviously if that's not there genetically, really it's hard to kind of base the need for that member to use that drug.

So we just want to make sure that those people are adequately being -- they truly need the drug and they have -- and the idiopathic short stature that's something, as you say, is very gray. Because, you know,

you don't want to not give them therapy, but you also want to make sure what truly is happening. Is the IDF level, you know, really low? Is it really showing that they're are at -- you know, division at IDF.

DR. BORGERT: So what you're saying is that perhaps with putting a ClinicalPA on the class and really looking -- you know, having, you know, a pharmacist review those tests and that sort of thing that maybe will sort of take care of the problem. At least somewhat address the issue.

DR. MARTORANA: Right. Because we review a lot -- to Dr. Romay's comment that you get these requests and they come in. And genetically, you know, mom's 4'11", dad's 5'1", and their mid parental height is 5-foot, and they're on track to be 5'2", and all of a sudden you're getting a request for the growth hormone. You know, what are you trying to do? You know, it's obvious that the kid is genetically predisposed and unfortunately he's got short parents.

DR. ROMAY: And a lot of times they're growth velocity is going to be right there.

It's, you know, on track to get them where they're going to be. So even looking at their growth velocity and looking at their bone age to see to make sure that they really truly two standard deviations below the norm.

DR. BORGERT: Well, I think then it sounds to me like maybe what we should do here at the DUR Board is, we will bring back to you all the ClinicalPA data -- the specifics of the ClinicalPA that get designed. And then we will do a pre and post. And we'll look at the diagnosis mix, and we'll also just look at overall utilization and we'll kind of see what impact that had on it. So I think that's probably the way the DUR Board should go at this point.

MS. ELLIOTT: Yes. And this has been a topic on every single meeting that we've had with the plans, is the tightening of the criteria for the human growth hormones, specifically ISS. So we -- I told them yesterday that we're going to bring it to the Board, we're going to look at parameters so it's not going to be open access like it is

right now, or at least that's the goal.

DR. BORGERT: So we should have those parameters developed by the April meeting of the DUR Board and we'll bring that back for the DUR Board to review and comment on.

THE CHAIRPERSON: Good.

DR. BORGERT: Any other comments about the topic of classes?

THE CHAIRPERSON: I think we streamlined everything.

DR. BORGERT: We're going to revisit growth hormone. Okay.

Another question that was asked the last time was about the PCSK-9 inhibitors, Praluent and Repatha. So my hyperlink is not working. You know why? Because I'm not on the Internet.

THE CHAIRPERSON: The package insert has parameters in place for most of these drugs.

DR. BORGERT: Right, right. So in -- to cut to the chase, we really have had very little uptake with these medications I think is really what the Committee was interested in asking.

We've had zero inquiries regarding

Praluent. And we have had, you know, a total of seven inquiries regarding Repatha. None of which -- none were approve and two were denied. So I don't know if the MCOs are seeing some of sort of the same thing, but that's what we're seeing in Fee-for-service is little uptake.

DR. ROMAY: I just want to go back. I don't know if we can go back, but looking to the oral oncology I mentioned that these are up and coming -- the updates?

DR. BORGERT: Correct.

DR. ROMAY: Are you looking to update also continuation of therapy criteria? Because there are, you know, some parameters that we do feel that the members should be hitting to make sure that the drug is really actually working, that there's no progression of disease. So looking at markers -- not really markers, but looking at, you know PD-1 analysis for different types of drugs, especially for the Opdivo and things like that. I know Opdivo is a medical benefit, but there's other drugs out there as well that have -- you know, looking at those

particular parameters to make sure that those drugs are actually really working?

DR. BORGERT: I'm trying to think of an example, because actually I'm board certified in oncology, so that's kind of my wheelhouse. I'm trying to think of an example of --

DR. ROMAY: Like for instance it's the -- like the Revlimids and things like that that you're looking for particular, you know, molecular remission.

DR. BORGERT: Right, right, right. Yeah. I think we do have that for the most part in our continuation of therapy criteria. Again, like I said, we do get a list of all FDA changes every week. So if there is some change in, you know, the recommendation, we will -- we do update criteria and address that.

I have to go back and look at it across the board. But off the top of my head I can't really think -- I mean, a lot of the drugs are -- you know, you look at the biomarker up front before you put them on. You know, whatever, there's several of them. You know, whether it's a EGFR or -- all the

TPIs basically that you look for that.

And, you know, now there's several new -- like if you failed Revlimid and now there's two other alternatives. So, you know, looking for that factor up front. But in terms of continuation of therapy --

DR. ROMAY: So it we would be running kind of restaging to make sure that there's a continuous progression up towards becoming, you know, in remission or destroying some kind of -- because we don't want to -- these drugs are very expensive to be put on. And at lot of times if there's resistance, members don't respond and they have to changed to another agent.

So where do you kind of make sure that the patient is really truly on continuation? Because the least we want to do is not approve it, obviously we want to make sure that that person gets clinically -- you know, clinically stable.

THE CHAIRPERSON: So the prior authorization, is that done annually with the submission of data by the oncologist or --

DR. BORGERT: Typically the length of

approval varies between three and six months for oral oncology agents and then they have to resubmit for a --

DR. ROMAY: And that's how we do it. We do it on a three to six month basis just to make sure that there is that response.

DR. BORGERT: Right.

DR. ROMAY: But where there's really no continuation of therapy criteria to go by and we're just looking on submission, there's really -- some of them do, but not all of them do.

DR. BORGERT: Right, right. You know, I think maybe the other maybe catch 22 you could run into there is, patients who are terminal or, you know, have an incurable disease a lot of times they will continue on therapy just until they have clinical progression.

You know, they're not scanning these patients all the time, they're not doing all that sort of stuff because -- I mean, what's the point, really. There's nothing more to offer them and they have an incurable disease, so they're basically just going to

continue on the drug until, you know, it's obvious that they have clinical symptoms of progression, so... I don't know.

But I can go back and look at that and see if there's anything that we need to tighten up there. And maybe we can talk up on some other specific examples --

DR. ROMAY: Sure.

DR. BORGERT: -- that we can take a look at.

DR. ROMAY: Sure.

THE CHAIRPERSON: Very good. And as far as the question for -- on this request for the PCSK-9 inhibitors, we don't have a prior auth -- I mean, it says here "prior auth request." I mean --

DR. BORGERT: We have prior auth criteria established. And I'm sorry, I forgot to get online so that my hyperlinks would work. I had a hyperlink to the ACHA website, but I forgot that I needed to get online to access that. So I'm sorry about that.

DR. MARTORANA: That is probably one we want to bring in. I mean, there's care numbers on requests, denials, and approvals

and we are starting to see some pressure from that.

DR. BORGERT: And, you know, basically the same type of thing with CF therapies which the Committee asked about, both which is Kalydeco and Orkambi. And, again, my hyperlinks, I'm sorry. I was going to show you the specific criteria.

But for those of you who aren't familiar with these medications, these are CF patients who have a specific mutation that has to be identified in order to qualify to receive these therapies. Like I know with Orkambi it's the 508 -- they have to have homozygous F508 for a patient or something like that.

So they have very specific criteria in terms of which CF patients and the mutations that they have that would respond to these drugs. So that's the basis of the criteria is making sure that these --

THE CHAIRPERSON: Or, yeah, the failure at regular statins with the combination.

DR. BORGERT: For the PCSK-9s, right, that's part of the FDA labeling is that they have -- they're on maximally tolerated statin

therapy.

THE CHAIRPERSON: Along with bococizumab as well.

DR. BORGERT: I think bococizumab is in our criteria for --

THE CHAIRPERSON: And that's on our preferred drug list as well?

DR. BORGERT: Yes, yes.

DR. CHAIRPERSON: So that would satisfy that.

DR. BORGERT: With the CF meds, we are having more uptake with those. We have approved five Orkambi requests and six Kalydeco requests in calendar year 2015, and that's just what we saw in Fee-for-service. So, again, that might be something that the MCOs want look at their utilization and see if it mirrors what we're seeing in -- we did not deny any requests for those two drugs. So it seems like when they're requesting it, it's appropriate. You know, they're requesting it for the appropriate patients.

We have had some discussions with outside groups regarding a few nuances to the criteria that we're evaluating changing, but

for right now we haven't denied anybody based on our current criteria. So it would be hard to make the argument that our criteria are too restrictive.

DR. ROMAY: Can I just go back to -- I know you mentioned at the beginning of our meeting today that Tobi was now -- it's now PDL, so there's no criteria to follow in terms of having a sputum culture or anything of that nature?

DR. BORGERT: We do have, don't we?

MS. ELLIOTT: AutoPA.

DR. BORGERT: Oh, AutoPA. It's going to be AutoPA.

DR. ROMAY: It's going to AutoPA. So it's not going to require any.

DR. BORGERT: Right. All right. That's all of the information that was requested for this quarter.

So just moving on to proposed topics for next quarter. I'll talk about what I've heard and then we'll open it up for the Committee members to make suggestions.

What I heard last time was talking about, you know, looking into some of the asthma

quality measures. Having this Board look into some of the asthma quality measure. You know, kind of a springboard conversation from the Pulmicort conversation.

And so looking a little bit into what those quality measures are, percent days covered for inhaled corticosteroids in patients with a diagnosis with persistent asthma. Percent based covered for long-acting beta agonists in patients with a diagnosis of persistent asthma. Those were two quality measures that are recommended for asthma. Another -- and then those obviously are evaluating adherence.

And then an asthma -- something called an asthma medication ratio, is the recommended asthma quality measure. And that is the percentage of patients with persistent asthma who had a ratio of controller meds to total asthma meds of greater than 0.5 or greater.

So, you know, basically that these patients aren't just being treated with short-acting beta agonists symptomatically. That they're on underlying therapy, you know, corticosteroids, first line, to manage it if

they have a diagnosis of persistent asthma.

And one of the nice things about the ICD-10s it does break out asthma by mild, moderate, and severe, persistent -- and it specifically talks about persistent asthma. So we can hone in on those patients that have persistent asthma as opposed to exercise induced asthma or things like that. So I think we can identify that population and look at one or all of those quality measures surrounding asthma if anybody is interested in doing that.

THE CHAIRPERSON: Well, the other thing when you look at this data sometimes the leukotriene inhibitors are also used to measure inhaled corticosteroids. So I think I would add that drug in there because a lot of -- some patients can't coordinate and some of them are intolerant due to thrush or side effects, you know.

DR. BORGERT: Right, right.

THE CHAIRPERSON: Some of the things that we see --

DR. BORGERT: Right.

THE CHAIRPERSON: -- that may or may not

be on there.

DR. BORGERT: And since we're going to narrow it down to the persistent asthma population, I think we can do that. I mean, in the past we've struggled a little bit with that because so many people are on it for seasonal rhinitis or that sort of thing with Singular. But we're going to just specifically look at the persistent asthma patients. So, yeah, we'll look at the leukotriene anti-agonists.

DR. ZITTELLO: Based on the quality measures it's a controller medication it's considered so we do need to look at that.

DR. BORGERT: Okay.

DR. OLSON: And I think we asked last time, can we tie this into ER visits or hospital admission data?

DR. BORGERT: I will do my best.

THE CHAIRPERSON: Admissions or visits period? Because I think there's more visits.

DR. OLSON: Well, I think tied into ER -- yeah, well --

THE CHAIRPERSON: ER visits.

DR. OLSON: Yeah.

DR. BORGERT: Well, with hospital admissions we do have the ability usually to get an admitting diagnosis. So, you know, we can look at hospital admissions specifically with an admitting diagnosis of asthma exacerbation or whatever the terminology is. So we can do that.

DR. OLSON: That would be great, yeah.

DR. BORGERT: We can do that.

THE CHAIRPERSON: Any other proposed topic? We have anticonvulsants, we talked about that.

DR. BORGERT: Right, right.

DR. ROMAY: I wanted to bring also, I know we've talked about this a lot in the past, the antipsychotics. We continuously see a huge epidemic of multi-pharmacy on those agents. We see people on three atypicals, which is very frightening to see that going on.

And it's really -- it's a hard sell when you reach out to that physician and try to, you know, kind of understand what the therapy is. And it's just very hard to, you know, break down that door and try to get them back

down to at least a single agent.

So there's a lot of mishandling of those. So I just want to see if maybe we can hone in on that a little bit more details on that.

THE CHAIRPERSON: I thought we had an edit in place for that already.

DR. BORGERT: We do. I'm trying remember what the antipsychotic polypharmacy edit is.

DR. ROMAY: Yeah, it is. But I just continue to see requests come through for that, for PA. And so --

DR. BORGERT: Yeah. Susan, I think that's -- I agree, I think that's the issue. I think the edit hasn't actually been -- it's Fee-for-service, yet it hasn't actually been programmed or implemented now. MCOs were --

DR. ROMAY: We have. We have in our local plan and we started seeing a huge influx, you know, of those members on two or more.

DR. BORGERT: So how does your edit work? Doe sit stop -- you know --

DR. ROMAY: It will message out. You know, but still we're seeing these physicians adamant about having them on three. So it's

hard to kind of -- from an educational standpoint to get them to --

THE CHAIRPERSON: And what's the justification on the prior auth? What are they writing on there?

DR. ROMAY: They're member is stable and they understand that the member been there -- you know, haven't been to the hospital, there's no decompensation. So it's kind of hard. But I think it's very dangerous to have a member on three of those.

THE CHAIRPERSON: Are they maxed out doses?

DR. ROMAY: Yeah, pretty much. I mean, we have a psychiatrist that we run them by, but still it's just very hard to kind of address that behavior.

DR. BORGERT: You know, in the pediatric population obviously we have USF on board that helps us with that, but with the adult population we don't have that luxury.

DR. ROMAY: Yeah. Inappropriate use too they use the Seroquel Extended -- Immediate Release for sleep which really doesn't have that indication. So that's another one they

add in there as kind of an adjunct to --

THE CHAIRPERSON: We had looked at that a few years back.

DR. BORGERT: Okay. Any other suggestions. Dr. Allen?

DR. ALLEN: Sure. I just wanted to say thank you this morning for running a very thorough and efficient meeting here. I think we're getting out on record time.

I just wanted to ask if we could take a look at Prevacid Solu Tab? After I'm looking at the data, the Q3 data. I noticed that the -- certainly from an economic perspective, the cost of Prevacid Solu Tab actually, you know, is more than Prevacid, or omeprazole, pantoprazole combined. And I think we're at about 2500 claims for Q3.

And I guess my question would be, are there that -- certainly with this Medicaid population there's going to be a lot of kids. But are there that many patients that actually need the solu tab? So for Zollinger-Ellison Syndrome, I mean, right, there is a -- I don't think there's a closed window on it. But the FDA indicates and

generally supports 8 to 12 weeks and then it can be stopped.

So I mean, after a review of the data perhaps there's an opportunity to implement an edit to stop it.

DR. BORGERT: We can look at the age group. We have an age limit, I think. But we can look at age group. And also if we kind find out if the have a G-tube or something like that. Because I think in that population that drug gets used in that population too. But we can try to look into that and just look at what the utilization picture looks like.

DR. ALLEN: And second in here is Bromfed DM. It certainly it doesn't have the same economic impact of Prevacid Solu Tabs, but I noticed that there's -- obviously there's a generic for the Bromfed DM cough syrup, and we had about -- close to about 200 claims in Q3 for the brand. So I can't imagine why 200 people would have to use the brand, but I might be missing something.

MS. ELLIOTT: I'm sorry, Moses, what was the drug?

DR. ALLEN: Bromfed DM, B-r-o-m-f-e-d.

DR. BORGERT: That wasn't one of the ones they had the recall on recently, was it?

DR. ALLEN: It might be.

DR. BORGERT: There was a recall on cough syrups, so...

DR. ROMAY: Was it probably Cardec DM?

DR. BORGERT: I'm sorry?

DR. ROMAY: Maybe the Cardec DM?

DR. BORGERT: It was on the manufacturers. I think it had to do with the unit dose cups not being accurate so that's they were worried about that.

DR. ALLEN: Because the Q3 compares as to generic from a utilization standpoint is at 29.28, and the brand is at 1.87 or something. So it's not going to break the bank or anything, but just something to keep an eye on.

And, lastly, from me I promise.

DR. BORGERT: That's fine. It's good to have input.

DR. ALLEN: Just from a OTC standpoint, so just right practically all over the non-sedating antihistamines are now on the

PDL, the desloratadine, the loratadine, et cetera. And I was just asking, is that the same approach with the Board or should the Board consider it the same approach with PPIs, of course Nexium and Prevacid and whatever else is over-the-counter now? And I just want know if there was ever an opportunity to do an economical comparison to see if it may be beneficial to have those products on the OTC?

DR. BORGERT: You know, I think we can take that back to provider Synergis and ask them that question and bring you back what we find out.

THE CHAIRPERSON: That's a recent update to the formulary because that wasn't on there a while ago. It was taken off and back on in terms of the Prevacid.

DR. OLSON: You know, tying into that, I know last meeting talked about even the acetaminophen over-the-counter and those products as well. Did we ever -- did that go anywhere?

DR. BORGERT: Remind me.

DR. OLSON: We talked about the Medicaid

approving pain for acetaminophen, or pain for ibuprofen.

DR. BORGERT: Oh, yes. I'm glad you brought that up. Yes, thank you. Yes, we did do that. For children under six. There are now acetaminophen products available on the PDL for children under six, specifically for -- to address the codeine issue. The removal of codeine approval in children under the age of six, there's now acetaminophen available and ibuprofen as well.

DR. OLSON: Still with a prescription under six they can get it?

DR. BORGERT: Yes, yes, yes.

DR. OLSON: Was that --

THE CHAIRPERSON: Do you remember when that went in, Arlene?

DR. OLSON: -- communicated out?

THE CHAIRPERSON: I got the letter a month ago, right.

DR. BORGERT: Yeah.

DR. OLSON: Did you?

DR. BORGERT: Yeah.

DR. OLSON: The providers got a letter on that one?

DR. BORGERT: Yeah. Well, it surrounded the whole coding thing and in there it mentioned the fact that -- it was actually a banner message. It was a banner message, not a provider letter. I misspoke.

But if you go and look up on the banner messages, you'll see it. And as part of that whole coding thing they have availability of acetaminophen for children under the age of six.

Just to follow-up on that, I don't know if anybody saw that the FDA Pulmonary Advisory Committee recently refuted it. And I think where it's going is, I think they're going to restrict it in anybody under 18, but we'll see. I mean, they really -- they recommended really, really narrow. So I guess we're a little bit ahead of the curve in terms of --

THE CHAIRPERSON: I actually looked at -- when you put it in the -- I actually looked it up and I'm like "what?"

DR. BORGERT: Yeah. So --

THE CHAIRPERSON: Very good. Any other input or any other --

DR. ROMAY: I wanted to just mention opioid antagonist the naloxones and that type of drugs. I just wanted to know if there's -- I know we want to, you know, have access -- our members have access to that drug, but right now currently it has a ClinicalPA but it doesn't really -- the criteria doesn't really allude to any kind of like what's required from the prescriber in terms of how the drug screen should be reported.

Right now a lot of times we have self-reporting from the doctors, and it's really kind of hard sometimes to really truly, you know, interpret whether it's really coming from the doctor's office or it's just -- because it's kind of like, "yes," "no," you know, the check off here or the check off there. And we find out over the course of time that sometimes those patients come back positive for, you know, either ecstasy or heroin.

So it kind of leads me to believe that a lot of times I don't know how true those results are coming from the physician. So I

don't know if we can mandate some kind of like -- it's okay to do a random drug screen, obviously, if they come in and you want to do a random drug screen in the office. But really they should be utilizing an outside lab to actually really do the analysis.

DR. BORGERT: And you want to see the drug screen as part of their continuation for therapy.

DR. ROMAY: Exactly. Right. Versus it just being a checkmark on bupropion or -- you know. Because a lot of times we get requests back that the members even negative to bupropion. So what are they doing? Are they selling it -- you know, that's a red flag for us. I mean, obviously those get denied, but truly to get an accurate result from a lab versus just a regular "yes/no" checkmark grid would be maybe something that we may want to consider just to substantiate the justification for the PA.

MS. ELLIOTT: So you're saying follow the condition with -- the checkmark with documentation?

DR. ROMAY: Right. Or actually have the

actual lab either from LabCorp or from -- showing the actual drug screen showing that they're negative for all these things.

DR. WILLIAMS: With them Fee-for-service they already look at those labs.

DR. ROMAY: Yeah, but I don't know for -- I don't know for -- when we see RPAs we get a lot of physicians just sending in that little grid that just says -- they check off "yes" on or "no" positive or negative. But it's not truly an actual lab analysis report coming back from either LabCorp or, you know, from Quest.

DR. WILLIAMS: That's a requirement with them Fee-for-service. If they don't have that lab attached, they'll ask for it. They'll send it back and say send us the labs.

DR. ROMAY: Right. But I don't think it's defined on the actual forms that we have now that it actually has to truly be from a lab.

DR. BORGERT: Okay. I will -- Susan, I'll delve into exactly the procedure for Fee-for-service and maybe look into updating

that PA form to reflect that requirement.

DR. ROMAY: Great. Thank you.

DR. MARTORANA: But that could just be a qualitative -- quantitative lab result.

DR. BORGERT: Right.

DR. WILLIAMS: On the PA form under the requirements it says that they have to send in the random drug screens. It's listed.

DR. ROMAY: As well?

DR. WILLIAMS: Yeah. It's under the prescriber's signature.

DR. ROMAY: Right. But we get those random drug screens but we actually don't get the -- they should be supplementing with an actual -- they should be sending out the drug screen out.

DR. WILLIAMS: So you want to request --

DR. ROMAY: I just want to --

DR. WILLIAMS: -- the labs, not --

DR. ROMAY: Right. Just to make sure that it's, you know, an adequate result versus an in office.

MS. ELLIOTT: Do you have a recommendation of how often you would like to see the random test?

DR. ROMAY: I would -- I mean, random I guess is something as it is random. So I don't know if you want to do it -- I think it depends on how that member has been in the past. If they have a history or relapse, I would do it more often, and so maybe every three months. I don't know.

DR. BORGERT: We can look into that. Any other requests, suggestions? I think it's a good idea like you guys were talking about where possible to follow up with, you know, how much the MCO data looks like the Fee-for-service data and that's something that we can consider here.

DR. MARTORANA: Just I guess the last time, the anticonvulsants we'll be bringing that back when we have the individual products, so are at least the top 5 or 10 in that class?

DR. BORGERT: Okay. We can do that.

DR. ROMAY: Just to add, in terms of like I know we mentioned having the MCOs bring back utilization data. Are we going to get like some kind of follow-up e-mail stating what exactly is required of us so we can

bring it to the next meeting?

MS. ELLIOTT: No. We're going to run that utilization. If we get in a bind, then we'll contact you.

DR. ROMAY: Okay got you. Thank you.

THE CHAIRPERSON: Okay. Does that close that topic? Any other suggestions? Very good.

Then next on our agenda is -- we had open discussion.

And next would be public comment. Do we have anyone from the audience that wishes to comment? No. Very well.

Vern our next meeting?

MR. HAMILTON: Wow. You all have really moved fast this morning. It's hard for me to keep up. I'm still asleep. You will note -- and I have already sent to all of you -- the schedule for the remainder of the year. But I think I put on the list that -- to be announced on the location you will notice that we are moving these meetings to the Tampa Hilton over on Lois Avenue, and that's where we will be meeting for the April, June, and September, I have contracts in place for

the Hilton. And we're looking forward to that. They have been very accommodating to our meetings. And I think the facilities will be very nice there. If you're not familiar with that location, it's not terribly far from here.

THE CHAIRPERSON: Just for the record, the June meeting date is --

MR. HAMILTON: The weekend of -- is it June 17th and 18th? I believe that's correct. The 17th is a Friday for P&T and the 18th is a Saturday for DUR.

THE CHAIRPERSON: And September's meeting date?

MR. HAMILTON: The last weekend of that month. Is that the 25th and 26th? No?

MS. SMITH: It's the 23rd and 24th.

MR. HAMILTON: 23rd and 24th.

MS. SMITH: The last day of the month is Friday the 30th.

MR. HAMILTON: So September 24th is a Saturday.

MS. SMITH: Yes.

MR. HAMILTON: But I sent all that to you in the e-mail previously.

THE CHAIRPERSON: Very good.

MR. HAMILTON: Because you all are such busy professionals, and we have not done it this way in the past, I'm going to be working to try to secure for a whole calendar year at a time. We've not done that traditionally here before, but it's getting more and more difficult to secure a location and the dates that we need for these meetings here in Tampa. And it helps you, I believe, in planning your calendar for these meetings. So hopefully by around late August, early September I will try to secure the dates for 2017.

THE CHAIRPERSON: Very good. Thank you.

MR. HAMILTON: Any questions? I think you noticed I passed out a new travel form. Christine Freeman is no longer in our unit and is not processing those, so we're moving to a new form that the bureau prefers. And it's just a guideline for sending those. You'll still use me to send those in and I will give them to another person now who will be processing them. I'm sorry I don't process your travel. But any questions that

come up, please send me an e-mail and I will follow up. I don't follow them unless I hear from you.

So I'm sorry about that, but I will be as communicative as possible in the processing of those.

THE CHAIRPERSON: Thank you, Vern. Thank you, Rebecca. And thank you everyone for serving and taking the time out of you busy Saturdays. I'd like to make a motion to adjourn.

DR. ALLEN: Second.

DR. MARTORANA: Second.

THE CHAIRPERSON: Very good. Thank you.

(WHEREUPON, the DUR Board Meeting adjourned at 10:55 a.m.)

CERTIFICATE OF REPORTER

STATE OF FLORIDA :

COUNTY OF HILLSBOROUGH :

I, Jacqueline L. Reichert, Court Reporter, Notary Public in and for the State of Florida

DO HEREBY CERTIFY that I was present at the foregoing proceedings at the time and place set forth in the caption thereof; that I was authorized to and did stenographically report the foregoing proceedings; and that the foregoing pages constitute a true and complete computer-aided transcript of my original stenographic notes to the best of my knowledge, skill and ability.

IN WITNESS WHEREOF, I have hereunto set my hand at Tampa, Hillsborough County, Florida this 26th day of January 2016.

JACQUELINE L. REICHERT
Notary Public, State of Florida
Commission No. EE 160968
Expires 3/27/2016

.

DRUG UTILIZATION REVIEW BOARD

Agency for Health Care Administration

Tampa Hilton Airport/Westshore

Saturday, September 24, 2016

8 a.m. - 10:45 a.m.

REPORTED BY: Sharon L. Boyd
Integra Reporting Group
Court Reporter
Notary Public
State of Florida

Pl. Trial Ex. 238

APPEARANCES:

BOARD MEMBERS

Anna Hayden, D.O. (Chair) - Absent
Jeffrey Martorana, M.D. (Vice-Chair) (acting chair)
Moses Allen, Pharm.D.
Diane Fagan, R.Ph.
Larry Field, D.O. - Absent
Venessa Goodnow, Pharm.D.
Kevin Olson, Pharm.D.
Alfred Romay, Pharm.D.
Luis Seanz, D.O. - Absent
Amy Zitiello, D.O.

AHCA STAFF

Kevin Dewar, Assistant General Counsel
Vern Hamilton, AHCA Liaison
Arlene Elliott, R.Ph., Pharmacy Policy Administrator
Susan Williams, R.Ph., C.Ph., Senior Pharmacist
Shevaun Harris, Bureau Chief, Medicaid Policy
Beth Kidder, Assistant Deputy Secretary, Medicaid Policy & Quality

MAGELLAN MEDICAID ADMINISTRATION

Elboni Moore, Pharm.D.
Rebecca Borgert, Pharm.D.
Selika Sampson, Pharm.D.
Stephanie McGriff, Pharm.D.

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P R O C E E D I N G S

THE CHAIRPERSON: Good morning. I officially have 8:02. Use the gavel? Good morning. I'm Dr. Jeff Martorana. And I think I would like to open up the Saturday, September 24 edition of the Drug Utilization Review Board. And we've got several new people here.

Actually, I'd first like to thank Dr. Borgert and all of her contributions to the committee over the years. I understand this is her last official meeting with us. She is moving on to a new role within Magellan. Thank you for all of your contributions to the committee.

And with that, she's brought some new learned team members that will be taking over, Drs. Stephanie McGriff and Selika Sampson.

And I think, kind of in that vein, if we would go around, since this is some new faces to them, and if we can all introduce ourselves, and who you are and what you do, that would be wonderful.

DR. ZITIELLO: I'm Dr. Amy Zitiello. And I actually have changed positions. I'm a pediatrician by trade, but I am now with Avalon Health Care Solutions as their vice-president and medical director, which is a lab benefits management company. I'm getting a crash course in targeted therapies, cancer.

DR. ROMAY: Good morning, everyone. My name is

Alfred Romay. I am director of pharmacy at Molina Health Care.

DR. OLSON: Kevin Olson, pharmacy manager, Johns Hopkins, All Children's.

DR. GOODNOW: Venessa Goodnow, director of pharmacy services at Jackson Memorial Hospital in Miami, Florida.

DR. FAGAN: Diane Fagan, director of pharmacy, Wellcare, here in Tampa.

DR. ALLEN: Moses Allen, director of pharmacy, Magellan Complete Care.

THE CHAIRPERSON: And Jeff Martorana. I'm a family physician, chief medical officer for Sunshine Health. Okay. Actually, before we start, we're going to have a little quiz this morning. I'm going to put our learned counsel on the spot. What happened today in 1789?

MR. DEWAR: I don't know. Failed.

THE CHAIRPERSON: It was the establishment of the Judiciary Act, establishing the Supreme Court. You'd better read the paper in the morning. Okay. I believe the first order on the agenda is Ms. Harris.

MS. HARRIS: Good morning, everyone. I'm not a morning person, so if I talk a little slower -- I'm just joking. Okay. All right. So thank you all for coming in this morning.

I want to give you a little bit of an overview over

a process that we have within the agency, because I think that it will help you all in review of a set of criteria that we're going to put in front of you in today's meeting.

So as you all know, under the Florida Medicaid Program, we cover any service that's medically necessary for a recipient under the age of 21, even if the service isn't listed on our fee schedule or listed in our policy. We have a special process that we go through to approve those types of services on an exceptions, or one-off basis, to determine if it's medically necessary.

We do all of that under the federal regulations called Early Periodic Screening and Diagnosis and Testing. EPSDT. And so -- but the service has to be medically necessary. And we have a formal definition and criteria that we use to determine if something is medically necessary.

As a part of our medical necessity definition, a service must be -- must not be experimental or investigational and must be generally accepted -- must be generally accepted professional medical standards.

And so there are times when a prescriber or a treating practitioner might order a service, a drug, a treatment, et cetera, and we have to go through the rigor of determining -- making sure that it meets that third prong of medical necessity, that it is a generally accepted professional medical standard.

And so, the agency was presented with a situation where we had to review the use of puberty suppression treatment for children and adolescents who are contending with gender dysphoria.

We went through a rigorous process of reviewing the literature out there to determine if it -- if use of that treatment is a generally accepted professional medical standard, because in -- the drugs that are used to suppress puberty, based on the FDA indications and the authorizing compendia, don't list gender dysphoria as a diagnosis for which these drugs can be used.

So we had to go look at the supporting literature, evidence-based literature, to determine if there's any indication that it would be appropriate to be used in those situations or for this diagnosis. And what we determined is that there may be instances where authorization of this treatment, or use of this treatment, outweighs some of the risks.

The evidence is not that strong that it is a generally accepted professional medical standard. There are -- so -- and so, we have to see where the literature evolves, where the research evolves on this. Not sure that we'll ever get there, quite honestly. It's a very small population of children and adolescents who are diagnosed with this condition.

So I'm not sure that you'll ever get to a place with the research trials where you'll be able to wholly say that it's not experimental or investigational or a generally accepted professional medical standard.

That being said, the literature was pretty clear that in this population, children experience great distress and undergo a great amount of psychotherapy and treatment to deal with the symptoms and feelings, et cetera. And so there are times when the feelings of distress are so great that we see instances of self-mutilitation, suicidal ideation, et cetera.

So what the agency determined is that while we will not cover it and add it to our PDL or fee schedule, et cetera, cover puberty suppression treatment for -- specifically to treat gender dysphoria, through what we call our exceptions process, which I just talked about a minute ago, we can review a one-off request on a very individualized basis to determine if that course of treatment is appropriate for that child, and poses as the best alternative, based on, you know, the child's current situation.

So, in the event that we get a request, we wanted to be prepared. We are going to be providing you with a copy of draft criteria that the agency prepared. It's really just to make sure that the clinicians who will be reviewing this have, at that first level review, something to go off of,

because there are no criteria.

And again, the FDA and compendia has not authorized use of this drug, or these drugs, for this condition. So we wanted to be prepared, and we thought it would be good if we had the DUR board review what the agency has developed, to give us any feedback. It would only be used in a special circumstance or an exceptions request that's presented to the agency, or one of the health plans. So we'll share that with you.

My team can chime in at any point. But I wanted to give you that backdrop, or history, so that you understand why you're being presented with the criteria, and also to make it clear, we're not wholesale covering this treatment.

THE CHAIRPERSON: And we're talking about the GnRH analogs?

MS. HARRIS: Yes.

DR. ZITIELLO: May I ask a question? The Tanner Stage requirement and the age requirement, what particular documentation or evidence-based literature did that come from?

MS. HARRIS: So that's actually a part of the -- oh. So the references are listed at the bottom of the second page. But the Tanner Stage II, III comes from the Endocrine Society Guidelines for use of the analogs and treatment of gender dysphoria.

THE CHAIRPERSON: I would also ask, because I don't see it in here, would there be any length of time that they have been in counseling prior to even consideration of going on drugs? So, you know, the first time that it's diagnosed and then, you know, to immediately go to a drug solution, I would like to see something to that sort, like at least six months of therapy.

DR. ZITIELLO: It says six months.

THE CHAIRPERSON: Okay. I must have missed that.

MS. HARRIS: It's the fourth bullet down.

THE CHAIRPERSON: Got it. Sorry.

MS. HARRIS: Let us know if you feel that time frame is not sufficient.

THE CHAIRPERSON: And then duration of therapy, obviously it says consent until 18. But then, when someone turns 21, and would no longer fall under the EPSDT, where do we go from there?

MS. HARRIS: So --

THE CHAIRPERSON: You pay me big money to ask the hard questions.

MS. HARRIS: So, as you know, there's a series of -- going down this path, the use of analogs is just the first step. At the age of, or beginning at the age of 16, it's recommended that if you are interested in sex reassignment surgery that you begin taking the cross-sex hormones,

ultimately leading up to the full surgical procedure.

It's a step-wise process that we'll have to look at as requests come up. We haven't had any of those requests yet. And then, at the age of 21, we wouldn't be governed by the EPSDT, so we wouldn't have to cover.

DR. ALLEN: So, just for clarity, are we making a decision on it now? Or do we have the opportunity to take it back and review and present recommendations?

MS. HARRIS: We'd like you to review it now. Only because we meet again in a quarter.

DR. ALLEN: Sure, sure.

THE CHAIRPERSON: Well, to that point, if you'd like to make a motion, but I would suggest that if we do act on this now, that we would bring it back the new quarter for review, so if -- you know, we all have our own experts. And not that you haven't done an exhaustive review, but if we kind of want to tweak it a little bit, that we not wait a full year to bring it back.

MS. HARRIS: Absolutely.

DR. ALLEN: Exactly, because I guess from my perspective, I mean, half of something is better than nothing, which is what we have now. So basically, that fact alone, I would be in favor of accepting the recommendation that's presented, but just have an opportunity to bring back additional suggestions, once we have an opportunity to review

it with our clinical staff.

MS. HARRIS: Absolutely. I think that's fair. And we would welcome that.

DR. ALLEN: Did I hear a second?

THE CHAIRPERSON: No. I didn't move.

DR. ALLEN: I'm sorry. I'd like to make a motion that we accept the recommended -- the recommendations for the policy that was presented to us.

THE CHAIRPERSON: With review next --

DR. ALLEN: With review next quarter.

DR. ZITIELLO: Second.

THE CHAIRPERSON: We've got a motion and a second Any further discussion? Questions? All in favor signify by saying aye.

THE COMMITTEE: Aye.

THE CHAIRPERSON: All opposed? The ayes have it. Okay.

MS. HARRIS: Thank you all.

THE CHAIRPERSON: Okay. The next order of business before us is the voting for chair and vice-chair of the committee. There were two nominations that were submitted. One was for Dr. Hayden and the other was for myself. And before I call for a vote, I will open it up to the floor for any floor nominations.

DR. ALLEN: Moses Allen. I'd like to nominate

Dr. Martorana.

THE CHAIRPERSON: Okay. So, with that, should I recuse myself and leave? Or we just open it up for a vote?

MS. ELLIOTT: I read the Robert's Rules and you do not have to leave.

THE CHAIRPERSON: I do not have to leave? Okay. All in favor for Dr. Hayden, please raise their hand. And all who would like to vote for myself, please raise their hand. I guess I am the newly-elected chair. Thank you.

Okay. Next is for vice-chair. There was only one nomination and that was for Dr. Moses Allen. So once again, I will open up the floor for any nominations. And you can nominate yourself if you'd like. Hearing none, all in favor for Dr. Allen? Okay. Congratulations.

Okay. All right. Next order of business is the approval of the minutes from the June 18 meeting.

DR. ALLEN: I'd like to make a motion to accept the minutes from the prior meeting.

THE CHAIRPERSON: Okay. I have a motion. Do I have a second? We're voting on to accept the minutes.

DR. FAGAN: Second.

THE CHAIRPERSON: Any opposition? Any discussion? Hearing none, minutes accepted.

MR. HAMILTON: Thank you very much. No corrections anybody found? I appreciate that.

THE CHAIRPERSON: Okay. And the next is the review of the P&T minutes from the June 17 meeting.

DR. ZITIELLO: Motion to accept.

DR. ALLEN: Second.

THE CHAIRPERSON: Any discussion? Any correctionS? Any opposition? Oh. We don't vote on this? Just a review? All right. Sorry. I'm going to be impeached. All right. Next up is the quarterly DUR reports.

DR. MOORE: Good morning. Before we get started, I would like to introduce our team. So we have Dr. Selika Sampson. As Dr. M said, this is Becky's last meeting with us. She has accepted a position within the company, so she'll still be a part of the family, but just not working on the Florida POS account.

Dr. Sampson comes from our clinical call center. She's been with the company since 2011, so she's not new to Magellan, but she's new to this role. She has a lot of experience. She's worked in the industry. She's worked in long-term care facilities. She's worked in the community. And she's a leader of our local community. So we're very excited to welcome her in to the clinical services side of Magellan.

Dr. Stephanie McGriff has also been with the company for a very long time. Actually, longer than me. She's been there for almost nine years. She's our clinical account

manager. She worked very closely with me when I was in that role, so she knows just about everything that I know, as far as how Magellan works on the POS side.

And I am -- I've moved over to the director of the account role. So that's kind of how we all play a part for the Florida POS team. And Becky's last time.

DR. BORGERT: Thanks, Elboni. Okay. Good morning, everyone. We will start with some follow-up items from things that we have pending, or questions that came up, or data that we have back now regarding topics that have come before the DUR board in the past.

The first item for follow-up is, if you will recall, as part of one of our P&T reviews, where we look at P&T classes that are -- the classes that are upcoming for the P&T to review, at one point, Pulmozyme was one of the drugs in one of those classes.

And at that time, the DUR board did vote to place an auto PA for diagnosis on Pulmozyme, since the only FDA-approved indication for that drug is for mucolytic therapy for cystic fibrosis patients. And so that edit on the fee for service side went into effect, I believe, in April -- April of 2016.

So the numbers are on the screen there, broken down by fee for service and MCO, and in the bottom are the totals. So if you look at the totals at the bottom, and you look to

the far right-hand column, under total pay, that is comparing the January through March of 2016, then looking at three months post implementation of the edit. And so, you can see, there was about a $500,000 cost savings.

So, if you annualize that over a year, that's about a two million dollar cost savings by attaching a diagnosis to Pulmozyme. So I think that was a successful edit, in terms of keeping that drug to its FDA-approved population. Questions about that? Okay.

The next topic is a topic that came out of -- I think it was one of our January quarterly activities, where we looked at top therapeutic classes for Florida Medicaid recipients and anticonvulsants. To no one's surprise, anticonvulsants were one of those top therapeutic classes.

And so, for the last couple of meetings, we've been sort of doing a deeper dive into anticonvulsants and -- I have some feedback, here, Vern. I don't know if it's bothering anybody else. But we've been doing a little bit of a deeper dive into anticonvulsant utilization.

So this is a slide that was presented at the last DUR meeting. So you can see here, broken down by most frequent, in terms of claims. Gabapentin, Levetiracetam, Topiramate, Lamotrigine, Divalproex, et cetera, et cetera, on and on. So that's kind of the breakdown of what our anticonvulsant mix looks like.

And then we also looked the last time at how many anticonvulsants were a particular recipient receiving. So -- and we also broke it down at the request of one of the DUR board members by pediatric patients, patients under the age of 18, and then adult patients that were 18 and over.

So this represents the number of recipients that received just one anticonvulsant in the first quarter of 2016, two anticonvulsants, and then three, four, five and six anticonvulsants. Because if you'll recall, we had some patients that were getting six and seven anticonvulsants within a ninety-day window.

So the most common scenario was for a recipient to receive two anticonvulsants, which I think seems probably understandable. And then, the thing that's new this time is, what we did last time is, we looked at -- we took those patients who were getting the most anticonvulsants.

Like, I think we took the recipients who were getting seven or eight -- that had received seven or eight anticonvulsants within that ninety-day period, and just kind of looked at them, just by age, and listed the drugs. And there were two recipients from that list that the DUR board asked for a little bit of further information on.

They asked for diagnoses, how many prescribers were prescribing those anticonvulsants. And then, there was also a question that came up about whether or not there was a

second clinical review being performed by the USF behavior health team for these patients.

So these were the two patients. The first patient was an eleven-year-old. And you can see there, they had seven different anticonvulsants that were filled over a ninety-day period. So when we looked at the diagnoses on file for these patients, it was pretty understandable.

Some of the pertinent diagnoses, probably, were cerebral palsy, obviously generalized idiopathic epilepsy that was intractable, congenital quadriplegia and dysphagia with a gastrostomy tube.

And this particular patient with the seven different anticonvulsants did only have -- had two different prescribers; however, those prescribers had the same -- were at the same facility, with the same address. So it didn't really look like it was, you know, seeing multiple providers.

And very much the same story with the fourteen-year-old. Again, seven different anticonvulsants. But diagnoses -- anoxic brain damage, non-fatal drowning, convulsions and also a gastrostomy tube.

So I think both of those patients, when you look at their diagnoses, kind of give you a picture of, those are the type of patients you maybe are not surprised are on multiple anticonvulsants. And again, there were three prescribers for those seven different anticonvulsants, but all three of those

prescribers had the same physical address. So they were probably within the same practice.

So I think it was good that it -- oh, and then, the question about behavioral, was USF looking at those patients? The answer is no, because the USF second medical review is strictly for behavioral health types of medications. So antipsychotics, stimulants, that sort of thing.

And neither of those two patients, A, had behavioral health diagnoses -- specific behavioral health diagnoses, or were on any other behavioral health medications. So USF was not involved with the care of those two patients.

So that's the follow-up information on those two patients that were receiving the highest number of anticonvulsants. Questions about that? Okay. I thought it looked pretty medically sound when we looked at it.

Okay. The next topic has to do with P&T classes that we looked at for the upcoming January P&T meeting. And one of the things that the committee talked about was possible inappropriate duplication therapy with GLP-1 receptor agonist and DPP-4 inhibitors.

So let me just try to walk through the pharmacology on this. I'm not a diabetes expert. So for type 2 diabetes, multiple classes of drugs. If you look there in step 2, most of those classes of drugs are listed -- Metformin, sulfonylureas, TZDs, DPP-4 inhibitors, SGL2 inhibitors, GLP-1

agonists and insulin. So that's kind of the armamentarium of pharmacologic classes available for management of type 2 diabetes patients.

And the way -- GLP-1 is what's called an incretin mimetic. So it's a hormone that's released from the gut. And what GLP-1 receptor agonists do is, they activate that receptor. So when GLP-1 is released, it causes insulin secretion from pancreatic beta cells. It decreases inappropriate glucagon suppression and it also slows gastric emptying.

So that's what GLP-1 does in normal physiologic state, in response to a carbohydrate or fat load. So that's the normal physiologic process.

So what a GLP-1 receptor agonist does is, it activates that receptor and causes GLP-1 to be released. Where the DPP-4 comes in is, DPP-4 is an enzyme that actually inactivates GLP-1.

So if you have a GLP-1 receptor agonist and a DPP-4 inhibitor, they're basically doing the same thing. They're both basically increasing the amount of GLP that's available systemically, because the agonist will obviously cause the release of GLP and -- which is glucagon-like peptide, by the way, and the DPP-4 would normally inactivate that.

But if you give somebody a DPP-4 inhibitor, to inhibit that enzyme, then you're keeping that GLP-1 around

longer than it would normally be. Everybody follow that? Okay. I just figured we'd kind of go through that, to understand this.

Okay. So when you look at the American Diabetes Association Guidelines for Standards of Medical Care in Diabetes, step one for most all patients, if there's no contraindication, is Metformin. And then if the hemoglobin A1C target is not met after three months, the recommendation is to move on to basically adding a drug from a different class. And then, at that point, if the A1C target is still not met after three months, the recommendation is to add a third drug.

And so, like, for instance, look at the very first box there. If, in step one, they were on Metformin, and then, in step two a sulfonylurea was added, then step three would be to add a TZD or a DPP-4 inhibitor or a SGLT2 or a GLP-1 agonist or insulin.

So I'm not going to go through every one of these, but I think the important thing to note is that if you have somebody that was put on a DPP-4 as step two, then you're not supposed to put them on a GLP-1 at step three, because those -- for the reasons we just talked about.

And likewise, if they were put on a GLP-1 in step two, DPP-4 as step three is not recommended. So the bottom line is basically we shouldn't be using those two drugs from

those two classes together for the treatment of diabetes.

So, having said all that to set the stage, the DUR board wanted to look at what kind of -- what we were seeing in the claims. So this is what we saw: We had about 8,600 patients for claims with DPP-4. Again, this is fee for service and MCO combined.

Only 62 had more than one DPP-4. This was in the second quarter of 2016, so a ninety-day period. We had 1800-ish claims for a GLP-1 agonist and we had nine patients who had claims for more than one GLP-1 receptor agonist.

Where there might be a problem is that -- so, if you got a DPP-4 or a GLP-1 -- so if you look at 86 plus 1800, that adds to 10,530. So those are all the patients that got one or the other. And of those 10,000 patients, we did have 356 patients who were getting both. So potentially something that the DUR board might want to talk about. I'll stop talking now.

DR. GOODNOW: Just a quick question. So how -- just so I'm reading the columns right, the 62 and the 9, and then, how does it jump to the 356? So 356 would be the combination of both, or --

DR. BORGERT: Combination. That means they got a DPP-4 and a GLP-1. So the first -- they got two DPP -- 62 patients got two DPP-4s. Nine patients got two GLP-1s. And 356 got a GLP-1 and a DPP-4.

DR. ALLEN: Would a remedy to this scenario be to implement a duplication of therapy edit?

DR. BORGERT: That's a possibility.

DR. ALLEN: I'd like to make that recommendation, or open it up to further discussion.

THE CHAIRPERSON: I do that.

DR. ALLEN: Sorry, Chair.

THE CHAIRPERSON: I have a motion for the -- for an edit, duplication of therapy edit. Do I have a second to that motion?

DR. ROMAY: Second.

THE CHAIRPERSON: Now, is there any further discussion? Is there any opposition? Hearing no opposition, we'd like to go ahead and institute a duplication of therapy edit.

DR. BORGERT: I guess the only question I would ask, just to think about -- and maybe Magellan could come up with a standard, but what would we want the look-back period to be? Because it could be that at some point, they'll change therapy. So what do you guys think about, in terms of when you look back, to see if they've had that previous therapy? What kind of window are you thinking about?

DR. ROMAY: I would say somewhere around a three-month period, and allow that washout, you know.

DR. BORGERT: So, look back 90 days, and if they've

had a claim for the other one within 90 days, the claim would deny for further review?

DR. ROMAY: Right.

DR. GOODNOW: I have a question. So if they -- let's say that they -- it will look like a duplication of therapy, but it's actually just they're switching from one to another. So you won't see it on the edit, but then we'll just -- when they go to file the second agent, that's when their clarification would occur?

DR. MOORE: Yes. That's what I was kind of thinking as Dr. Romay was talking. So I think that we should allow it maybe for one time. And then if there's a second time that we notice it, then deny it. Because there could be a chance that the patient filled one, they got switched, and filled the other within that 90 days.

DR. BORGERT: All right. Thank you. Did you vote on it? I know we made a motion.

THE CHAIRPERSON: Yes, we did.

DR. BORGERT: Okay. Thank you. Okay. The next topic also came out of reviewing upcoming P&T classes, and that was looking at Zolpidem, particularly in female recipients.

And if you'll recall, back in 2013, the FDA mandated labeling changes for Zolpidem products, due to basically increased adverse effects that were being documented and

reported, in terms of patients being impaired the following morning. And particularly they made the notation that women, in particular, seemed to be more affected by this, and that the starting dose for women should be five milligrams for the immediate-release product and should be no more than 6.25 for the extended-release product.

So one of the things we talked about at the last meeting was, it looked like most of our female patients were getting 10 milligrams. So when we looked at it, what we found was that there were about 15,000 female patients -- these are female patients only -- about 15,000 patients who were getting -- excuse me -- 15,000 claims for 7,000 recipients.

And if you looked at all the Zolpidem -- and again, just females -- you know, 20,000-ish claims, 9,000-ish recipients. So 75 percent of the recipients, female recipients, were getting ten milligrams or more of Zolpidem. So what we want with -- so the new part of this information is, the committee said, well, let's look back and see, have they previously been on five milligrams and the dose has been increased.

So when we looked in this history for a prior prescription for five milligrams in the previous six months, we only found 423 of those 7,000 recipients who had a prescription for five milligrams in the previous five months.

So not very many. Comments for the board?

THE CHAIRPERSON: So I guess that would be maybe an opportunity for a step through edit to say before you can get to ten, you've got to at least go through five.

DR. ZITIELLO: Would you add the extended-release as well, the 6.25, even though --

DR. BORGERT: Right. Yes.

THE CHAIRPERSON: So you would --

DR. BORGERT: And this was actually greater than or equal to ten milligrams. So we lumped the extended-release in with this.

DR. GOODNOW: Should there also be a term limit for the fives, like maybe three months? Or a certain duration, instead of just the single fill? Or do we want to also have, like a -- how long they need to be on the five before increasing?

THE CHAIRPERSON: Is there anything in the literature to suggest that --

DR. BORGERT: You know the FDA labeling doesn't give a length of therapy. It just says, you know, to begin with five milligrams. And you know, it doesn't. So I think -- no. I don't know. I'm not aware of a duration of which you have to try that and fail it before you are eligible to move on.

THE CHAIRPERSON: Because, you know, to

Dr. Goodnow's point, I'm sure there's a lot of people that would just give you one month, and then jack it up.

DR. GOODNOW: That would be my concern. But I don't think, clinically, there is a duration that is --

DR. BORGERT: I supposed theoretically they shouldn't even be on this long term. But that's a whole different discussion.

DR. OLSON: So you're looking for a motion?

THE CHAIRPERSON: Yes. And I would say on that motion, do we want to go ahead and impose a 30 or 60 or ninety-day piece to it?

DR. OLSON: I say 30 -- recommend 30 days.

THE CHAIRPERSON: Thirty days? Okay. So a motion to have a step edit for the 5 or 6.25 ER with a thirty-day trial. Do I have a second?

DR. ROMAY: Second.

THE CHAIRPERSON: Any further discussion? Any opposition? Hearing no opposition we'll go ahead with a step edit of 5 and 6.25 for 30 days prior to the 10 and 12.5.

DR. BORGERT: Okay. Thank you. Okay. This was a quarterly activity from the second quarter of 2016. We looked at the overall utilization of compounded medications. And as part of that data, when we were looking at that -- when the DUR board was looking at that, you guys kind of really focused in on compounds that involved bulk powders.

And there was some question as to why we had so many claims that were involving bulk powders. And so, we broke that information out specifically and it did appear that a very large number of our compounds contain a bulk powder as a covered ingredient.

Because, you know, when they submit the claims, we didn't even look at the ones that weren't included as covered in the compounds. We looked at the ones that were included as covered in the compounds. And we had 766 claims, 366 recipients. And a good deal of the money involved in those compound claims were tied up with these claims that used -- that involved bulk powders.

So when we looked at that, the request from the DUR board was to look for patterns, to look for certain prescribers, to look for certain pharmacies, to look for certain, you know, compounds that were being dispensed regularly. And when we looked at it, in fact, there was a pattern.

There was a particular compound, and this compound contains these ingredients: diclofenac -- I think they must be using a tablet, because that wasn't a bulk powder. Diclofenac, gabapentin powder, bupivacaine powder, cyclobenzaprine -- tablet, I guess -- clonidine powder and then a cream base. And so, that compound seemed to show up over and over and over again when we looked at the data in

the first quarter of 2016.

And there was only one prescriber who was prescribing that. And it involved 124 claims for 67 recipients at a total of $555,761 for the quarter. And it was mostly the same pharmacy. There were a couple of different pharmacies, but by and large, it was a pharmacy.

DR. ALLEN: So -- if I may --

DR. BORGERT: I think the appropriate place for this is probably the agency.

MS. ELLIOTT: I just wanted to make a comment that from one of our quarterly meetings with the plans, a recommendation was that to put a cap dollar amount on these compound prescriptions, and we did. We accepted that recommendation that the max is $300. For a compound that cost more than that, they would have to send prior auth and it would be reviewed for appropriateness.

DR. BORGERT: And perhaps this one particular provider would be information that we might pass along to NPI. I don't know how the agency feels about that. That would obviously be an agency decision. But that might be something -- an appropriate place for this information to go.

THE CHAIRPERSON: I would second that recommendation very highly. We could all go in a little mini bus and have a discussion, I'm sure.

DR. ALLEN: So just for clarity, our plan had the

same findings. I probably could name the physician and the pharmacy. We had the exact same statistics here. But I guess that from a clarity standpoint, Arlene's point with the implementation of the max cost edit on the compounds of $300, I think this will probably flush out a lot of the issues anyway.

But of a secondary concern, the bulk powders, by FDA definition, they're not considered an FDA-approved drug. So would the agency also -- well, I guess, just for clarity, are we -- does the agency currently cover them?

I guess I'm not completely understanding how they were approved in the compound anyway. And would they -- could a patient potentially get a compound with a bulk powder today if it's under $300?

DR. BORGERT: I don't know the answer to that.

DR. MOORE: The agency does not reimburse -- generally speaking, they don't reimburse for bulk powders. There are a few bulk powders that the agency will reimburse for, such as, like, the progesterone, estrogen, because those things are compounded. But generally speaking, we do take a look at this.

Will it be caught by the edit? So that's kind of a tricky question, because it depends on how the pharmacy is submitting the compound. So if the pharmacy submits the compound with a the indicator on there that says, hey, I'm a

compound, we do look at each and every ingredient in there to see if it is payable, or if it is reimbursable.

But if the pharmacy decides to put a submission clarification code of 8 that says, you know, regardless of what's in here, as long as I have at least one payable ingredient in here, the claim will adjudicate. The pharmacy will not be reimbursed for the products that are not reimbursed through Florida Medicaid, but as long as the system sees one payable agent, the compound will pay. It will adjudicate.

The agency isn't paying for products that they do not reimburse for in that compound. So the pharmacy's at risk for losing, in that instance.

MS. ELLIOTT: But in that case, we will stop at the 300. It will deny.

DR. MOORE: Right. But he said if it's under 300.

DR. GOODNOW: And just to clarify that amount, if there are some compounds where the actual active ingredient is more than $300, how would that be taken into consideration?

DR. MOORE: So that would require prior authorization, and it would go to our clinical call center for review -- the regular PA process.

MS. ELLIOTT: And if I also -- if I could add, for your information, that there is a lot of compounds that don't

have powders or ointments, or whatever. So, you know, it's like for kids that cannot swallow tablets. So we are focusing on compounds like this. And this is not a $300 compound. This is a thousand-plus compound.

DR. OLSON: So that limit is going to apply to bulk powder compounds, not other commercial product compounds -- tablets and other? Or is it applying to all compounds?

MS. ELLIOTT: It's more like topical compounds are the ones that seem to be the highest price.

DR. OLSON: But is there a $300 limit only on topicals, or does it apply to all orals and topicals?

MS. ELLIOTT: Not the orals. We have -- at the beginning, we -- it included everything that came in as a compound. And it was problematic, because of the kids.

THE CHAIRPERSON: I don't think we need a motion or action on that.

DR. BORGERT: I don't know that we need to do anything. It's just kind of more informational, information for the committee.

THE CHAIRPERSON: Would it also be prudent for this prescriber -- and I don't know if it's out of protocol or not -- to send a letter from this committee, saying that we reviewed your practices and we find them highly irregular?

DR. BORGERT: I think probably the place is for Medicaid Program Integrity. But I'll let the agency speak to

that.

MS. HARRIS: Yes. We will be following up, if we haven't already.

DR. BORGERT: And the next question that came out of our review of compounds was about the Revatio suspensions that we were seeing on the list of compounded medications.

So a little bit of further information about that. It turns out that the commercially available products have been available since September of 2014. I don't -- none of us could remember exactly when it -- but when you look at FDB, it actually became -- the first date that it actually became available, September of 2014.

The commercial product is a powder for reconstitution that results in a ten milligram per ML suspension. It's 120 MLs at a wholesale acquisition cost of about $6,500.

There are directions in compendia for extemporaneous compounding of Revatio suspension, and I think this probably dates back to prior to there being a commercial product, when children needed this product.

So clinical pharmacology, other compendia have directions for extemporaneous compounding. And the directions for that extemporaneous compounding results in a 2.5 milligram per ML suspension, per the directions. We did have many claims for extemporaneously compounded Revatio

suspensions.

The reimbursement ranged anywhere from $3.91 that the pharmacy got paid, and that was a 270 ML prescription -- claim, all the way up to 27.56 for a 648 ML product that was dispensed.

And then, I just have there, for your reference, the dosing. It is a milligram per kilogram every eight hours for neonates and infants; 10 milligrams Q 8 for children under 20 kilos; and 20 milligrams every Q 8 for children 20 kilos and above. As you can see there, most of the utilization is actually in fee for service, as opposed to the MCOs.

DR. GOODNOW: I just have a quick question for the variation in reimbursement. It there any reason for that?

DR. BORGERT: I think it has maybe to do with what Elboni was just saying, in terms of the way that the pharmacy submits the -- what code they utilize. Any other questions about the Revatio?

DR. ROMAY: I was under the impression since there was a commercially available product on the market that it couldn't be extemporaneously made. Is that -- am I correct with that? Or is that something that we're kind of veering off from?

DR. BORGERT: I don't know the answer to that.

MS. ELLIOTT: That is a federal rule from CMS. Yes. So I don't know if we want to find out -- since most of them

are fee for service, would we -- we can find out who is the one that is still compounding it and contact them.

DR. ROMAY: The Revatio suspension is a lot pricier. On the cost basis, it probably would be a better angle. But, you know, we can look at it and see what we decide on it.

DR. BORGERT: Thank you. Okay. The next item for follow-up has to do with -- if you'll recall, one of the quarterly activities we did is, we looked at high-utilizing members. And so, we kind of picked an arbitrary definition of a high-utilizing member.

And the original definition that we picked was any patient who received nine or more different -- excuse me -- 15 or more -- let me get the numbers right, here. Yes. Nine or more different medications within a sixty-day window. So that was the cut-off that we used.

So we wanted -- what we brought back, when we looked at that quarterly activity is, how many members did we have that were getting nine distinct -- so, not different strengths of the same medication, but nine different medications within a sixty-day window.

And we had an astounding number. We had 47,533 recipients that accounted for one and a half million claims, when we used that as a definition -- how many people got nine or more prescriptions within 60 days.

So that was kind of an unmanageable number, and so

we decided to kind of just look at the worst of the worst, or whatever -- the highest of the highest, is maybe a better way to phrase that.

So we -- because we, literally, had patients who were getting 30 medications within that sixty-day window. So we used nine as the cut-off, but it went all the way up to some patients were receiving 30 different meds within that sixty-day window. So we kind of decided to start there and focus on that, since it was such a huge number of patients.

And so, what we did is, we cut it down to a thirty-day window. And so, we said, anybody who had 15 drugs or more -- 15 or more different drugs within a thirty-day window. And we had -- Magellan has compiled all of those medication profiles and broken them down by the different plans.

And that information will be passed along to the agency, because that was one of the requests, was that, you know, you guys maybe would bring this up in a call, or you know, that we could provide the agency with that information, and then they could follow up as they felt was appropriate.

So we have all that information for the members. You've got 15 or more medications within a thirty-day period. And we have the entire medication profile for each recipient, broken down by plan. And that information will be passed along to the agency.

DR. ALLEN: Could I ask a question, just about that data?

DR. BORGERT: Yes.

DR. ALLEN: Just to make sure there weren't any false positives. I guess where I'm going with this is, depending on what the refill-too-soon tolerance is, I guess a patient could theoretically get 10 on the first of the month, but he's eligible for a refill on the 24th of the month, or the 25th, right?

And if he's taking nine medications during that month's profile, it would essentially look like he's taking 18 medications, if that makes any sense. I just wanted to know if that was taken into consideration.

DR. BORGERT: Well, we looked at -- I'm not sure I understand your question, but we looked at distinct HSNs. So if they would have refilled it, it wouldn't have counted against them. Do you see what I'm saying? These were distinct HSNs. So the HSN is basically the drug, not strength specific.

So whatever -- if you were on gabapentin, there's multiple different strengths. But at the HSN level, it's gabapentin. So you only get counted for gabapentin once, no matter how many times you got that, or got the different strength within the thirty-day window. Okay. So that's part one of this topic.

Part two of this topic that came out of the board's discussion regarding this topic was people -- the board was concerned about members with HIV who were perhaps not getting complete regimens. So I can't remember exactly how the conversation went, but what came out as a follow-up of the high utilizing recipients was a desire to look at patients who are on HIV regimens, and were they getting complete regimens for their -- for the treatment of HIV.

So what we did to try to look at that was, we tried to look at patients who received only one HIV medication. Now, we excluded Atripla, Genvoya, Stribild -- you know, Complera -- all the ones that -- where it is appropriate to just have -- because they have multiple chemical entities within the same tablet, so, that's -- they're designed to be single drug regimens. So we excluded those.

And so -- but then, with the other HIV medications, we looked at within -- and we started to look at a thirty-day window, and we had a really large number. So what we did is, we expanded it to a ninety-day window. We said, okay, you know, maybe something happened with the refill. Maybe you didn't get it exactly on time. So we were going to limit it to a thirty-day window. We looked at 90 days.

And we said, how many patients only got one HIV med, excluding those, in a ninety-day window. And we had 1,029 recipients who only received one HIV medication, excluding

those, within a ninety-day window.

Now, some of those are probably explainable. Within that 1,029, there were 54 recipients with an age of zero who got one-time fills for zidovudine, 50 milligrams for five. So that's probably postnatal exposure. So those are probably appropriate.

We had 267 patients out of 1,029 who received Truvada. So that likely could have been pre-exposure prophylaxis therapy. So that likely could have been appropriate, as well.

If you want a specific breakdown of what these drugs were that they were only getting one of, this is the breakdown by pharmacologic class of drugs, in terms of -- so you can see, the highest one there, in terms of number of recipients, was the Truvada.

So that -- you know -- and again, if we say, okay, that's probably pre-exposure prophylaxis therapy. But there were, you know, several patients who were receiving only one of these types of classes. And I know Dr. Saenz was the one who kind of brought this topic up, and he's not here today, but that's the information, and I'm bringing it back to the committee for any comments, or to ask questions.

THE CHAIRPERSON: Comments? Questions?

DR. ALLEN: Great information.

THE CHAIRPERSON: Go ahead.

DR. ALLEN: No questions. Great information.

THE CHAIRPERSON: Now, these were fee for service findings that we were looking at?

DR. BORGERT: No. We're looking at both, fee for service and MCO. So a thousand, and if you take away roughly 300 or so of those, you're left with about 6- or 700 patients who are only getting one. I think Dr. Saenz, some of his concerns were that patients didn't understand.

You know, maybe they went to the pharmacy and the pharmacy didn't have one of the medications, or something, and they said, "We're going to fill this one. Come back and get the other one," and then they never did. Or I think he was concerned about maybe people selling their medications.

THE CHAIRPERSON: Yes. I know that was one concern. I guess the only potential follow-up I could see is if those unique members could be identified to the MCOs.

DR. BORGERT: Okay.

THE CHAIRPERSON: I'm sure our case managers, whatever, would be more than happy to do outreach to see if it is truly a misunderstanding, or see that they're on the appropriate regimens. Relatively small number, that spreadsheet, they could probably handle.

DR. BORGERT: Okay.

DR. GOODNOW: I think definitely, now that we're aware of the information, I think it's good, if there is a

potential for an intervention of a patient.

DR. BORGERT: I'm sorry. I couldn't hear you. What did you say?

DR. GOODNOW: Just saying, now that we know the information, that if this is an opportunity for an actual intervention to assist the patient, if it is maybe an outreach issue, either for the provider or the patient, I think it's definitely significant enough to reach out to them.

DR. BORGERT: I will compile those -- the list of recipients with their medication profile and I'll pass it on to the agency to pass it on to the MCOs, or however the agency wants to handle it.

MS. ELLIOTT: So you're running the same report for them, to also bring it over also for the next meeting, so we can see if the numbers for those recipients stay the same or change?

THE CHAIRPERSON: No. The ones that she's already run the report on is to give us --

DR. BORGERT: I think the request was for those 6- or 700 patients that were impacted who only had one HIV medication, which is probably an inappropriate regimen for them, that we provide that recipient information and those claims information to the particular plans and have those recipients too, that they do internal follow-ups to see, you

know, why is that happening.

MS. ELLIOTT: I got that. I was just saying if we bring the results, or kind of similar results for all of them -- because we can only give them the specific patients for the specific plans.

DR. BORGERT: Sure.

MS. ELLIOTT: So we would have, like, the summer for the next meeting or the -- because we're running the reporting for the same patients, right? Or we're getting those numbers for the specific patients, but what I'm saying is, if we see a pattern still in the next --

DR. BORGERT: So basically repeat the analysis?

MS. ELLIOTT: That's my suggestion.

DR. BORGERT: Okay. Sure. Right. Absolutely. So, you know, we disseminate that information. We give the plans time to, you know, intervene, or do whatever they -- you know, do their due diligence and find out if there's interventions that need to happen with the provider or the member. And then we basically re-assess and see if the situation has improved.

MS. ELLIOTT: That's what I --

DR. BORGERT: Yes. We'll have to think about what that time frame will look like, because obviously we need to get the data to the MCOs to give you guys time to, you know, research it and figure out what, if anything, that needs to

happen. And then we can remeasure again. Maybe -- I'm guessing maybe in the spring, or something, would be a good time to remeasure that -- the indicator.

All right. We are on to -- that ends the follow-up section of the presentation. We are on to new business. Vern, I'll let you -- okay. So the first item of new business is a request that came from the P&T committee at the June P&T committee meeting.

They specifically requested that the DUR board take a look at drugs that go into what we refer to at Magellan -- we have a market basket that we call Cytokine Antagonists. And basically these are medications for things like rheumatoid arthritis, Crohn's Disease, psoriasis and psoriatic arthritis, et cetera.

So when you look pharmacologically at the drugs that we're talking about here, they kind of fall into one of three buckets. We have the biologic TNFs, or tumor necrosis factor -- they're actually tumor necrosis factor inhibitors. And these are biologic products. And so, the list is there -- Humira, Enbrel, Remicade, Cimzia, Simponi. So those are our biologic TNF inhibitors.

And then, we also have other biologic drugs that they don't work by the same exact mechanism. They are biologics, but they don't work by the same exact mechanism. So they're not TNF inhibitors. A lot of these are

interleukin inhibitors -- IL-6, IL-17, IL-23. So that's the list of the other biologics that are not TNF-inhibitor based mechanism of action.

And then we have two drugs that are non-biologics. These are oral medications. And those are Otezla and Xeljanz. So those are the three buckets of drugs that we're thinking about when we're going to look at this polypharmacy issue. So we're going to look at guidelines. We're going to look at what's happening. And again, this was a request of the P&T committee.

So, again, it's a little bit of a diverse bag of diseases that we use these drugs in. So we need to look at, maybe, several guidelines. RA is probably the number one overall utilization.

So when you look at the guidelines from -- the 2015 guidelines from the American College of Rheumatology -- I don't want to read all this to you, but the bottom line is -- and I'm going to just skip to -- cut to the chase, and then I'll go back. There are no recommendations in any of those three guidelines to either use two TNF inhibitors together, to use a TNF and a nonTNF biologic, and -- or a TNF or nonbiologic with a nonbiologic.

So, I know it's a little bit confusing, but basically the point is, don't use two -- don't -- in the biologic TNFs, don't use two of those together. Don't use

one from a biologic and a nonbiologic. Don't use that together. And then, if you're using one of these oral ones, it shouldn't be combined with either of those classes, either.

So I'll go through the guidelines, just to kind of help everybody understand. So, in RA, basically, your bottom line is, if you're going to use combination therapy, it's Methotrexate or a conventional DMARD -- sulfasalazine, leflunomide, with a TNF inhibitor or a nonTNF biologic, or a nonbiologic. So Methotrexate or a conventional DMARD in combination with any of those three. But not those three combined together.

And then, for psoriasis and psoriatic arthritis, the American Academy of Dermatology says monotherapy with either a TNF inhibitor or another type of biologic is acceptable as first-line therapy after failure of topical or phototherapy.

And in patients who have moderate to severe psoriatic arthritis, use one of those drugs or a combination of Methotrexate plus one of those drugs.

So, again -- and then, lastly when we look for the management of Crohn's or ulcerative colitis with these drugs, same type of thing -- antiTNFs in combination with thiopurines. That would be something like mercaptopurine. And then, other drugs in the maintenance setting.

Bottom line is, and I think what the P&T committee was

trying to get at is, we don't use those three buckets of drugs in combination, per the guidelines, for any of those. And so when we looked at it, what we found is that we had 16 recipients who were getting two different TNF inhibitors within a quarter. We had five recipients who were getting a TNF and a nonTNF biologic. And we had six recipients who were getting either a TNF inhibitor or a nonbiologic plus the nonbiologic.

So -- however, it's maybe not as bad as it looks, because -- and here's exactly what that looked like, in terms of the drugs. So you can see, 13 of them -- so we had 27 recipients. And so half of them, almost, were getting Enbrel and Humira. But when I looked at that, when I looked at the service dates on the claims, it looked like probably at least ten of those patients were switching therapy. Not concomitant therapy.

However, there were three patients who most definitely got both drugs filled on the same day every month. So there were a few big outliers.

And the same is true kind of with the rest of these. There were a few that looked like maybe they were switching therapy. But there were also at least four or five patients who were getting those two -- both drugs filled, particularly, like, the Otezla and the Enbrel. They were getting both filled on the same day every single month.

So, it wasn't a huge problem, but we did have some issues. So that was information that the P&T specifically asked to come to DUR. So that's the information for the DUR board.

THE CHAIRPERSON: So, much like our previous discussion, I think a thirty-day overlap is probably something that would be -- like you said, someone that's changing from one agent to another. But we could certainly put an edit, or look to put an edit for not duplication of these three classes.

MS. ELLIOTT: I have a question.

DR. BORGERT: Yes.

MS. ELLIOTT: Did you look at the physicians? Are they different --

DR. BORGERT: Yes. I did look at the physicians. And a lot of times, it was the same physician. As a matter of fact, I would say the majority of the time, it was the same physician who was prescribing both drugs.

Whether it was the -- it looked like a switch, or whether it was they got the same two drugs on the same day, by and large, it was the same -- not obviously across the board, but for each individual recipient was -- it tended to be the same provider.

DR. ROMAY: I think it's very important to capture that and put a hard stop, so we can at least have the

opportunity to reach out, if we see that duplication. And especially if it's two different providers, we can kind of, you know, get and see which one -- maybe they're not talking to each other, which happens a lot, and we don't get that opportunity to have an intervention.

DR. BORGERT: I know there were at least a couple of instances where it was a different providers. But the majority were the same. One thing I thought, you know, just having looked at the data, I don't know if a thirty-day window might be enough, because, you know, a lot of times they got -- you know, let's just say -- okay. So we're in September.

So they got, you know, Enbrel in September and then they were switched to Humira in October, but it might not have been exactly 30 days. I mean, it might have been six weeks, or something like that. So I'm not sure that 30 days is going to be a big enough window. So maybe 60 days.

DR. ROMAY: And I think we also have to look at the fact that, you know, we have to give these biologicals a chance to work. A lot of these providers are just getting -- you know, there's a lot of discussions that come around when patients have been on these medications. I mean, I get it from when I speak to the providers. They say, "These patients are xenophobic," or, "They can't come in because they're not complying with their medications."

So I get it. But there's a lot of leakage, you know, between those therapies that really should give a chance, at least a six-month period, to get that medication, to really see if it's working or not.

DR. ALLEN: Trying to find the best way to frame my question. This is second quarter data, correct?

DR. BORGERT: Second quarter. Correct.

DR. ALLEN: So my time line might be off.

DR. BORGERT: No. You're right. I know where you're going.

DR. ALLEN: So Enbrel and Humira during that time were both on the PDL.

DR. BORGERT: There was probably some overlap in terms of the PDL changing with that. Exactly.

DR. ALLEN: So, in theory, Enbrel and Humira would have just -- there wouldn't have been a dupe therapy edit to prevent that from happening previously?

DR. BORGERT: No.

DR. MOORE: There is a dupe edit, but it doesn't stop the claim. It posts at the pharmacy.

DR. ALLEN: So, just for clarity, would that just be the messaging, or does the pharmacist have to go in and put in a code?

DR. MOORE: It was soft. No code necessary.

THE CHAIRPERSON: Dr. Romay, would you like to

propose a hard edit?

DR. ROMAY: Definitely. I propose that.

DR. ALLEN: Second.

CHAIR: With a sixty-day?

DR. ROMAY: Yes.

THE CHAIRPERSON: Any -- so I've got a motion by Dr. Allen and a second by Dr. Romay --

DR. ALLEN: Reverse.

THE CHAIRPERSON: -- with the hard edit, 60 days. Any further discussion? Questions? Any opposition? Hearing no opposition, the motion carries.

DR. BORGERT: Thank you. Okay. So what we'll do is, once the edit is implemented, we'll give a period of time and then we'll do a follow-up analysis to see the impact of the edit. And we'll also take that information back to P&T, since it was a request directly from P&T. But that's the action the DUR board took, based on review of the information.

And what Elboni said just reminded me of something I forgot to mention. When we were looking at the high utilizing recipients -- remember when we were talking about these patients who were getting 15 meds in 30 days? One of the other things that had come out of the discussion in June was, what about the Produr edits that are -- what Elboni just said made me thing about it -- that are therapeutic dupe and

ingredient dupe.

Why are those not stopping them? Or, are those stopping them? And so, we tried to pull that information. We tried to look at, okay, were any of these Produr edits that were overridden by the -- hard edits that were overridden by the pharmacy, by using the service -- professional service codes.

We tried to look at that to see if maybe we could pinpoint, you know, some bad actors that were just blowing through the Produr edits. And unfortunately what I found out was that when we get the encounter data, the Produr information is not part of that encounter data. Or it's certainly not consistently part of that.

So there's really no way for us to capture that information on a large scale basis for the MCO. So rather than bring back bad data, we just decided to scrap that, and trying to look at that, because we just didn't have the information.

We didn't have the Produr information in the encounter data that would enable us to really look at that in a systematic way. I just thought of that. I just remembered that. And I wanted to bring that to the board.

DR. ROMAY: I know we're looking at, specifically those Produrs, and things like that, that can be overridden at the pharmacy. Can we maybe perhaps look at those edits

that we currently have that are overridable at the POS? Maybe look at them more closely, to see if maybe there's opportunities to kind of turn those off?

I know we're trying to provide access to the members, and not have them walk out without something, but I think we need to do something a little bit more streamlined, so we can at least look at what's being overridden at the POS level.

DR. BORGERT: So, I just want to make sure I understand your question, or your request. So what you're requesting is that in terms of Produr edits that we have -- maybe, say, for therapeutic duplication or ingredient duplication, where it's just like a -- messaging to the pharmacy, it doesn't stop the claim, you'd like to have information about what those are to review, to see if -- maybe convert those to a hard stop? Is that even something we can do, Elboni?

DR. MOORE: The ones that we do have activated, we do provide to the plans on a weekly basis. It's on that comprehensive drug file that you all have. So you all have possession of which Produr edits that fee for service has activated. If you want us to try to pull it up today, if you want to discuss it today, we can try to do that. So, it's up to the board.

DR. ROMAY: That wouldn't include the therapeutic

ingredients that we were talking about earlier?

DR. MOORE: We do have the therapeutic duplication edit activated. It does deny for particular situations, but not everything. So some are soft, some are hard. But most are soft.

DR. ROMAY: Yes. I mean, that's probably what I would want to look at, to see what those are, so we can at least -- because I know, a lot of times there are players out there that will override that just to get the claim to pay. And to really look at patient safety, you know, make sure that they have the right recommendation.

DR. MOORE: So what I'll do is, I'll let Becky continue. I'll pull it up. I'll send it over to her and she can pull it up at the end, and we can come back to it and discuss it.

DR. BORGERT: Thank you, Elboni. Okay. We're on to the new business section about upcoming P&T classes. If you look in your packet that came to you, there was an Excel spreadsheet. I will pull up the Excel spreadsheet here so that it's on the screen. I'm sorry I can't make it much bigger than this, for some reason.

But basically, there were three classes that we pulled out this time to look at. So the first one to look at is the topical immunomodulators. And obviously the product here is Imiquimod. I think that's how you pronounce this.

And so, this is the utilization of Imiquimod in our population between April and June -- April 1 and June 30.

And so, one of the things that I found a little bit interesting is, it's not FDA approved in children under the age of 12. And so, of that utilization that we just looked at, we did have 55 recipients and 59 claims with this amount of money for Imiquimod.

As I looked at it, it looked like probably molluscum contagiosum, and I wanted to get everybody's opinion on that. And you know, I will definitely need the board expertise here, you know. In the literature, it says, you know, self-limiting condition, you shouldn't treat it, blah, blah, blah. But, you know, I'll defer to the board and get their input on what they think about that.

DR. ZITIELLO: I suppose you would like me to speak up on this. Since leaving Amerigroup, I can tell you that the vast majority that we got for this age group were for viral warts, molluscum contagiosum. I don't have a real strong feeling on -- this is a self-limiting illness, just like warts.

I can say personally that I did a lot of denials for these. I'm surprised there is any that are coming through. Yes, cosmetically it's a little stressful. My own daughter has had it and she did not go on Imiquimod. Again, it's self-limited, so I don't really see the reason for that.

DR. BORGERT: My understanding is, it's a preferred agent.

DR. ZITIELLO: The denials were really based on diagnosis. Obviously there are indications for this.

DR. BORGERT: Sure. Absolutely. And I have the indications listed here -- actinic keratosis, basal cell carcinoma, HPV. Those are the indications. But typically, obviously, not conditions that you normally see in children under the age of 12. So from what I'm hearing you saying is that when you reviewed them, in your medical opinion, you mostly tended to deny them.

DR. ZITIELLO: Almost 100 percent.

THE CHAIRPERSON: So if we put an age edit --

DR. BORGERT: Actually, we do have a minimum age of 12. So, you know, I don't know that -- and a quantity limit. But I don't know -- you know, still, it looks like some plans were still approving it. I don't know. Just an FYI, more than anything really to the board to think about, in terms of is it therapy that makes sense to continue to do.

Other P&T classes to maybe think about, I just wanted to bring this to the board, just to make sure the board was aware of this, that in May of 2016, the FDA did put out further warnings regarding fluoroquinolones, advising that the serious side effects associated with fluoroquinolones generally outweigh the benefits for patients

who had acute sinusitis, acute bronchitis and uncomplicated UTIs who have other treatment options.

So the FDA now says that for these conditions, fluoroquinolones should be reserved for those who do not have alternative treatment options. So I just wanted to make sure the board was aware of that recommendation by the FDA. We typically bring that type of stuff to the board.

And then to just provide you with a list of -- you know, there, in the left-hand column, is our preferred and nonpreferred, fluoroquinolones. And you can take a look there at the utilization, both by fee for service and MCO, and just see if the board had any comments or anything that they wanted to do with fluoroquinolones based on that FDA information.

DR. GOODNOW: I apologize. This is a very, very silly question. But on fee for service, amount paid, there are a couple of choices at the bottom -- a couple of agents just with a zero amount paid. Is that just because the fee for service they were in, maybe the portion to -- like, there wasn't --

DR. BORGERT: My guess would probably be that they had coordination of benefits. Like, they had another plan, maybe, that picked it up. And then, so Medicaid's portion of the prescription was zero, that whatever other insurance paid for it -- covered the entire amount.

THE CHAIRPERSON: So, other than a step through --

DR. BORGERT: And you know, antibiotics are tough, because, you know, they're acute therapy. You don't want to stop them at the pharmacy, and yet you've got the FDA, you know, saying don't use it for acute sinusitis, bronchitis or UTIs, and they are very obviously -- you can run the utilization numbers and see, you know, we have, you know, 40,000 claims in a quarter for Cipro. They're obviously highly utilized medications. But it's really, really tough.

DR. ROMAY: Can we maybe suggest putting, like, a banner message, just as an educational standpoint, saying, you know -- you know, I know there's a lot of overprescribing antibiotics out in the community, including Zithromax.

I mean, everybody gets a Z-Pak every time they walk through the door, or they call a physician and get it. So I think we've seen that a lot, even though it's inexpensive, but we're creating a lot of resistance out in the community. So I think maybe a banner message could circumvent that.

THE CHAIRPERSON: And we do have a hard age edit on this? Isn't there evidence of bone marrow suppression for use under the age of 12? Or -- not bone marrow --

DR. BORGERT: Or cystic fibrosis.

DR. ZITIELLO: I was going to say on that banner message, perhaps add some of the information about bronchitis.

DR. BORGERT: And I suppose as we're coming into cold and flu season, too, it's probably timely to think about that.

DR. MOORE: We've done a similar initiative in the past through DUR. We did a letter campaign to provide to the community, talking about, you know, antibiotic resistance, and when it should be used, and perhaps when it shouldn't be for viral instances. So, like Becky just said, coming into the cough and cold season, it wouldn't hurt to do it again.

DR. BORGERT: And provide them at the same time this information from the FDA about, hey remember that the FDA is saying that the risks of these drugs outweigh the benefits, in these types of infections. Even if you do need an antibiotic, this it probably not the best choice.

DR. OLSON: Just a question to the IV solution claims that are coming through there. Where is that coming from? It's small dollars, but there's --

DR. BORGERT: Yes. I mean, sometimes those are billed through point of sale. So, like, maybe if it's a home infusion pharmacy, or something like that, that was billed through point of sale, that's what that is.

Okay. So a banner message will be drafted and that will be brought back to the board at the January meeting.

And then, there is -- the other class that we pulled out to look at was the tricyclic antidepressants. I know one