Exhibit 26

2021, Apr. 2021 Release CP:Procedures

Subset: Gender Affirmation Surgery (1, 2, 3, 4, 5, 6, 7, 8)

Requested Service: Penectomy for Gender Affirmation Surgery

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Primary gender affirmation surgery

1. Strong and persistent cross-gender identification ≥ 6 months (9)
   - ☐ A) Yes
   - ☐ B) No

   • If option Yes selected, then go to question 2
   • No other options lead to the requested service

2. Choose all that apply: (9)
   - ☐ A) Marked incongruence between experienced or expressed gender and primary or secondary sex characteristics
   - ☐ B) Strong desire to not have current primary or secondary sex characteristics because of the incongruence with experienced or expressed gender
   - ☐ C) Strong desire to have primary or secondary sex characteristics of the other gender
   - ☐ D) Strong desire to be the other gender or an alternative gender
   - ☐ E) Strong desire to be treated as the other gender
   - ☐ F) Strong confidence that typical feelings and reactions are of the other gender
   - ☐ G) Other clinical information (add comment)

   • If 2 or more options A, B, C, D, E or F selected and option G not selected, then go to question 3
   • No other options lead to the requested service

Primary gender affirmation surgery (continued...)

3. Choose all that apply: [9]
   - ☐ A) Clinically significant distress or impairment in social or occupational or other important areas of functioning
   - ☐ B) Clinically significant increased risk of suffering
   - ☐ C) Other clinical information (add comment)

   • If 1 or more options A or B selected and option C not selected, then go to question 4
   • No other options lead to the requested service

4. Gender affirmation surgery, Choose one:
   - ☐ A) Female-to-male surgery, genital [10, 11]
   - ☐ B) Female-to-male surgery, other [10, 11]
   - ☐ C) Male-to-female surgery, genital [12, 13]
   - ☐ D) Male-to-female surgery, other [12, 13]
   - ☐ E) Other clinical information (add comment)

   • If option C selected, then go to question 5
   • No other options lead to the requested service

5. Choose all that apply:
   - ☐ A) Referrals from two behavioral health specialists clearing patient for gender affirmation surgery [14, 15]
   - ☐ B) Persistent and well-documented gender dysphoria [14]
   - ☐ C) Capacity to make fully informed decisions and to consent [14]
   - ☐ D) No psychiatric disorder by history or psychiatric disorder controlled [16, 17]
   - ☐ E) Other clinical information (add comment)

   • If the number of options selected is 4 and option E not selected, then go to question 6
   • No other options lead to the requested service

6. Choose all that apply:
   - ☐ A) Cross-sex hormone therapy ≥ 12 months or hormone therapy contraindicated [18]
   - ☐ B) Lived ≥ 12 months in gender role congruent with gender identity [19]
   - ☐ C) Other clinical information (add comment)

   • If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here **(Outpatient)** [20]
   • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
Delaying treatment for those with gender dysphoria is not a reasonable treatment option. This can lead to negative consequences, such as delay or arrest in emotional, social, or intellectual development. Isolating oneself from family and friends, being excluded from society, becoming a victim of bullying and self-harm all may be seen when there is an impediment or interruption in care. Some individuals, notably adolescents, may develop psychiatric issues including anxiety, depression, and suicidal ideation (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

3:
Guidelines agree that gender affirmation surgical intervention is appropriate for individuals 18 years of age or older, as these procedures are irreversible; however, behavioral health counseling and hormone therapy may be used to treat individuals who have been diagnosed with gender dysphoria at an earlier age. The sooner the diagnosis is made and treatment options are discussed, the more successful the individual is when transitioning (Hembree et al., Endocr Pract 2017, 23: 1437; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

4:
According to the American Psychiatric Association, the Diagnostic and Statistical Manual of Mental Disorders defines gender dysphoria as a condition where sex assigned at birth is incongruent with experienced or desired gender, resulting in distress and suffering. Distress must persist for at least six months and result in a desire to change (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). Transgender persons are described as someone whose gender identity, behavior or expression, is not typical of that assigned at birth, including those who are gender dysphoric. In the United States, approximately 0.6%, or 1.4 million adults identify as transgender individuals. The prevalence is similar worldwide and has doubled in the last decade (Flores et al., How many adults identify as Transgender in the United States? 2016).
Therapeutic options for gender dysphoria or transgender individuals include psychotherapy, hormonal treatment, and gender affirmation surgery (GAS). Dressing, acting, or speaking consistent with the correct gender, taking hormones, changing one's name, and surgical intervention are possible activities carried out to identify with the correct gender. Some transgender individuals do not define themselves as conforming to the gender binary (male or female) and may also use terms such as gender non-conforming, pangender, agender, bigender, polygender, gender fluid, gender queer, or gender neutral. This will impact their treatment choices (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013).
GAS is a treatment option for gender dysphoria and is often the final stage of transition. GAS is not a single procedure, but part of a complex process involving multiple medical, psychiatric, and surgical modalities working in conjunction with each other to assist the candidate for gender affirmation achieve successful outcomes. Before undertaking GAS, candidates need to undergo important medical and psychological evaluations to confirm that surgery is the most appropriate treatment choice. Procedures vary significantly from female-to-male and male-to-female and are generally comprised of a series of primary and secondary sex character changes, chest reconstruction, facial alterations and voice-modification. After working with a transgender care team, a surgical plan is tailored to the individual's needs to relieve gender dysphoria. Treatment standardization in this population is not possible as clinical presentations and symptoms will vary significantly with each individual. A specialized, multidisciplinary transgender care team may include, but is not limited to, practitioners in primary care, behavioral health, speech and language therapy, dermatology, endocrinology, urology, gynecology, and plastic surgery. Collaborative care, joint participation in goal setting along with regular follow-up is crucial (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional

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Statistics around GAS are primarily estimations. Private facilities are not mandated to report this data; there are variations on how surgical procedures are staged and many of the procedures are identified as simply cosmetic, therefore making data collection difficult. In addition, the complexity and various reconstructive scenarios distinguishing procedures with multiple stages from revisional affirmation surgery is not truly accounted for. Although estimates vary, the American Society of Plastic Surgeons stated that there was a 155% increase in gender affirmation surgeries in 2017, approximating over 8,300 facial, body contouring and sex surgeries (American Society of Plastic Surgeons, 2017 Plastic Surgery Statistics Report. 2018).

6:
These criteria include the following procedures:

Bilateral Mastectomy
Breast Augmentation
Clitoroplasty
Gender Confirmation Surgery
Gender Reassignment Surgery
Hysterectomy
Intersex Surgery
Labiaplasty
Male Chest Contouring
Metoidioplasty
Orchiectomy
Ovariectomy
Penectomy
Penile Prosthesis
Permanent Hair Removal
Phalloplasty
Salpingo-oophorectomy
Scrotoplasty
Sex Reassignment Surgery
Transgender Surgery
Transsexual Surgery
Urethroplasty
Vaginoplasty
Vulvoplasty

7:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

8:

This is a procedure that can be performed for either medically necessary or cosmetic purposes. The criteria as written are intended solely for use in determining the medical appropriateness of this procedure and do not cover this procedure when performed for cosmetic reasons.

9:
Prior to surgical intervention for gender affirmation, gender dysphoria must be present as outlined by the Diagnostic and Statistical Manual of Mental Disorders. If a pronounced distress between the assigned gender at birth and the gender that is desired persists for at least six months, and there is significant distress in social or occupational settings, the diagnosis of gender dysphoria can be made. It is accompanied by marked incongruence between experienced or expressed gender and sex characteristics, strong desire to be an alternate gender, strong desire to be treated as the other gender, to not have or to change assigned sex characteristics, or having strong confidence that typical feelings are of the other gender (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013). InterQual® consultants agree that the Diagnostic and Statistical Manual of Mental Disorders is the most widely accepted for the diagnosis of gender dysphoria.

10:
The most common female-to-male (FtM) genital procedures include hysterectomy, ovariectomy, salpingo-oophorectomy, metoidioplasty, phalloplasty, penile prosthesis, scrotoplasty, and urethroplasty. Permanent hair removal can be done prior to a number of genital surgeries.

The most common FtM chest procedures are mastectomy and male chest contouring. There are also various body contouring, facial and voice modification surgeries (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

11:
Surgical risks in female-to-male (FtM) genital and breast surgeries include, but are not limited to, infection, unsightly scarring, nipple necrosis, contour irregularities, urinary tract stenosis, fistulas, necrosis of neophallus, micropenis, and incapacity to stand while urinating. FtM genital surgery has been less successful than male-to-female genital surgery because of the difficulty creating a functional and aesthetic penis from smaller clitoral tissue (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

12:
The most common male-to-female (MtF) genital procedures include orchiectomy, penectomy, clitoroplasty, labiaplasty, urethroplasty, vaginoplasty, and vulvoplasty.

The most common MtF chest procedure is breast augmentation. Permanent hair removal can be done prior to a number of genital surgeries. There are also various body contouring, facial and voice modification surgeries that may be appropriate MtF procedures (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

13:
Some surgical risks in male-to-female genital and breast augmentation surgeries include, but are not limited to, infection, capsular fibrosis, partial necrosis of the vagina or labia, fistulas from the bladder or bowel into the vagina, stenosis of the urethra, the vagina being too short or small for coitus, anorgasmia, lower urinary tract infection from a shortened urethra, and dysfunctional bladder (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

14:
Therapy is intended to explore gender concerns, assess the intensity of and help alleviate gender dysphoria, assist in determining appropriate subsequent steps in treatment, assess existing mental health concerns, and evaluate outcomes of interventions (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). A behavioral health specialist must document persistent gender dysphoria, the ability to make fully informed decisions, and assure there are no active psychiatric disorders to impede decision making or interfere with successful postoperative care (Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). The individual should be assessed before surgery and demonstrate an understanding of the procedure, surgical options, and potential risks and outcomes. The patient should be aware of the risk of sterility as a result of hormone therapy and gender affirmation surgery. Discussions regarding fertility preservation options prior to these interventions, as well as ongoing oncological risk monitoring, are necessary (Hembree et al., Endocr

Pract 2017, 23: 1437; Wylie et al., Lancet 2016, 388: 401-11; American Psychological, Am Psychol 2015, 70: 832-64; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). There is no recommended length of therapy or number of sessions an individual must attend or complete preceding surgery. It is however, strongly suggested that transgender individuals have access to therapy throughout the process as it can be a supportive adjunct to gender affirming surgery (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

15:
It is required that individuals seeking chest or breast surgery, to treat gender dysphoria, submit one referral letter from a behavioral health specialist to the surgeon stating psychotherapy requisites have been met. Surgeons generally require two referral letters before proceeding with genital surgery. It is recommended that at least one of the behavioral health professionals submitting a letter should have a doctoral degree (e.g., Ph.D., M.D., Ed.D., D.Sc., D.S.W., Psy.D) or a master's level degree in a clinical behavioral science field (e.g., M.S.W., L.C.S.W., Nurse Practitioner, Advanced Practice Nurse, Licensed Professional Councilor, Marriage and Family Therapist). Since there is not a standardized letter format outlining specific content that needs to be communicated between the behavioral health specialist and surgeon, letter writing varies. Often, referrals will include diagnostic criteria of gender dysphoria from the Diagnostic and Statistical Manual of Mental Disorders, standards of care met from The World Professional Association for Transgender Health, the individual's duration and compliance with therapy, as well as an understanding of procedures, individual readiness and consent. Typically, an explanation that the criteria for surgery have been met and a brief description of the clinical rationale for supporting the individual's request for surgery are also recorded. Ideally, the mental health professional should document willingness to coordinate care with the primary and surgical care team (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

16:
A significant number of gender dysphoric patients have a history of diagnosed or undiagnosed psychopathology including substance abuse, post-traumatic stress disorder, mood disorders, and anxiety. Although no specific conditions are exclusionary, all patients should be screened to ensure stability and a complete understanding of the procedure and postoperative follow-up. Depression may occur anytime throughout the transition process and individuals are encouraged to continue with psychotherapy during and after transition as needed (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Dhejne et al., Int Rev Psychiatry 2016, 28: 44-57; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

17:
Symptoms or behaviors are considered to be controlled when they have responded to therapeutic and/or pharmacologic interventions.

18:
Surgical intervention should not be performed until the patient is 18 years or older. Hormone therapy, however, may begin sooner if not contraindicated. Guidelines suggest pubertal suppression can begin at Tanner stage 2 as better outcomes are seen when initiated with puberty. These guidelines do not agree on an age to begin cross-sex hormone therapy, but do agree that cross-sex hormone therapy should be taken for at least 12 months prior to genital surgery and female-to-male (FtM) mastectomy, and male chest contouring. For best results in male-to-female (MtF) breast augmentation surgery, some guidelines suggest at least 2 years of cross-sex hormone therapy because breasts continue to grow during this time, while others agree 12 months is sufficient (Hembree et al., Endocr Pract 2017, 23: 1437; Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

Pubertal suppressing hormones halt gonadotropin secretion and lead to gradual regression of development of sex characteristics. Girls breasts will not continue to grow and will reduce in size, and menstruation will stop. Boys will experience a cessation in virilization and decreased testicular volume. The effects of these hormones are fully reversible. If the patient has surpassed puberty, cross-sex hormone therapy can begin. Cross-sex hormone therapy leads to the development of opposing sex characteristics and is only partially reversible. In FtM patients, the aim of cross-sex hormone therapy is to cause gradual clitoral enlargement, vaginal atrophy, fat redistribution, voice deepening, facial and body hair growth, suppress menses as well as increase libido, muscle mass and height. The goal for MtF individuals is to reduce height, decrease libido, grow breasts, redistribute body fat, decrease muscle mass, and soften the skin (Hembree et al., Endocr Pract 2017, 23: 1437).

A systematic review reports that hormonal treatment improves depression, self-esteem, anxiety, personality-related psychopathology, and higher emotional quality of life in both FtM and MtF patients. This review also suggests improved body uneasiness in MtF. Many individuals do not continue with affirmation surgery if hormone therapy and other lifestyle changes have significantly decreased gender dysphoria (Costa and Colizzi, Neuropsychiatr Dis Treat 2016, 12: 1953-66).

19:
Living in the preferred gender role congruent with gender identity is a key component to successful transition prior to irreversible genital intervention. A minimum of twelve months is required to experience life events and incorporate transition in different personal and social settings. External response is observed and allows the individual to experience everyday life as the gender they identify with. Continuous living in the correct gender role must be documented by a behavioral health specialist (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

20:
I/O Setting:
Bilateral Mastectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Clitoroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Hysterectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Intersex Surgery - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Metoidioplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Ovariectomy/Salpingo-oophorectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Phalloplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Scrotoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Urethroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Vaginoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
All others - Outpatient

ICD-10-CM (circle all that apply): F64.0, F64.1, F64.2, F64.8, F64.9, Z87.890, Other _____

ICD-10-PCS (circle all that apply): 0VTS0ZZ, 0VTS4ZZ, 0VTSXZZ, Other _____

CPT® (circle all that apply): 54125, 54130, 54135, Other _____

2021, Apr. 2021 Release CP:Procedures

Subset: Gender Affirmation Surgery (1, 2, 3, 4, 5, 6, 7, 8)

Requested Service: Phalloplasty for Gender Affirmation Surgery

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Primary gender affirmation surgery

1. Strong and persistent cross-gender identification ≥ 6 months (9)
   - ☐ A) Yes
   - ☐ B) No

   • If option Yes selected, then go to question 2
   • No other options lead to the requested service

2. Choose all that apply: (9)
   - ☐ A) Marked incongruence between experienced or expressed gender and primary or secondary sex characteristics
   - ☐ B) Strong desire to not have current primary or secondary sex characteristics because of the incongruence with experienced or expressed gender
   - ☐ C) Strong desire to have primary or secondary sex characteristics of the other gender
   - ☐ D) Strong desire to be the other gender or an alternative gender
   - ☐ E) Strong desire to be treated as the other gender
   - ☐ F) Strong confidence that typical feelings and reactions are of the other gender
   - ☐ G) Other clinical information (add comment)

   • If 2 or more options A, B, C, D, E or F selected and option G not selected, then go to question 3
   • No other options lead to the requested service

Primary gender affirmation surgery (continued...)

3. Choose all that apply: [9]
   - ☐ A) Clinically significant distress or impairment in social or occupational or other important areas of functioning
   - ☐ B) Clinically significant increased risk of suffering
   - ☐ C) Other clinical information (add comment)

   • If 1 or more options A or B selected and option C not selected, then go to question 4
   • No other options lead to the requested service

4. Gender affirmation surgery, Choose one:
   - ☐ A) Female-to-male surgery, genital [10, 11]
   - ☐ B) Female-to-male surgery, other [10, 11]
   - ☐ C) Male-to-female surgery, genital [12, 13]
   - ☐ D) Male-to-female surgery, other [12, 13]
   - ☐ E) Other clinical information (add comment)

   • If option A selected, then go to question 5
   • No other options lead to the requested service

5. Choose all that apply:
   - ☐ A) Referrals from two behavioral health specialists clearing patient for gender affirmation surgery [14, 15]
   - ☐ B) Persistent and well-documented gender dysphoria [14]
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   • If the number of options selected is 4 and option E not selected, then go to question 6
   • No other options lead to the requested service

6. Choose all that apply:
   - ☐ A) Cross-sex hormone therapy ≥ 12 months or hormone therapy contraindicated [18]
   - ☐ B) Lived ≥ 12 months in gender role congruent with gender identity [19]
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Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

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Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

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Ovariectomy
Penectomy
Penile Prosthesis
Permanent Hair Removal
Phalloplasty
Salpingo-oophorectomy
Scrotoplasty
Sex Reassignment Surgery
Transgender Surgery
Transsexual Surgery
Urethroplasty
Vaginoplasty
Vulvoplasty

7:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

8:

This is a procedure that can be performed for either medically necessary or cosmetic purposes. The criteria as written are intended solely for use in determining the medical appropriateness of this procedure and do not cover this procedure when performed for cosmetic reasons.

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Prior to surgical intervention for gender affirmation, gender dysphoria must be present as outlined by the Diagnostic and Statistical Manual of Mental Disorders. If a pronounced distress between the assigned gender at birth and the gender that is desired persists for at least six months, and there is significant distress in social or occupational settings, the diagnosis of gender dysphoria can be made. It is accompanied by marked incongruence between experienced or expressed gender and sex characteristics, strong desire to be an alternate gender, strong desire to be treated as the other gender, to not have or to change assigned sex characteristics, or having strong confidence that typical feelings are of the other gender (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013). InterQual® consultants agree that the Diagnostic and Statistical Manual of Mental Disorders is the most widely accepted for the diagnosis of gender dysphoria.

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The most common female-to-male (FtM) genital procedures include hysterectomy, ovariectomy, salpingo-oophorectomy, metoidioplasty, phalloplasty, penile prosthesis, scrotoplasty, and urethroplasty. Permanent hair removal can be done prior to a number of genital surgeries.

The most common FtM chest procedures are mastectomy and male chest contouring. There are also various body contouring, facial and voice modification surgeries (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

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Surgical risks in female-to-male (FtM) genital and breast surgeries include, but are not limited to, infection, unsightly scarring, nipple necrosis, contour irregularities, urinary tract stenosis, fistulas, necrosis of neophallus, micropenis, and incapacity to stand while urinating. FtM genital surgery has been less successful than male-to-female genital surgery because of the difficulty creating a functional and aesthetic penis from smaller clitoral tissue (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

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The most common male-to-female (MtF) genital procedures include orchiectomy, penectomy, clitoroplasty, labiaplasty, urethroplasty, vaginoplasty, and vulvoplasty.

The most common MtF chest procedure is breast augmentation. Permanent hair removal can be done prior to a number of genital surgeries. There are also various body contouring, facial and voice modification surgeries that may be appropriate MtF procedures (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

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Some surgical risks in male-to-female genital and breast augmentation surgeries include, but are not limited to, infection, capsular fibrosis, partial necrosis of the vagina or labia, fistulas from the bladder or bowel into the vagina, stenosis of the urethra, the vagina being too short or small for coitus, anorgasmia, lower urinary tract infection from a shortened urethra, and dysfunctional bladder (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

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Therapy is intended to explore gender concerns, assess the intensity of and help alleviate gender dysphoria, assist in determining appropriate subsequent steps in treatment, assess existing mental health concerns, and evaluate outcomes of interventions (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). A behavioral health specialist must document persistent gender dysphoria, the ability to make fully informed decisions, and assure there are no active psychiatric disorders to impede decision making or interfere with successful postoperative care (Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). The individual should be assessed before surgery and demonstrate an understanding of the procedure, surgical options, and potential risks and outcomes. The patient should be aware of the risk of sterility as a result of hormone therapy and gender affirmation surgery. Discussions regarding fertility preservation options prior to these interventions, as well as ongoing oncological risk monitoring, are necessary (Hembree et al., Endocr

Pract 2017, 23: 1437; Wylie et al., Lancet 2016, 388: 401-11; American Psychological, Am Psychol 2015, 70: 832-64; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). There is no recommended length of therapy or number of sessions an individual must attend or complete preceding surgery. It is however, strongly suggested that transgender individuals have access to therapy throughout the process as it can be a supportive adjunct to gender affirming surgery (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

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It is required that individuals seeking chest or breast surgery, to treat gender dysphoria, submit one referral letter from a behavioral health specialist to the surgeon stating psychotherapy requisites have been met. Surgeons generally require two referral letters before proceeding with genital surgery. It is recommended that at least one of the behavioral health professionals submitting a letter should have a doctoral degree (e.g., Ph.D., M.D., Ed.D., D.Sc., D.S.W., Psy.D) or a master's level degree in a clinical behavioral science field (e.g., M.S.W., L.C.S.W., Nurse Practitioner, Advanced Practice Nurse, Licensed Professional Councilor, Marriage and Family Therapist). Since there is not a standardized letter format outlining specific content that needs to be communicated between the behavioral health specialist and surgeon, letter writing varies. Often, referrals will include diagnostic criteria of gender dysphoria from the Diagnostic and Statistical Manual of Mental Disorders, standards of care met from The World Professional Association for Transgender Health, the individual's duration and compliance with therapy, as well as an understanding of procedures, individual readiness and consent. Typically, an explanation that the criteria for surgery have been met and a brief description of the clinical rationale for supporting the individual's request for surgery are also recorded. Ideally, the mental health professional should document willingness to coordinate care with the primary and surgical care team (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

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A significant number of gender dysphoric patients have a history of diagnosed or undiagnosed psychopathology including substance abuse, post-traumatic stress disorder, mood disorders, and anxiety. Although no specific conditions are exclusionary, all patients should be screened to ensure stability and a complete understanding of the procedure and postoperative follow-up. Depression may occur anytime throughout the transition process and individuals are encouraged to continue with psychotherapy during and after transition as needed (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Dhejne et al., Int Rev Psychiatry 2016, 28: 44-57; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

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Symptoms or behaviors are considered to be controlled when they have responded to therapeutic and/or pharmacologic interventions.

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Surgical intervention should not be performed until the patient is 18 years or older. Hormone therapy, however, may begin sooner if not contraindicated. Guidelines suggest pubertal suppression can begin at Tanner stage 2 as better outcomes are seen when initiated with puberty. These guidelines do not agree on an age to begin cross-sex hormone therapy, but do agree that cross-sex hormone therapy should be taken for at least 12 months prior to genital surgery and female-to-male (FtM) mastectomy, and male chest contouring. For best results in male-to-female (MtF) breast augmentation surgery, some guidelines suggest at least 2 years of cross-sex hormone therapy because breasts continue to grow during this time, while others agree 12 months is sufficient (Hembree et al., Endocr Pract 2017, 23: 1437; Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

Pubertal suppressing hormones halt gonadotropin secretion and lead to gradual regression of development of sex characteristics. Girls breasts will not continue to grow and will reduce in size, and menstruation will stop. Boys will experience a cessation in virilization and decreased testicular volume. The effects of these hormones are fully reversible. If the patient has surpassed puberty, cross-sex hormone therapy can begin. Cross-sex hormone therapy leads to the development of opposing sex characteristics and is only partially reversible. In FtM patients, the aim of cross-sex hormone therapy is to cause gradual clitoral enlargement, vaginal atrophy, fat redistribution, voice deepening, facial and body hair growth, suppress menses as well as increase libido, muscle mass and height. The goal for MtF individuals is to reduce height, decrease libido, grow breasts, redistribute body fat, decrease muscle mass, and soften the skin (Hembree et al., Endocr Pract 2017, 23: 1437).

A systematic review reports that hormonal treatment improves depression, self-esteem, anxiety, personality-related psychopathology, and higher emotional quality of life in both FtM and MtF patients. This review also suggests improved body uneasiness in MtF. Many individuals do not continue with affirmation surgery if hormone therapy and other lifestyle changes have significantly decreased gender dysphoria (Costa and Colizzi, Neuropsychiatr Dis Treat 2016, 12: 1953-66).

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Living in the preferred gender role congruent with gender identity is a key component to successful transition prior to irreversible genital intervention. A minimum of twelve months is required to experience life events and incorporate transition in different personal and social settings. External response is observed and allows the individual to experience everyday life as the gender they identify with. Continuous living in the correct gender role must be documented by a behavioral health specialist (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

20:
I/O Setting:
Bilateral Mastectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Clitoroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Hysterectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Intersex Surgery - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Metoidioplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Ovariectomy/Salpingo-oophorectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Phalloplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Scrotoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Urethroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Vaginoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
All others - Outpatient

ICD-10-CM (circle all that apply): F64.0, F64.1, F64.2, F64.8, F64.9, Z87.890, Other _____

CPT® (circle all that apply): 55899, Other _____

InterQual®

2021, Apr. 2021 Release CP:Procedures

Subset: Gender Affirmation Surgery (1, 2, 3, 4, 5, 6, 7, 8)

Requested Service: Orchiectomy for Gender Affirmation Surgery

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Primary gender affirmation surgery

1. Strong and persistent cross-gender identification ≥ 6 months (9)
   - ☐ A) Yes
   - ☐ B) No

   • If option Yes selected, then go to question 2
   • No other options lead to the requested service

2. Choose all that apply: (9)
   - ☐ A) Marked incongruence between experienced or expressed gender and primary or secondary sex characteristics
   - ☐ B) Strong desire to not have current primary or secondary sex characteristics because of the incongruence with experienced or expressed gender
   - ☐ C) Strong desire to have primary or secondary sex characteristics of the other gender
   - ☐ D) Strong desire to be the other gender or an alternative gender
   - ☐ E) Strong desire to be treated as the other gender
   - ☐ F) Strong confidence that typical feelings and reactions are of the other gender
   - ☐ G) Other clinical information (add comment)

   • If 2 or more options A, B, C, D, E or F selected and option G not selected, then go to question 3
   • No other options lead to the requested service

Primary gender affirmation surgery (continued...)

3. Choose all that apply: [9]
   - ☐ A) Clinically significant distress or impairment in social or occupational or other important areas of functioning
   - ☐ B) Clinically significant increased risk of suffering
   - ☐ C) Other clinical information (add comment)

   • If 1 or more options A or B selected and option C not selected, then go to question 4
   • No other options lead to the requested service

4. Gender affirmation surgery, Choose one:
   - ☐ A) Female-to-male surgery, genital [10, 11]
   - ☐ B) Female-to-male surgery, other [10, 11]
   - ☐ C) Male-to-female surgery, genital [12, 13]
   - ☐ D) Male-to-female surgery, other [12, 13]
   - ☐ E) Other clinical information (add comment)

   • If option C selected, then go to question 5
   • No other options lead to the requested service

5. Choose all that apply:
   - ☐ A) Referrals from two behavioral health specialists clearing patient for gender affirmation surgery [14, 15]
   - ☐ B) Persistent and well-documented gender dysphoria [14]
   - ☐ C) Capacity to make fully informed decisions and to consent [14]
   - ☐ D) No psychiatric disorder by history or psychiatric disorder controlled [16, 17]
   - ☐ E) Other clinical information (add comment)

   • If the number of options selected is 4 and option E not selected, then go to question 6
   • No other options lead to the requested service

6. Choose all that apply:
   - ☐ A) Cross-sex hormone therapy ≥ 12 months or hormone therapy contraindicated [18]
   - ☐ B) Lived ≥ 12 months in gender role congruent with gender identity [19]
   - ☐ C) Other clinical information (add comment)

   • If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here **(Outpatient)** [20]
   • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
Delaying treatment for those with gender dysphoria is not a reasonable treatment option. This can lead to negative consequences, such as delay or arrest in emotional, social, or intellectual development. Isolating oneself from family and friends, being excluded from society, becoming a victim of bullying and self-harm all may be seen when there is an impediment or interruption in care. Some individuals, notably adolescents, may develop psychiatric issues including anxiety, depression, and suicidal ideation (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

3:
Guidelines agree that gender affirmation surgical intervention is appropriate for individuals 18 years of age or older, as these procedures are irreversible; however, behavioral health counseling and hormone therapy may be used to treat individuals who have been diagnosed with gender dysphoria at an earlier age. The sooner the diagnosis is made and treatment options are discussed, the more successful the individual is when transitioning (Hembree et al., Endocr Pract 2017, 23: 1437; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

4:
According to the American Psychiatric Association, the Diagnostic and Statistical Manual of Mental Disorders defines gender dysphoria as a condition where sex assigned at birth is incongruent with experienced or desired gender, resulting in distress and suffering. Distress must persist for at least six months and result in a desire to change (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). Transgender persons are described as someone whose gender identity, behavior or expression, is not typical of that assigned at birth, including those who are gender dysphoric. In the United States, approximately 0.6%, or 1.4 million adults identify as transgender individuals. The prevalence is similar worldwide and has doubled in the last decade (Flores et al., How many adults identify as Transgender in the United States? 2016).
Therapeutic options for gender dysphoria or transgender individuals include psychotherapy, hormonal treatment, and gender affirmation surgery (GAS). Dressing, acting, or speaking consistent with the correct gender, taking hormones, changing one's name, and surgical intervention are possible activities carried out to identify with the correct gender. Some transgender individuals do not define themselves as conforming to the gender binary (male or female) and may also use terms such as gender non-conforming, pangender, agender, bigender, polygender, gender fluid, gender queer, or gender neutral. This will impact their treatment choices (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013).
GAS is a treatment option for gender dysphoria and is often the final stage of transition. GAS is not a single procedure, but part of a complex process involving multiple medical, psychiatric, and surgical modalities working in conjunction with each other to assist the candidate for gender affirmation achieve successful outcomes. Before undertaking GAS, candidates need to undergo important medical and psychological evaluations to confirm that surgery is the most appropriate treatment choice. Procedures vary significantly from female-to-male and male-to-female and are generally comprised of a series of primary and secondary sex character changes, chest reconstruction, facial alterations and voice-modification. After working with a transgender care team, a surgical plan is tailored to the individual's needs to relieve gender dysphoria. Treatment standardization in this population is not possible as clinical presentations and symptoms will vary significantly with each individual. A specialized, multidisciplinary transgender care team may include, but is not limited to, practitioners in primary care, behavioral health, speech and language therapy, dermatology, endocrinology, urology, gynecology, and plastic surgery. Collaborative care, joint participation in goal setting along with regular follow-up is crucial (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional

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5:
Although there are many publications on gender affirmation surgery (GAS), most articles are observational case studies, have less than 30 participants, do not have strong evidence, or are focused on surgical technique. There is a paucity of published evidence that is adequately powered or designed to allow definitive conclusions on safety and efficacy of the individual surgical procedures. Surgical technique and observational case studies represent the largest body of evidence. Future research is needed to improve patient selection, surgical procedure selection and patient outcome.

Statistics around GAS are primarily estimations. Private facilities are not mandated to report this data; there are variations on how surgical procedures are staged and many of the procedures are identified as simply cosmetic, therefore making data collection difficult. In addition, the complexity and various reconstructive scenarios distinguishing procedures with multiple stages from revisional affirmation surgery is not truly accounted for. Although estimates vary, the American Society of Plastic Surgeons stated that there was a 155% increase in gender affirmation surgeries in 2017, approximating over 8,300 facial, body contouring and sex surgeries (American Society of Plastic Surgeons, 2017 Plastic Surgery Statistics Report. 2018).

6:
These criteria include the following procedures:

Bilateral Mastectomy
Breast Augmentation
Clitoroplasty
Gender Confirmation Surgery
Gender Reassignment Surgery
Hysterectomy
Intersex Surgery
Labiaplasty
Male Chest Contouring
Metoidioplasty
Orchiectomy
Ovariectomy
Penectomy
Penile Prosthesis
Permanent Hair Removal
Phalloplasty
Salpingo-oophorectomy
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19:
Living in the preferred gender role congruent with gender identity is a key component to successful transition prior to irreversible genital intervention. A minimum of twelve months is required to experience life events and incorporate transition in different personal and social settings. External response is observed and allows the individual to experience everyday life as the gender they identify with. Continuous living in the correct gender role must be documented by a behavioral health specialist (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

20:
I/O Setting:
Bilateral Mastectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Clitoroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Hysterectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Intersex Surgery - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Metoidioplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Ovariectomy/Salpingo-oophorectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Phalloplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Scrotoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Urethroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Vaginoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
All others - Outpatient

ICD-10-CM (circle all that apply): F64.0, F64.1, F64.2, F64.8, F64.9, Z87.890, Other _____

ICD-10-PCS (circle all that apply): 0VT90ZZ, 0VT94ZZ, 0VTB0ZZ, 0VTB4ZZ, 0VTC0ZZ, 0VTC4ZZ, Other _____

CPT® (circle all that apply): 54520, 54690, Other _____

2021, Apr. 2021 Release CP:Procedures

Subset: Gender Affirmation Surgery (1, 2, 3, 4, 5, 6, 7, 8)

Requested Service: Ovariectomy/Salpingo-oophorectomy for Gender Affirmation Surgery

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Primary gender affirmation surgery

1. Strong and persistent cross-gender identification ≥ 6 months (9)
   - ☐ A) Yes
   - ☐ B) No

   • If option Yes selected, then go to question 2
   • No other options lead to the requested service

2. Choose all that apply: (9)
   - ☐ A) Marked incongruence between experienced or expressed gender and primary or secondary sex characteristics
   - ☐ B) Strong desire to not have current primary or secondary sex characteristics because of the incongruence with experienced or expressed gender
   - ☐ C) Strong desire to have primary or secondary sex characteristics of the other gender
   - ☐ D) Strong desire to be the other gender or an alternative gender
   - ☐ E) Strong desire to be treated as the other gender
   - ☐ F) Strong confidence that typical feelings and reactions are of the other gender
   - ☐ G) Other clinical information (add comment)

   • If 2 or more options A, B, C, D, E or F selected and option G not selected, then go to question 3
   • No other options lead to the requested service

Primary gender affirmation surgery (continued...)

3. Choose all that apply: [9]
   - ☐ A) Clinically significant distress or impairment in social or occupational or other important areas of functioning
   - ☐ B) Clinically significant increased risk of suffering
   - ☐ C) Other clinical information (add comment)

   • If 1 or more options A or B selected and option C not selected, then go to question 4
   • No other options lead to the requested service

4. Gender affirmation surgery, Choose one:
   - ☐ A) Female-to-male surgery, genital [10, 11]
   - ☐ B) Female-to-male surgery, other [10, 11]
   - ☐ C) Male-to-female surgery, genital [12, 13]
   - ☐ D) Male-to-female surgery, other [12, 13]
   - ☐ E) Other clinical information (add comment)

   • If option A selected, then go to question 5
   • No other options lead to the requested service

5. Choose all that apply:
   - ☐ A) Referrals from two behavioral health specialists clearing patient for gender affirmation surgery [14, 15]
   - ☐ B) Persistent and well-documented gender dysphoria [14]
   - ☐ C) Capacity to make fully informed decisions and to consent [14]
   - ☐ D) No psychiatric disorder by history or psychiatric disorder controlled [16, 17]
   - ☐ E) Other clinical information (add comment)

   • If the number of options selected is 4 and option E not selected, then go to question 6
   • No other options lead to the requested service

6. Choose all that apply:
   - ☐ A) Cross-sex hormone therapy ≥ 12 months or hormone therapy contraindicated [18]
   - ☐ B) Lived ≥ 12 months in gender role congruent with gender identity [19]
   - ☐ C) Other clinical information (add comment)

   • If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here [20]
   • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
Delaying treatment for those with gender dysphoria is not a reasonable treatment option. This can lead to negative consequences, such as delay or arrest in emotional, social, or intellectual development. Isolating oneself from family and friends, being excluded from society, becoming a victim of bullying and self-harm all may be seen when there is an impediment or interruption in care. Some individuals, notably adolescents, may develop psychiatric issues including anxiety, depression, and suicidal ideation (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

3:
Guidelines agree that gender affirmation surgical intervention is appropriate for individuals 18 years of age or older, as these procedures are irreversible; however, behavioral health counseling and hormone therapy may be used to treat individuals who have been diagnosed with gender dysphoria at an earlier age. The sooner the diagnosis is made and treatment options are discussed, the more successful the individual is when transitioning (Hembree et al., Endocr Pract 2017, 23: 1437; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

4:
According to the American Psychiatric Association, the Diagnostic and Statistical Manual of Mental Disorders defines gender dysphoria as a condition where sex assigned at birth is incongruent with experienced or desired gender, resulting in distress and suffering. Distress must persist for at least six months and result in a desire to change (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). Transgender persons are described as someone whose gender identity, behavior or expression, is not typical of that assigned at birth, including those who are gender dysphoric. In the United States, approximately 0.6%, or 1.4 million adults identify as transgender individuals. The prevalence is similar worldwide and has doubled in the last decade (Flores et al., How many adults identify as Transgender in the United States? 2016).
Therapeutic options for gender dysphoria or transgender individuals include psychotherapy, hormonal treatment, and gender affirmation surgery (GAS). Dressing, acting, or speaking consistent with the correct gender, taking hormones, changing one's name, and surgical intervention are possible activities carried out to identify with the correct gender. Some transgender individuals do not define themselves as conforming to the gender binary (male or female) and may also use terms such as gender non-conforming, pangender, agender, bigender, polygender, gender fluid, gender queer, or gender neutral. This will impact their treatment choices (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013).
GAS is a treatment option for gender dysphoria and is often the final stage of transition. GAS is not a single procedure, but part of a complex process involving multiple medical, psychiatric, and surgical modalities working in conjunction with each other to assist the candidate for gender affirmation achieve successful outcomes. Before undertaking GAS, candidates need to undergo important medical and psychological evaluations to confirm that surgery is the most appropriate treatment choice. Procedures vary significantly from female-to-male and male-to-female and are generally comprised of a series of primary and secondary sex character changes, chest reconstruction, facial alterations and voice-modification. After working with a transgender care team, a surgical plan is tailored to the individual's needs to relieve gender dysphoria. Treatment standardization in this population is not possible as clinical presentations and symptoms will vary significantly with each individual. A specialized, multidisciplinary transgender care team may include, but is not limited to, practitioners in primary care, behavioral health, speech and language therapy, dermatology, endocrinology, urology, gynecology, and plastic surgery. Collaborative care, joint participation in goal setting along with regular follow-up is crucial (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional

Association for Transgender Health. 2011, 7: 1-112).

5:
Although there are many publications on gender affirmation surgery (GAS), most articles are observational case studies, have less than 30 participants, do not have strong evidence, or are focused on surgical technique. There is a paucity of published evidence that is adequately powered or designed to allow definitive conclusions on safety and efficacy of the individual surgical procedures. Surgical technique and observational case studies represent the largest body of evidence. Future research is needed to improve patient selection, surgical procedure selection and patient outcome.

Statistics around GAS are primarily estimations. Private facilities are not mandated to report this data; there are variations on how surgical procedures are staged and many of the procedures are identified as simply cosmetic, therefore making data collection difficult. In addition, the complexity and various reconstructive scenarios distinguishing procedures with multiple stages from revisional affirmation surgery is not truly accounted for. Although estimates vary, the American Society of Plastic Surgeons stated that there was a 155% increase in gender affirmation surgeries in 2017, approximating over 8,300 facial, body contouring and sex surgeries (American Society of Plastic Surgeons, 2017 Plastic Surgery Statistics Report. 2018).

6:
These criteria include the following procedures:

Bilateral Mastectomy
Breast Augmentation
Clitoroplasty
Gender Confirmation Surgery
Gender Reassignment Surgery
Hysterectomy
Intersex Surgery
Labiaplasty
Male Chest Contouring
Metoidioplasty
Orchiectomy
Ovariectomy
Penectomy
Penile Prosthesis
Permanent Hair Removal
Phalloplasty
Salpingo-oophorectomy
Scrotoplasty
Sex Reassignment Surgery
Transgender Surgery
Transsexual Surgery
Urethroplasty
Vaginoplasty
Vulvoplasty

7:
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

8:

This is a procedure that can be performed for either medically necessary or cosmetic purposes. The criteria as written are intended solely for use in determining the medical appropriateness of this procedure and do not cover this procedure when performed for cosmetic reasons.

9:
Prior to surgical intervention for gender affirmation, gender dysphoria must be present as outlined by the Diagnostic and Statistical Manual of Mental Disorders. If a pronounced distress between the assigned gender at birth and the gender that is desired persists for at least six months, and there is significant distress in social or occupational settings, the diagnosis of gender dysphoria can be made. It is accompanied by marked incongruence between experienced or expressed gender and sex characteristics, strong desire to be an alternate gender, strong desire to be treated as the other gender, to not have or to change assigned sex characteristics, or having strong confidence that typical feelings are of the other gender (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013). InterQual® consultants agree that the Diagnostic and Statistical Manual of Mental Disorders is the most widely accepted for the diagnosis of gender dysphoria.

10:
The most common female-to-male (FtM) genital procedures include hysterectomy, ovariectomy, salpingo-oophorectomy, metoidioplasty, phalloplasty, penile prosthesis, scrotoplasty, and urethroplasty. Permanent hair removal can be done prior to a number of genital surgeries.

The most common FtM chest procedures are mastectomy and male chest contouring. There are also various body contouring, facial and voice modification surgeries (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

11:
Surgical risks in female-to-male (FtM) genital and breast surgeries include, but are not limited to, infection, unsightly scarring, nipple necrosis, contour irregularities, urinary tract stenosis, fistulas, necrosis of neophallus, micropenis, and incapacity to stand while urinating. FtM genital surgery has been less successful than male-to-female genital surgery because of the difficulty creating a functional and aesthetic penis from smaller clitoral tissue (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

12:
The most common male-to-female (MtF) genital procedures include orchiectomy, penectomy, clitoroplasty, labiaplasty, urethroplasty, vaginoplasty, and vulvoplasty.

The most common MtF chest procedure is breast augmentation. Permanent hair removal can be done prior to a number of genital surgeries. There are also various body contouring, facial and voice modification surgeries that may be appropriate MtF procedures (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

13:
Some surgical risks in male-to-female genital and breast augmentation surgeries include, but are not limited to, infection, capsular fibrosis, partial necrosis of the vagina or labia, fistulas from the bladder or bowel into the vagina, stenosis of the urethra, the vagina being too short or small for coitus, anorgasmia, lower urinary tract infection from a shortened urethra, and dysfunctional bladder (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

14:
Therapy is intended to explore gender concerns, assess the intensity of and help alleviate gender dysphoria, assist in determining appropriate subsequent steps in treatment, assess existing mental health concerns, and evaluate outcomes of interventions (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). A behavioral health specialist must document persistent gender dysphoria, the ability to make fully informed decisions, and assure there are no active psychiatric disorders to impede decision making or interfere with successful postoperative care (Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). The individual should be assessed before surgery and demonstrate an understanding of the procedure, surgical options, and potential risks and outcomes. The patient should be aware of the risk of sterility as a result of hormone therapy and gender affirmation surgery. Discussions regarding fertility preservation options prior to these interventions, as well as ongoing oncological risk monitoring, are necessary (Hembree et al., Endocr

Pract 2017, 23: 1437; Wylie et al., Lancet 2016, 388: 401-11; American Psychological, Am Psychol 2015, 70: 832-64; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). There is no recommended length of therapy or number of sessions an individual must attend or complete preceding surgery. It is however, strongly suggested that transgender individuals have access to therapy throughout the process as it can be a supportive adjunct to gender affirming surgery (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

15:
It is required that individuals seeking chest or breast surgery, to treat gender dysphoria, submit one referral letter from a behavioral health specialist to the surgeon stating psychotherapy requisites have been met. Surgeons generally require two referral letters before proceeding with genital surgery. It is recommended that at least one of the behavioral health professionals submitting a letter should have a doctoral degree (e.g., Ph.D., M.D., Ed.D., D.Sc., D.S.W., Psy.D) or a master's level degree in a clinical behavioral science field (e.g., M.S.W., L.C.S.W., Nurse Practitioner, Advanced Practice Nurse, Licensed Professional Councilor, Marriage and Family Therapist). Since there is not a standardized letter format outlining specific content that needs to be communicated between the behavioral health specialist and surgeon, letter writing varies. Often, referrals will include diagnostic criteria of gender dysphoria from the Diagnostic and Statistical Manual of Mental Disorders, standards of care met from The World Professional Association for Transgender Health, the individual's duration and compliance with therapy, as well as an understanding of procedures, individual readiness and consent. Typically, an explanation that the criteria for surgery have been met and a brief description of the clinical rationale for supporting the individual's request for surgery are also recorded. Ideally, the mental health professional should document willingness to coordinate care with the primary and surgical care team (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

16:
A significant number of gender dysphoric patients have a history of diagnosed or undiagnosed psychopathology including substance abuse, post-traumatic stress disorder, mood disorders, and anxiety. Although no specific conditions are exclusionary, all patients should be screened to ensure stability and a complete understanding of the procedure and postoperative follow-up. Depression may occur anytime throughout the transition process and individuals are encouraged to continue with psychotherapy during and after transition as needed (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Dhejne et al., Int Rev Psychiatry 2016, 28: 44-57; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

17:
Symptoms or behaviors are considered to be controlled when they have responded to therapeutic and/or pharmacologic interventions.

18:
Surgical intervention should not be performed until the patient is 18 years or older. Hormone therapy, however, may begin sooner if not contraindicated. Guidelines suggest pubertal suppression can begin at Tanner stage 2 as better outcomes are seen when initiated with puberty. These guidelines do not agree on an age to begin cross-sex hormone therapy, but do agree that cross-sex hormone therapy should be taken for at least 12 months prior to genital surgery and female-to-male (FtM) mastectomy, and male chest contouring. For best results in male-to-female (MtF) breast augmentation surgery, some guidelines suggest at least 2 years of cross-sex hormone therapy because breasts continue to grow during this time, while others agree 12 months is sufficient (Hembree et al., Endocr Pract 2017, 23: 1437; Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

Pubertal suppressing hormones halt gonadotropin secretion and lead to gradual regression of development of sex characteristics. Girls breasts will not continue to grow and will reduce in size, and menstruation will stop. Boys will experience a cessation in virilization and decreased testicular volume. The effects of these hormones are fully reversible. If the patient has surpassed puberty, cross-sex hormone therapy can begin. Cross-sex hormone therapy leads to the development of opposing sex characteristics and is only partially reversible. In FtM patients, the aim of cross-sex hormone therapy is to cause gradual clitoral enlargement, vaginal atrophy, fat redistribution, voice deepening, facial and body hair growth, suppress menses as well as increase libido, muscle mass and height. The goal for MtF individuals is to reduce height, decrease libido, grow breasts, redistribute body fat, decrease muscle mass, and soften the skin (Hembree et al., Endocr Pract 2017, 23: 1437).

A systematic review reports that hormonal treatment improves depression, self-esteem, anxiety, personality-related psychopathology, and higher emotional quality of life in both FtM and MtF patients. This review also suggests improved body uneasiness in MtF. Many individuals do not continue with affirmation surgery if hormone therapy and other lifestyle changes have significantly decreased gender dysphoria (Costa and Colizzi, Neuropsychiatr Dis Treat 2016, 12: 1953-66).

19:
Living in the preferred gender role congruent with gender identity is a key component to successful transition prior to irreversible genital intervention. A minimum of twelve months is required to experience life events and incorporate transition in different personal and social settings. External response is observed and allows the individual to experience everyday life as the gender they identify with. Continuous living in the correct gender role must be documented by a behavioral health specialist (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

20:
I/O Setting:
Bilateral Mastectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Clitoroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Hysterectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Intersex Surgery - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Metoidioplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Ovariectomy/Salpingo-oophorectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Phalloplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Scrotoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Urethroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Vaginoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
All others - Outpatient

ICD-10-CM (circle all that apply): F64.0, F64.1, F64.2, F64.8, F64.9, Z87.890, Other _____

ICD-10-PCS (circle all that apply): 0UT00ZZ, 0UT04ZZ, 0UT08ZZ, 0UT0FZZ, 0UT10ZZ, 0UT14ZZ, 0UT18ZZ, 0UT1FZZ, 0UT20ZZ, 0UT24ZZ, 0UT27ZZ, 0UT28ZZ, 0UT2FZZ, 0UT50ZZ, 0UT54ZZ, 0UT57ZZ, 0UT58ZZ, 0UT5FZZ, 0UT60ZZ, 0UT64ZZ, 0UT67ZZ, 0UT68ZZ, 0UT6FZZ, 0UT70ZZ, 0UT74ZZ, 0UT77ZZ, 0UT78ZZ, 0UT7FZZ, Other _____

CPT® (circle all that apply): 58661, 58700, 58720, 58953, 58956, Other _____

InterQual®

2021, Apr. 2021 Release CP:Procedures

Subset: Gender Affirmation Surgery (1, 2, 3, 4, 5, 6, 7, 8)

Requested Service: Vaginoplasty for Gender Affirmation Surgery

Age: Age ≥ 18

Exhibit
Ex 0018

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:	Date:	
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Primary gender affirmation surgery

1. Strong and persistent cross gender identification ≥ 6 months (9)
   - ☐ A) Yes
   - ☐ B) No

   • If option Yes selected, then go to question 2
   • No other options lead to the requested service

2. Choose all that apply: (9)
   - ☐ A) Marked incongruence between experienced or expressed gender and primary or secondary sex characteristics
   - ☐ B) Strong desire to not have current primary or secondary sex characteristics because of the incongruence with experienced or expressed gender
   - ☐ C) Strong desire to have primary or secondary sex characteristics of the other gender
   - ☐ D) Strong desire to be the other gender or an alternative gender
   - ☐ E) Strong desire to be treated as the other gender
   - ☐ F) Strong confidence that typical feelings and reactions are of the other gender
   - ☐ G) Other clinical information (add comment)

   • If 2 or more options A, B, C, D, E or F selected and option G not selected, then go to question 3
   • No other options lead to the requested service

Primary gender affirmation surgery (continued...)

3. Choose all that apply: [9]
   - ☐ A) Clinically significant distress or impairment in social or occupational or other important areas of functioning
   - ☐ B) Clinically significant increased risk of suffering
   - ☐ C) Other clinical information (add comment)

   • If 1 or more options A or B selected and option C not selected, then go to question 4
   • No other options lead to the requested service

4. Gender affirmation surgery, Choose one:
   - ☐ A) Female-to-male surgery, genital [10, 11]
   - ☐ B) Female-to-male surgery, other [10, 11]
   - ☐ C) Male-to-female surgery, genital [12, 13]
   - ☐ D) Male-to-female surgery, other [12, 13]
   - ☐ E) Other clinical information (add comment)

   • If option C selected, then go to question 5
   • No other options lead to the requested service

5. Choose all that apply:
   - ☐ A) Referrals from two behavioral health specialists clearing patient for gender affirmation surgery [14, 15]
   - ☐ B) Persistent and well-documented gender dysphoria [14]
   - ☐ C) Capacity to make fully informed decisions and to consent [14]
   - ☐ D) No psychiatric disorder by history or psychiatric disorder controlled [16, 17]
   - ☐ E) Other clinical information (add comment)

   • If the number of options selected is 4 and option E not selected, then go to question 6
   • No other options lead to the requested service

6. Choose all that apply:
   - ☐ A) Cross-sex hormone therapy ≥ 12 months or hormone therapy contraindicated [18]
   - ☐ B) Lived ≥ 12 months in gender role congruent with gender identity [19]
   - ☐ C) Other clinical information (add comment)

   • If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here [20]
   • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
Delaying treatment for those with gender dysphoria is not a reasonable treatment option. This can lead to negative consequences, such as delay or arrest in emotional, social, or intellectual development. Isolating oneself from family and friends, being excluded from society, becoming a victim of bullying and self-harm all may be seen when there is an impediment or interruption in care. Some individuals, notably adolescents, may develop psychiatric issues including anxiety, depression, and suicidal ideation (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

3:
Guidelines agree that gender affirmation surgical intervention is appropriate for individuals 18 years of age or older, as these procedures are irreversible; however, behavioral health counseling and hormone therapy may be used to treat individuals who have been diagnosed with gender dysphoria at an earlier age. The sooner the diagnosis is made and treatment options are discussed, the more successful the individual is when transitioning (Hembree et al., Endocr Pract 2017, 23: 1437; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

4:
According to the American Psychiatric Association, the Diagnostic and Statistical Manual of Mental Disorders defines gender dysphoria as a condition where sex assigned at birth is incongruent with experienced or desired gender, resulting in distress and suffering. Distress must persist for at least six months and result in a desire to change (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). Transgender persons are described as someone whose gender identity, behavior or expression, is not typical of that assigned at birth, including those who are gender dysphoric. In the United States, approximately 0.6%, or 1.4 million adults identify as transgender individuals. The prevalence is similar worldwide and has doubled in the last decade (Flores et al., How many adults identify as Transgender in the United States? 2016).
Therapeutic options for gender dysphoria or transgender individuals include psychotherapy, hormonal treatment, and gender affirmation surgery (GAS). Dressing, acting, or speaking consistent with the correct gender, taking hormones, changing one's name, and surgical intervention are possible activities carried out to identify with the correct gender. Some transgender individuals do not define themselves as conforming to the gender binary (male or female) and may also use terms such as gender non-conforming, pangender, agender, bigender, polygender, gender fluid, gender queer, or gender neutral. This will impact their treatment choices (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013).
GAS is a treatment option for gender dysphoria and is often the final stage of transition. GAS is not a single procedure, but part of a complex process involving multiple medical, psychiatric, and surgical modalities working in conjunction with each other to assist the candidate for gender affirmation achieve successful outcomes. Before undertaking GAS, candidates need to undergo important medical and psychological evaluations to confirm that surgery is the most appropriate treatment choice. Procedures vary significantly from female-to-male and male-to-female and are generally comprised of a series of primary and secondary sex character changes, chest reconstruction, facial alterations and voice-modification. After working with a transgender care team, a surgical plan is tailored to the individual's needs to relieve gender dysphoria. Treatment standardization in this population is not possible as clinical presentations and symptoms will vary significantly with each individual. A specialized, multidisciplinary transgender care team may include, but is not limited to, practitioners in primary care, behavioral health, speech and language therapy, dermatology, endocrinology, urology, gynecology, and plastic surgery. Collaborative care, joint participation in goal setting along with regular follow-up is crucial (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional

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These criteria include the following procedures:

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Clitoroplasty
Gender Confirmation Surgery
Gender Reassignment Surgery
Hysterectomy
Intersex Surgery
Labiaplasty
Male Chest Contouring
Metoidioplasty
Orchiectomy
Ovariectomy
Penectomy
Penile Prosthesis
Permanent Hair Removal
Phalloplasty
Salpingo-oophorectomy
Scrotoplasty
Sex Reassignment Surgery
Transgender Surgery
Transsexual Surgery
Urethroplasty
Vaginoplasty
Vulvoplasty

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InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

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This is a procedure that can be performed for either medically necessary or cosmetic purposes. The criteria as written are intended solely for use in determining the medical appropriateness of this procedure and do not cover this procedure when performed for cosmetic reasons.

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Prior to surgical intervention for gender affirmation, gender dysphoria must be present as outlined by the Diagnostic and Statistical Manual of Mental Disorders. If a pronounced distress between the assigned gender at birth and the gender that is desired persists for at least six months, and there is significant distress in social or occupational settings, the diagnosis of gender dysphoria can be made. It is accompanied by marked incongruence between experienced or expressed gender and sex characteristics, strong desire to be an alternate gender, strong desire to be treated as the other gender, to not have or to change assigned sex characteristics, or having strong confidence that typical feelings are of the other gender (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013). InterQual® consultants agree that the Diagnostic and Statistical Manual of Mental Disorders is the most widely accepted for the diagnosis of gender dysphoria.

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The most common female-to-male (FtM) genital procedures include hysterectomy, ovariectomy, salpingo-oophorectomy, metoidioplasty, phalloplasty, penile prosthesis, scrotoplasty, and urethroplasty. Permanent hair removal can be done prior to a number of genital surgeries.

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The most common male-to-female (MtF) genital procedures include orchiectomy, penectomy, clitoroplasty, labiaplasty, urethroplasty, vaginoplasty, and vulvoplasty.

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Some surgical risks in male-to-female genital and breast augmentation surgeries include, but are not limited to, infection, capsular fibrosis, partial necrosis of the vagina or labia, fistulas from the bladder or bowel into the vagina, stenosis of the urethra, the vagina being too short or small for coitus, anorgasmia, lower urinary tract infection from a shortened urethra, and dysfunctional bladder (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

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Therapy is intended to explore gender concerns, assess the intensity of and help alleviate gender dysphoria, assist in determining appropriate subsequent steps in treatment, assess existing mental health concerns, and evaluate outcomes of interventions (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). A behavioral health specialist must document persistent gender dysphoria, the ability to make fully informed decisions, and assure there are no active psychiatric disorders to impede decision making or interfere with successful postoperative care (Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). The individual should be assessed before surgery and demonstrate an understanding of the procedure, surgical options, and potential risks and outcomes. The patient should be aware of the risk of sterility as a result of hormone therapy and gender affirmation surgery. Discussions regarding fertility preservation options prior to these interventions, as well as ongoing oncological risk monitoring, are necessary (Hembree et al., Endocr

Pract 2017, 23: 1437; Wylie et al., Lancet 2016, 388: 401-11; American Psychological, Am Psychol 2015, 70: 832-64; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). There is no recommended length of therapy or number of sessions an individual must attend or complete preceding surgery. It is however, strongly suggested that transgender individuals have access to therapy throughout the process as it can be a supportive adjunct to gender affirming surgery (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

15:
It is required that individuals seeking chest or breast surgery, to treat gender dysphoria, submit one referral letter from a behavioral health specialist to the surgeon stating psychotherapy requisites have been met. Surgeons generally require two referral letters before proceeding with genital surgery. It is recommended that at least one of the behavioral health professionals submitting a letter should have a doctoral degree (e.g., Ph.D., M.D., Ed.D., D.Sc., D.S.W., Psy.D) or a master's level degree in a clinical behavioral science field (e.g., M.S.W., L.C.S.W., Nurse Practitioner, Advanced Practice Nurse, Licensed Professional Councilor, Marriage and Family Therapist). Since there is not a standardized letter format outlining specific content that needs to be communicated between the behavioral health specialist and surgeon, letter writing varies. Often, referrals will include diagnostic criteria of gender dysphoria from the Diagnostic and Statistical Manual of Mental Disorders, standards of care met from The World Professional Association for Transgender Health, the individual's duration and compliance with therapy, as well as an understanding of procedures, individual readiness and consent. Typically, an explanation that the criteria for surgery have been met and a brief description of the clinical rationale for supporting the individual's request for surgery are also recorded. Ideally, the mental health professional should document willingness to coordinate care with the primary and surgical care team (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

16:
A significant number of gender dysphoric patients have a history of diagnosed or undiagnosed psychopathology including substance abuse, post-traumatic stress disorder, mood disorders, and anxiety. Although no specific conditions are exclusionary, all patients should be screened to ensure stability and a complete understanding of the procedure and postoperative follow-up. Depression may occur anytime throughout the transition process and individuals are encouraged to continue with psychotherapy during and after transition as needed (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Dhejne et al., Int Rev Psychiatry 2016, 28: 44-57; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

17:
Symptoms or behaviors are considered to be controlled when they have responded to therapeutic and/or pharmacologic interventions.

18:
Surgical intervention should not be performed until the patient is 18 years or older. Hormone therapy, however, may begin sooner if not contraindicated. Guidelines suggest pubertal suppression can begin at Tanner stage 2 as better outcomes are seen when initiated with puberty. These guidelines do not agree on an age to begin cross-sex hormone therapy, but do agree that cross-sex hormone therapy should be taken for at least 12 months prior to genital surgery and female-to-male (FtM) mastectomy, and male chest contouring. For best results in male-to-female (MtF) breast augmentation surgery, some guidelines suggest at least 2 years of cross-sex hormone therapy because breasts continue to grow during this time, while others agree 12 months is sufficient (Hembree et al., Endocr Pract 2017, 23: 1437; Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

Pubertal suppressing hormones halt gonadotropin secretion and lead to gradual regression of development of sex characteristics. Girls breasts will not continue to grow and will reduce in size, and menstruation will stop. Boys will experience a cessation in virilization and decreased testicular volume. The effects of these hormones are fully reversible. If the patient has surpassed puberty, cross-sex hormone therapy can begin. Cross-sex hormone therapy leads to the development of opposing sex characteristics and is only partially reversible. In FtM patients, the aim of cross-sex hormone therapy is to cause gradual clitoral enlargement, vaginal atrophy, fat redistribution, voice deepening, facial and body hair growth, suppress menses as well as increase libido, muscle mass and height. The goal for MtF individuals is to reduce height, decrease libido, grow breasts, redistribute body fat, decrease muscle mass, and soften the skin (Hembree et al., Endocr Pract 2017, 23: 1437).

A systematic review reports that hormonal treatment improves depression, self-esteem, anxiety, personality-related psychopathology, and higher emotional quality of life in both FtM and MtF patients. This review also suggests improved body uneasiness in MtF. Many individuals do not continue with affirmation surgery if hormone therapy and other lifestyle changes have significantly decreased gender dysphoria (Costa and Colizzi, Neuropsychiatr Dis Treat 2016, 12: 1953-66).

19:
Living in the preferred gender role congruent with gender identity is a key component to successful transition prior to irreversible genital intervention. A minimum of twelve months is required to experience life events and incorporate transition in different personal and social settings. External response is observed and allows the individual to experience everyday life as the gender they identify with. Continuous living in the correct gender role must be documented by a behavioral health specialist (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

20:
I/O Setting:
Bilateral Mastectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Clitoroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Hysterectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Intersex Surgery - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Metoidioplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Ovariectomy/Salpingo-oophorectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Phalloplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Scrotoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Urethroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Vaginoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
All others - Outpatient

ICD-10-CM (circle all that apply): F64.0, F64.1, F64.2, F64.8, F64.9, Z87.890, Other _____

CPT® (circle all that apply): 57335, Other _____

2021, Apr. 2021 Release CP:Procedures

Subset: Gender Affirmation Surgery (1, 2, 3, 4, 5, 6, 7, 8)

Requested Service: Hysterectomy for Gender Affirmation Surgery

Age: Age ≥ 18

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorization: / / to / /	

ICD-10:

CPT®:

INSTRUCTIONS: Answer the following questions

☐ 10. Primary gender affirmation surgery

1. Strong and persistent cross-gender identification ≥ 6 months (9)
   - ☐ A) Yes
   - ☐ B) No

   • If option Yes selected, then go to question 2
   • No other options lead to the requested service

2. Choose all that apply: (9)
   - ☐ A) Marked incongruence between experienced or expressed gender and primary or secondary sex characteristics
   - ☐ B) Strong desire to not have current primary or secondary sex characteristics because of the incongruence with experienced or expressed gender
   - ☐ C) Strong desire to have primary or secondary sex characteristics of the other gender
   - ☐ D) Strong desire to be the other gender or an alternative gender
   - ☐ E) Strong desire to be treated as the other gender
   - ☐ F) Strong confidence that typical feelings and reactions are of the other gender
   - ☐ G) Other clinical information (add comment)

   • If 2 or more options A, B, C, D, E or F selected and option G not selected, then go to question 3
   • No other options lead to the requested service

Primary gender affirmation surgery (continued...)

3. Choose all that apply: [9]
   - ☐ A) Clinically significant distress or impairment in social or occupational or other important areas of functioning
   - ☐ B) Clinically significant increased risk of suffering
   - ☐ C) Other clinical information (add comment)

   • If 1 or more options A or B selected and option C not selected, then go to question 4
   • No other options lead to the requested service

4. Gender affirmation surgery, Choose one:
   - ☐ A) Female-to-male surgery, genital [10, 11]
   - ☐ B) Female-to-male surgery, other [10, 11]
   - ☐ C) Male-to-female surgery, genital [12, 13]
   - ☐ D) Male-to-female surgery, other [12, 13]
   - ☐ E) Other clinical information (add comment)

   • If option A selected, then go to question 5
   • No other options lead to the requested service

5. Choose all that apply:
   - ☐ A) Referrals from two behavioral health specialists clearing patient for gender affirmation surgery [14, 15]
   - ☐ B) Persistent and well-documented gender dysphoria [14]
   - ☐ C) Capacity to make fully informed decisions and to consent [14]
   - ☐ D) No psychiatric disorder by history or psychiatric disorder controlled [16, 17]
   - ☐ E) Other clinical information (add comment)

   • If the number of options selected is 4 and option E not selected, then go to question 6
   • No other options lead to the requested service

6. Choose all that apply:
   - ☐ A) Cross-sex hormone therapy ≥ 12 months or hormone therapy contraindicated [18]
   - ☐ B) Lived ≥ 12 months in gender role congruent with gender identity [19]
   - ☐ C) Other clinical information (add comment)

   • If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here [20]
   • No other options lead to the requested service

Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

Notes:

1:
InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:
Delaying treatment for those with gender dysphoria is not a reasonable treatment option. This can lead to negative consequences, such as delay or arrest in emotional, social, or intellectual development. Isolating oneself from family and friends, being excluded from society, becoming a victim of bullying and self-harm all may be seen when there is an impediment or interruption in care. Some individuals, notably adolescents, may develop psychiatric issues including anxiety, depression, and suicidal ideation (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

3:
Guidelines agree that gender affirmation surgical intervention is appropriate for individuals 18 years of age or older, as these procedures are irreversible; however, behavioral health counseling and hormone therapy may be used to treat individuals who have been diagnosed with gender dysphoria at an earlier age. The sooner the diagnosis is made and treatment options are discussed, the more successful the individual is when transitioning (Hembree et al., Endocr Pract 2017, 23: 1437; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

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Pract 2017, 23: 1437; Wylie et al., Lancet 2016, 388: 401-11; American Psychological, Am Psychol 2015, 70: 832-64; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). There is no recommended length of therapy or number of sessions an individual must attend or complete preceding surgery. It is however, strongly suggested that transgender individuals have access to therapy throughout the process as it can be a supportive adjunct to gender affirming surgery (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

15:
It is required that individuals seeking chest or breast surgery, to treat gender dysphoria, submit one referral letter from a behavioral health specialist to the surgeon stating psychotherapy requisites have been met. Surgeons generally require two referral letters before proceeding with genital surgery. It is recommended that at least one of the behavioral health professionals submitting a letter should have a doctoral degree (e.g., Ph.D., M.D., Ed.D., D.Sc., D.S.W., Psy.D) or a master's level degree in a clinical behavioral science field (e.g., M.S.W., L.C.S.W., Nurse Practitioner, Advanced Practice Nurse, Licensed Professional Councilor, Marriage and Family Therapist). Since there is not a standardized letter format outlining specific content that needs to be communicated between the behavioral health specialist and surgeon, letter writing varies. Often, referrals will include diagnostic criteria of gender dysphoria from the Diagnostic and Statistical Manual of Mental Disorders, standards of care met from The World Professional Association for Transgender Health, the individual's duration and compliance with therapy, as well as an understanding of procedures, individual readiness and consent. Typically, an explanation that the criteria for surgery have been met and a brief description of the clinical rationale for supporting the individual's request for surgery are also recorded. Ideally, the mental health professional should document willingness to coordinate care with the primary and surgical care team (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

16:
A significant number of gender dysphoric patients have a history of diagnosed or undiagnosed psychopathology including substance abuse, post-traumatic stress disorder, mood disorders, and anxiety. Although no specific conditions are exclusionary, all patients should be screened to ensure stability and a complete understanding of the procedure and postoperative follow-up. Depression may occur anytime throughout the transition process and individuals are encouraged to continue with psychotherapy during and after transition as needed (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Dhejne et al., Int Rev Psychiatry 2016, 28: 44-57; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

17:
Symptoms or behaviors are considered to be controlled when they have responded to therapeutic and/or pharmacologic interventions.

18:
Surgical intervention should not be performed until the patient is 18 years or older. Hormone therapy, however, may begin sooner if not contraindicated. Guidelines suggest pubertal suppression can begin at Tanner stage 2 as better outcomes are seen when initiated with puberty. These guidelines do not agree on an age to begin cross-sex hormone therapy, but do agree that cross-sex hormone therapy should be taken for at least 12 months prior to genital surgery and female-to-male (FtM) mastectomy, and male chest contouring. For best results in male-to-female (MtF) breast augmentation surgery, some guidelines suggest at least 2 years of cross-sex hormone therapy because breasts continue to grow during this time, while others agree 12 months is sufficient (Hembree et al., Endocr Pract 2017, 23: 1437; Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

Pubertal suppressing hormones halt gonadotropin secretion and lead to gradual regression of development of sex characteristics. Girls breasts will not continue to grow and will reduce in size, and menstruation will stop. Boys will experience a cessation in virilization and decreased testicular volume. The effects of these hormones are fully reversible. If the patient has surpassed puberty, cross-sex hormone therapy can begin. Cross-sex hormone therapy leads to the development of opposing sex characteristics and is only partially reversible. In FtM patients, the aim of cross-sex hormone therapy is to cause gradual clitoral enlargement, vaginal atrophy, fat redistribution, voice deepening, facial and body hair growth, suppress menses as well as increase libido, muscle mass and height. The goal for MtF individuals is to reduce height, decrease libido, grow breasts, redistribute body fat, decrease muscle mass, and soften the skin (Hembree et al., Endocr Pract 2017, 23: 1437).

A systematic review reports that hormonal treatment improves depression, self-esteem, anxiety, personality-related psychopathology, and higher emotional quality of life in both FtM and MtF patients. This review also suggests improved body uneasiness in MtF. Many individuals do not continue with affirmation surgery if hormone therapy and other lifestyle changes have significantly decreased gender dysphoria (Costa and Colizzi, Neuropsychiatr Dis Treat 2016, 12: 1953-66).

19:
Living in the preferred gender role congruent with gender identity is a key component to successful transition prior to irreversible genital intervention. A minimum of twelve months is required to experience life events and incorporate transition in different personal and social settings. External response is observed and allows the individual to experience everyday life as the gender they identify with. Continuous living in the correct gender role must be documented by a behavioral health specialist (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

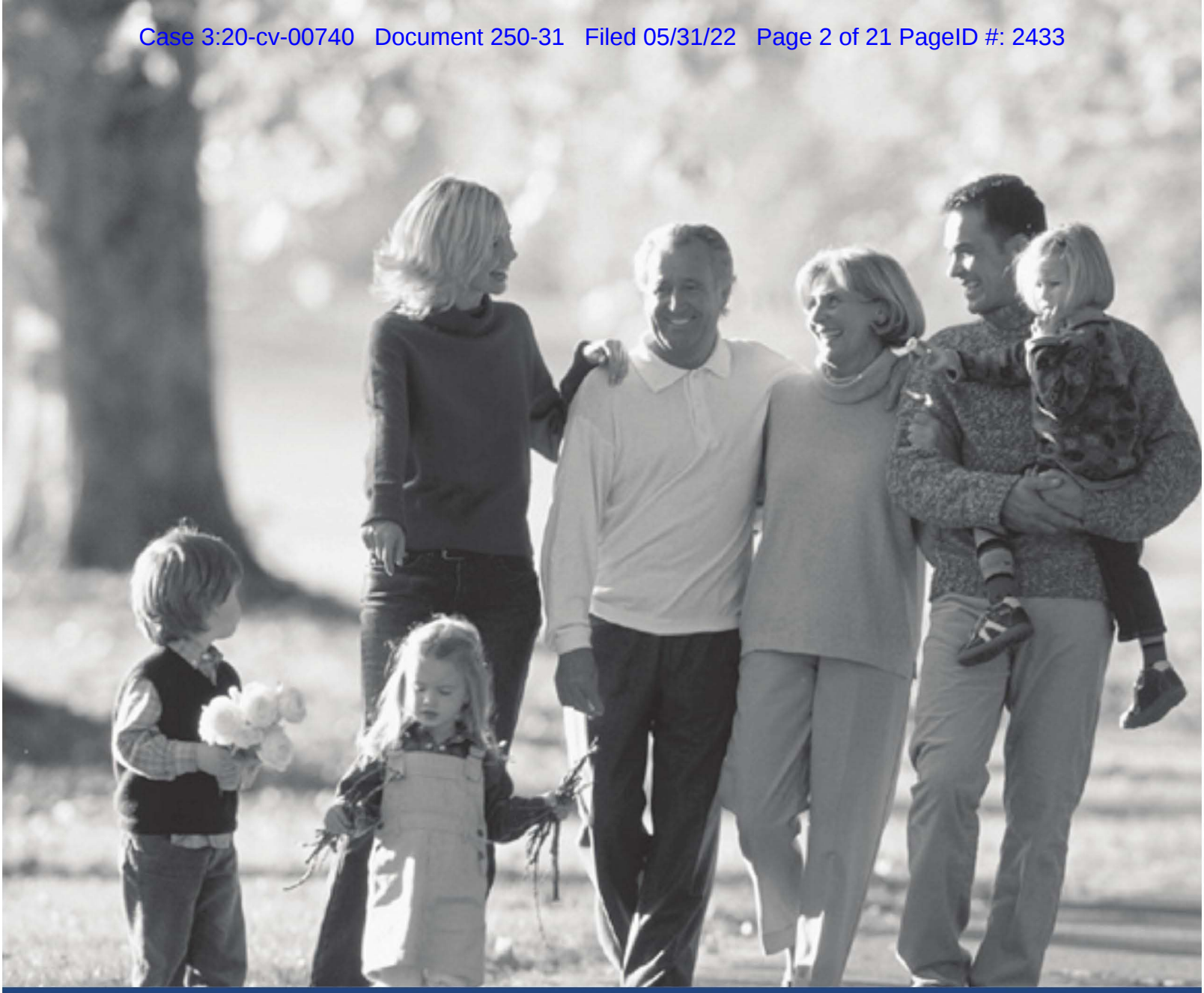
20:
I/O Setting:
Bilateral Mastectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Clitoroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Hysterectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Intersex Surgery - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Metoidioplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Ovariectomy/Salpingo-oophorectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Phalloplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Scrotoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Urethroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
Vaginoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.
All others - Outpatient

ICD-10-CM (circle all that apply): F64.0, F64.1, F64.2, F64.8, F64.9, Z87.890, Other _____

ICD-10-PCS (circle all that apply): 0UT90ZL, 0UT90ZZ, 0UT94ZL, 0UT94ZZ, 0UT97ZL, 0UT97ZZ, 0UT98ZL, 0UT98ZZ, 0UT9FZL, 0UT9FZZ, 0UTC0ZZ, 0UTC4ZZ, 0UTC7ZZ, 0UTC8ZZ, Other _____

CPT® (circle all that apply): 58150, 58180, 58260, 58262, 58275, 58290, 58291, 58541, 58542, 58543, 58544, 58552, 58553, 58554, 58570, 58571, 58572, 58573, Other _____

Exhibit 27



MEDICAID 101

An Overview of West Virginia's Medicaid Program

WEST VIRGINIA Department of Health & Human Resources
BUREAU FOR MEDICAL SERVICES

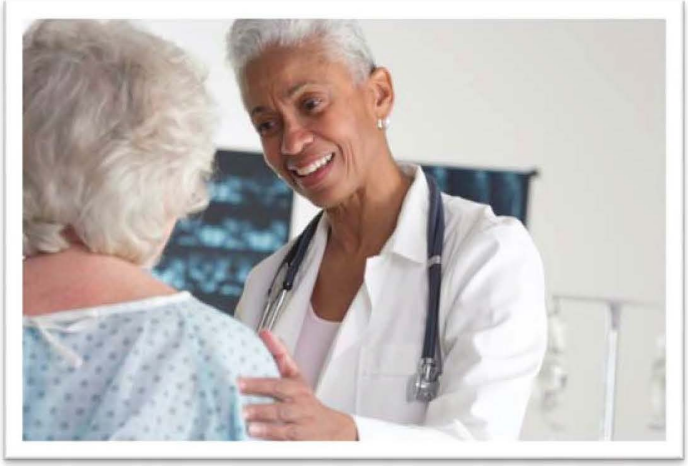
Exhibit 03

Medicaid: The Basics

Medicaid is a public benefit program that provides health insurance and medical services to eligible individuals. Medicaid is financed by state and federal governments and is administered by states. In West Virginia, the Bureau for Medical Services (BMS) within the West Virginia Department of Health and Human Resources (DHHR) is the single state agency responsible for administering the West Virginia Medicaid program.

Across the country, Medicaid is the nation's single largest health insurer, covering more than 73 million individuals in May 2018, or about 22% of the US population.[1] Medicaid contributes substantially to the financing of the US health care system, supporting local public health infrastructure, hospitals, mental health centers, at-home-care, community clinics, nursing homes, physicians, and many other health professionals and administrators.

The Medicaid program is critical to the health and well-being of hundreds of thousands of West Virginians. This manual is intended to provide you with a brief overview of the West Virginia Medicaid program, including how the Medicaid program is financed, Medicaid care delivery models, covered services, and trends in Medicaid enrollment and spending. The information in this manual should not be considered Medicaid policy. Rather, this manual is intended to serve as an accessible resource to answer frequently asked questions related to the Medicaid program. Every effort was taken to document data sources used in the creation of this book. If you have additional questions related to Medicaid program, or any of the information in this manual, please see the contact information in the Appendix.



MEDICAID VS. MEDICARE

Medicaid: A public assistance program that serves low-income people of all ages. Medicaid is jointly funded by states and the federal government but is administered by states. Patients with Medicaid usually do not have out-of-pocket costs related to covered medical expenses.

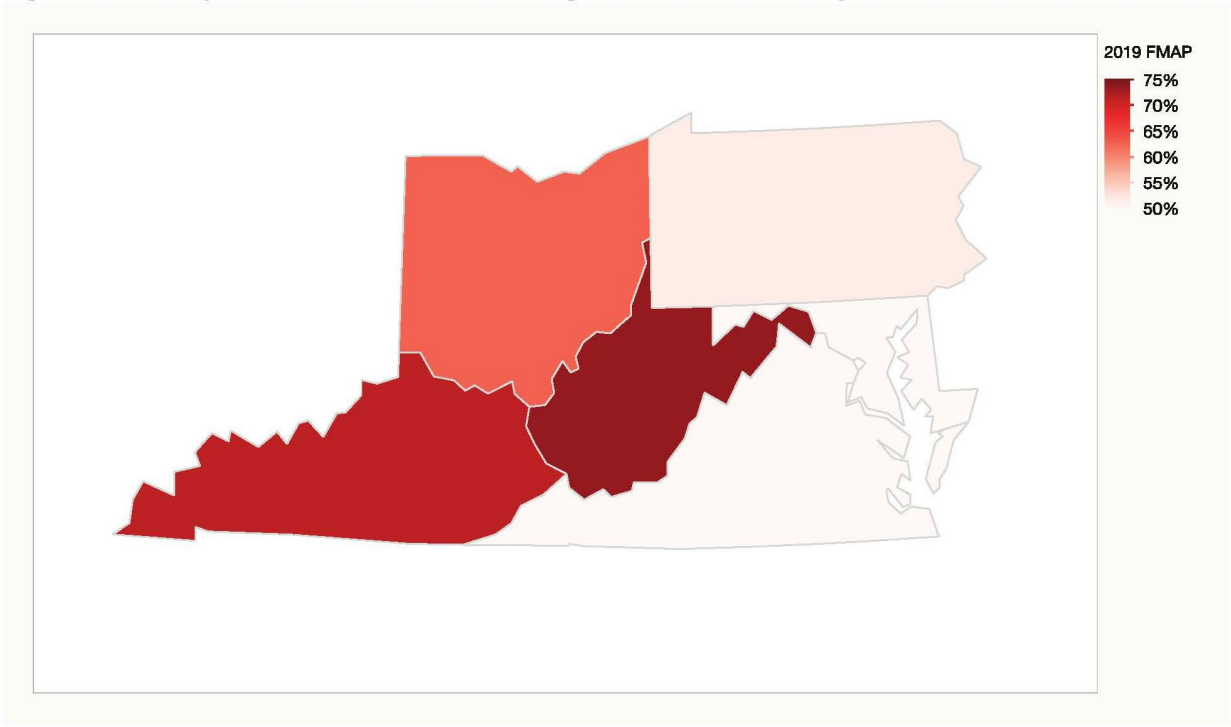
Medicare: An insurance program funded and administered by the federal government. Medicare provides health insurance for hospital and medical care to seniors age 65 and older and some individuals under age 65 with disabilities. Medicare beneficiaries typically have some out-of-pocket costs.

Who pays for Medicaid?

A state-federal partnership

Medicaid is jointly funded by state and federal governments. The majority of Medicaid funding is provided by the federal government. The federal government shares financial responsibility for the Medicaid program by matching state spending with federal dollars. The federal share of those costs is determined by the Federal Medical Assistance Percentages (FMAP). The FMAP is calculated annually using a formula set forth in federal statute and is inversely proportional to a states per capita income relative to the US average. States with lower per capita incomes have higher FMAPs. As seen in Figure 1, West Virginia has the highest FMAP in the region.

Figure 1: Fiscal year 2019 FMAP in West Virginia and surrounding states



In fiscal year 2019, West Virginia's FMAP is 74.3%.[2] This means that the federal government pays for 74.3% of the costs for eligible Medicaid services, while BMS is only responsible for 25.7% of the costs. In practice, if a Medicaid member has a hospital stay that results in $1,000 in costs, the federal government will pay $743, while BMS will pay only $257. In this sense, the FMAP acts as a multiplier for state spending. For example, in West Virginia, every $100 in state spending on Medicaid services will bring in $290 in matching federal funds. States may also receive an enhanced FMAP for covering certain services or populations. Perhaps most notably, states currently receive a 94% FMAP for the Medicaid expansion population.[3] These matching funds directly benefit patients receiving medical care while also helping to finance the healthcare infrastructure in areas with large Medicaid populations.

State Medicaid programs are often seen as low-hanging fruit when financially strapped states are forced to make budget cuts. However, thanks to the FMAP, Medicaid spending acts as a tremendous financial boon for the state. The Kaiser Commission on Medicaid and the Uninsured recently compiled findings from 29 different studies examining the economic impact of Medicaid spending and found that in all studies examined Medicaid spending had a positive impact on local economies.[3] These studies also found that Medicaid spending generates economic activity within the state by providing jobs, personal income, and state tax revenues. While most state government expenditures reallocate spending from one sector to another, Medicaid is one of the few state government spending opportunities that is guaranteed to pull in money from outside the state and directly benefit the local economy.

Medicaid care delivery systems

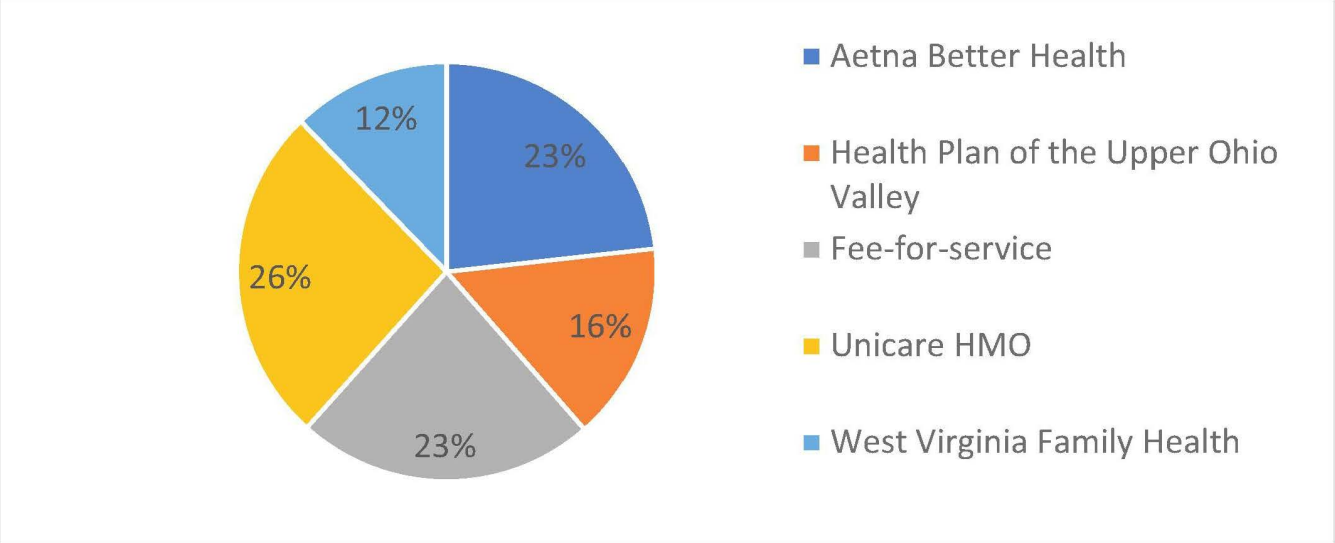
States are generally given leeway to set standards and policies for how they deliver medical and pharmacy services to Medicaid enrollees. States are also able to choose how services are purchased and payments distributed to Medicaid providers. The two most common care delivery systems are fee-for-service and managed care.

Fee-for-service: States directly pay providers a flat fee for each service delivered.

Managed care: States contract with health plans or managed care organizations (MCOs) and pay these groups a monthly per member capitation payment to provide all covered Medicaid services.

More than 75% of West Virginia Medicaid beneficiaries receive their benefits via the managed care delivery system through the Mountain Health Trust program. The Mountain Health Trust program contracts with four Managed Care Organizations (MCOs) for the provision of medical benefits. The four MCOs contracted through the program include Aetna Better Health of West Virginia (formerly Coventry Health Care of West Virginia), Health Plan of the Upper Ohio Valley, Unicare, and West Virginia Family Health. Individuals who are not covered by an MCO receive all benefits via the fee-for-service delivery system and are typically eligible for Medicaid through a waiver program such as the Intellectual/Developmental Disabilities Waiver or the Traumatic Brain Injury Waiver. Importantly, some Medicaid benefits, including pharmacy benefits, long-term care services, and non-emergency medical transportation are still paid via the fee-for-service delivery system for all Medicaid beneficiaries.

Figure 2: Approximate percent of Medicaid beneficiaries enrolled in each MCO



Covered benefits and services

The federal government requires every state Medicaid program to cover a specific set of benefits and services. The services that programs are required to cover have changed greatly since the Medicaid program's inception in 1965, given advancements in medical technologies and changes in the makeup of the Medicaid population. In addition to the required covered services, states are allowed some flexibility in terms of offering additional benefits so long as services are equitable in terms of availability and scope for all Medicaid beneficiaries.

Medicaid programs are required to cover the following services:

- Inpatient and outpatient hospital services
- Physician services
- Nursing facility services
- Early periodic screening, diagnostic and treatment services for children, including dental services
- Laboratory and x-ray services
- Home health services including nursing services, home health aides, and medical supplies and equipment
- Rural health clinic services
- Federally qualified health center services
- Transportation to medical care
- Certified pediatric and family nurse practitioner services
- Emergency medical services for certain noncitizens, also known as emergency medical assistance
- Family planning services, including nurse midwife services
- Tobacco cessation counseling for pregnant women

West Virginia's Medicaid program also covers the following optional services:

- Alcohol and drug treatment
- Chiropractic services
- Emergency dental care for adults
- Orthodontics for children
- Emergency hospital services
- Post-cataract eyeglasses for adults
- Hearing aids for children
- Home care including personal care assistant services
- Hospice care
- Medical equipment and supplies
- Prescriptions and medication therapy management
- Both physical and mental rehabilitative services
- Inpatient and outpatient substance use disorder treatment
- Case management
- Care coordination
- Autism spectrum disorder services

Who is eligible for Medicaid in West Virginia?

West Virginia Medicaid provides health insurance to a diverse population of individuals. All individuals who meet federally established income eligibility requirements are guaranteed Medicaid coverage. However, states are also allowed some flexibility in terms of eligibility requirements and can extend coverage to certain optional populations. The vast majority of Medicaid beneficiaries in West Virginia fall into one of the following categories:

Pregnant women and children

It is extremely important that women receive adequate medical care while they are pregnant. Fortunately, Medicaid provides prenatal care to many pregnant women without other forms of insurance. More than half of all births in West Virginia are paid for by Medicaid. Medicaid is also the primary health insurance program for low-income children from birth to age 18. Nearly half of all West Virginia children receive health care and important developmental services through Medicaid. Ensuring the health and developmental success of pregnant women and children is a sound investment in West Virginia's future.

Aged and disabled population

Medicaid is the primary insurer for many individuals with mental or physical disabilities. Individuals who are aged, blind, or disabled, and who have limited assets to support themselves may be eligible for supplemental security income (SSI) from the federal government. In West Virginia, all individuals who receive SSI automatically become eligible for Medicaid. Once enrolled, these individuals may receive health care, therapy, and long-term care services with few or no out-of-pocket costs. Medicaid also supports seniors in West Virginia by paying for some low-income Medicare beneficiaries' co-pays, deductibles, and premiums as well as certain medical services. For example, Medicaid pays for the majority of all nursing home care for West Virginia seniors.

Expansion adults

Historically, adults aged 19-64 without dependent children were not eligible for Medicaid coverage. However, with the passage of the Patient Protection and Affordable Care Act, states were given the option of expanding Medicaid eligibility to adults with incomes up to 133% of the federal poverty level. West Virginia is one of 36 states to expand Medicaid eligibility to this population. Importantly, the federal government pays an enhanced FMAP for Medicaid services provided to this population.

MEDICAID VS. CHIP

While Medicaid insures many children in West Virginia, some children receive benefits through the Children's Health Insurance Program (CHIP). Medicaid is intended to provide health benefits to the poorest children in the state. CHIP expands health insurance coverage to children in families who have incomes above the Medicaid eligibility threshold who do not have commercial insurance. Services provided through CHIP are generally comparable to those offered under the Medicaid program, however states have more flexibility in determining the breadth of coverage for CHIP services.

How is Medicaid eligibility determined?

Medicaid eligibility is dependent on a host of factors including household income, family size, age, disability, and citizenship status. The specifications for these criteria vary by eligibility category. For example, pregnant women may make up to 158% of the federal poverty level (FPL) and qualify for Medicaid eligibility, while adults in the expansion population may only

make up to 133% of the FPL. West Virginia Medicaid's income eligibility thresholds, as a percentage of the FPL, for various groups are displayed in Figure 3. Figure 4 displays the 2018 FPL designations for different family sizes; families that make less than this amount are deemed in poverty. Regardless of eligibility group, individuals must pass an annual asset test to become eligible for Medicaid benefits. Assets include items such as a car above a certain value, personal savings, and life insurance policies. Notably, a family home is not considered an asset for Medicaid eligibility.

Figure 3: Eligibility thresholds as a percent of the FPL for various Medicaid groups[5]

Population	Eligibility threshold as a percent of FPL
Children	
Ages 0 – 1	158%
Ages 1 – 5	141%
Ages 6 – 18	133%
CHIP	300%
Adults	
Aged and Disabled*	Up to 300% of SSI Limit
Expansion population	133%
Pregnant Women	158%

*Eligibility for the aged and disabled population is based on social security income (SSI) limits. Certain individuals can make up to 300% of the SSI limit and qualify for Medicaid benefits

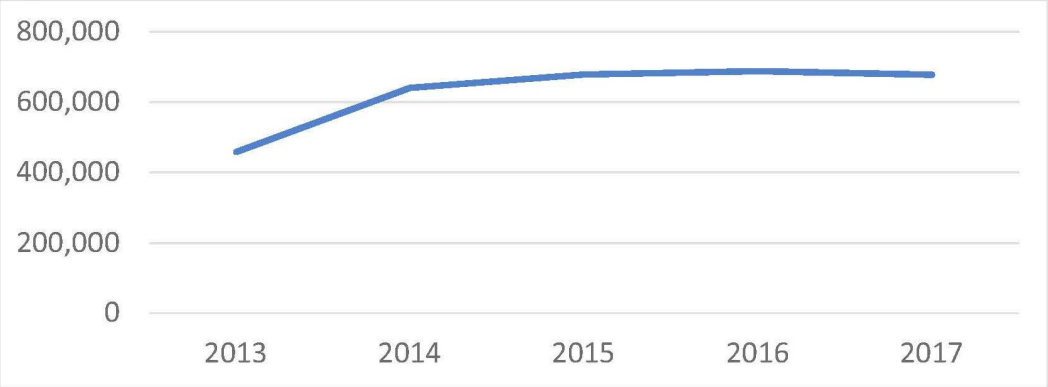
Figure 4: 2018 FPL by family size[6]

Family Size	FPL Threshold
Individuals	$12,140
2	$16,460
3	$20,780
4	$25,100
5	$29,420
6	$33,740
7	$38,060
8+	$42,380

Medicaid enrollment by the numbers

Figure 5 displays the number of individuals enrolled with West Virginia Medicaid at any point in a calendar year from 2013 – 2017. Please note that the number of individuals enrolled with Medicaid on any given day will be significantly less than the number enrolled at any point in the calendar year. For example, there are about 530,000 individuals enrolled in Medicaid on any particular day of the month, while there are generally more than 650,000 individuals enrolled at some point over the course of an entire year.

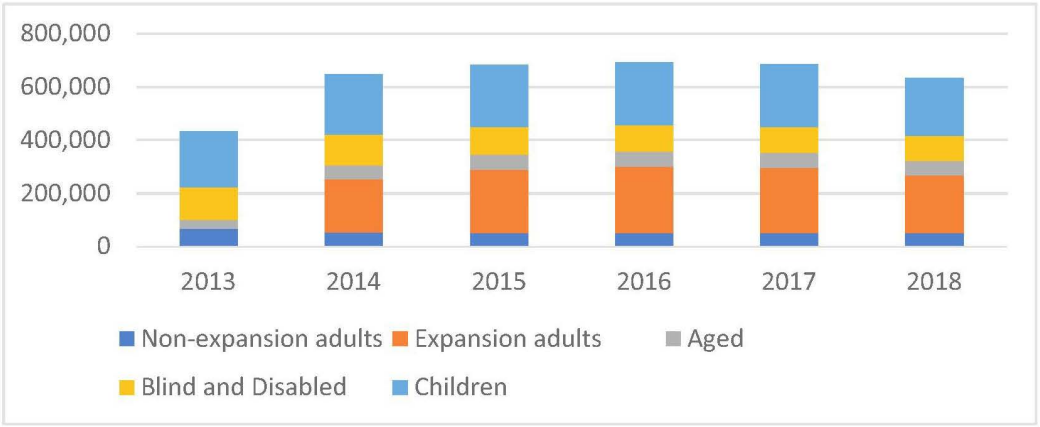
Figure 5: Total annual Medicaid enrollment 2013 – 2017



In 2017, more than 675,000 West Virginians were enrolled in Medicaid at some point during the year. This represents approximately one third of the state's total population in 2017. West Virginia chose to expand Medicaid eligibility under the Affordable Care Act in 2014. From 2013 to 2014, Medicaid enrollment increased by more than 50%, and has remained relatively stable since then.

Figure 6 displays trends in Medicaid enrollment from 2013 – 2017 by Medicaid eligibility category. Changes in Medicaid enrollment from 2013 – 2017 have been driven almost entirely by the adult expansion population. The number of blind and disabled individuals enrolled in Medicaid has decreased slightly over this time period.

Figure 6: Annual Medicaid enrollment by eligibility group 2013 – 2017



Given the dramatic increases in Medicaid enrollment over the last five years, West Virginia now has one of the lowest uninsured rates in the country. Figure 7 displays trends in the percentage of West Virginians with Medicaid coverage relative to the percent of uninsured West Virginians. While more than one-third of the state's population was enrolled with Medicaid at some point in 2017, only about 6% of the state's population was uninsured for the majority of the year.

Figure 7: Percent of West Virginians with Medicaid relative to percent uninsured 2013 – 2017[7,8]

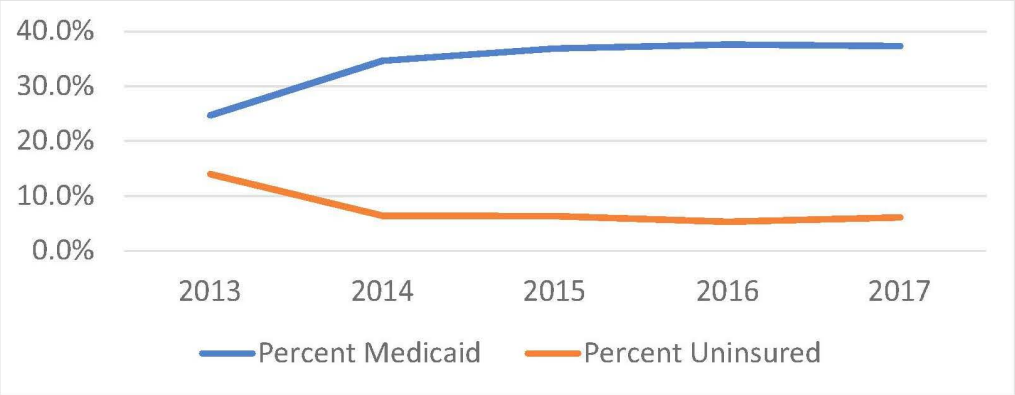
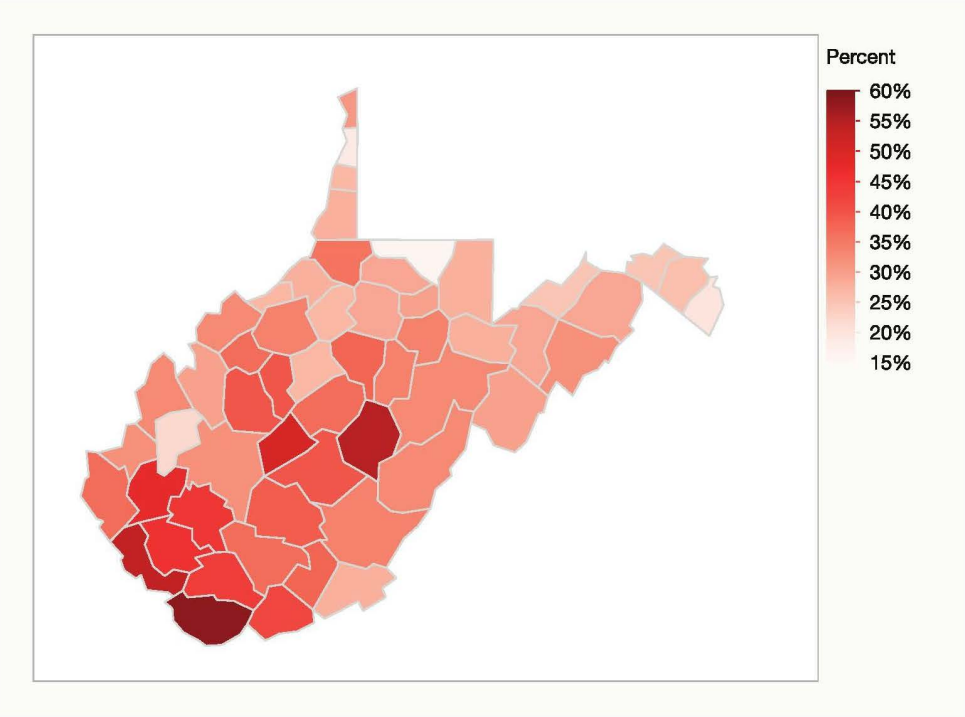


Figure 8 displays the percent of individuals enrolled in Medicaid in each county in West Virginia during calendar year 2017. Generally speaking, counties in the southern region of the state had higher rates of Medicaid coverage relative to counties in the Northern region or Eastern Panhandle.

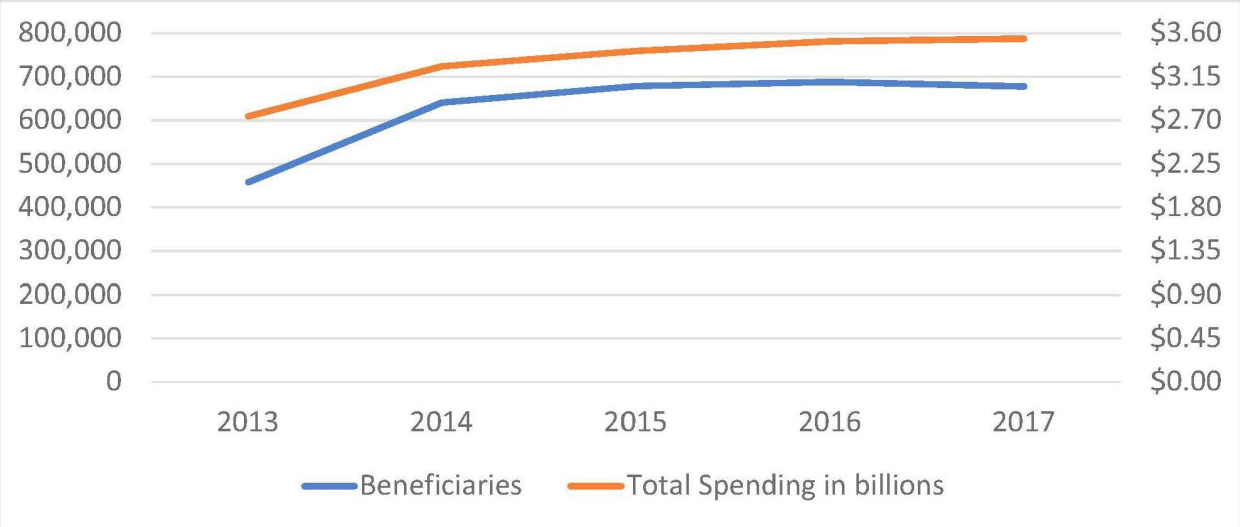
Figure 8: Percent of individuals with Medicaid in each county in calendar year 2017



Medicaid spending by the numbers

Annual Medicaid enrollment increased substantially following implementation of Medicaid expansion under the Affordable Care Act. Understandably, Medicaid spending also increased over this time period, however it was outpaced by increases in Medicaid enrollment. Figure 9 displays trends in annual Medicaid enrollment and spending from 2013 – 2017.

Figure 9: Annual Medicaid enrollment and spending 2013 – 2017



Medicaid enrollment increased by more than 50% from 2013 to 2014, but total Medicaid spending increased by less than 20% over the same time period. While the adult expansion population has largely driven increases in Medicaid enrollment, this population accounts for a relatively small proportion of total Medicaid spending. Figure 10A displays the percent of Medicaid beneficiaries by eligibility category in calendar year 2017, while Figure 10B displays the percent of spending attributable to each eligibility category in the same year.

Figure 10A: Percent of Medicaid beneficiaries by eligibility group in calendar year 2017

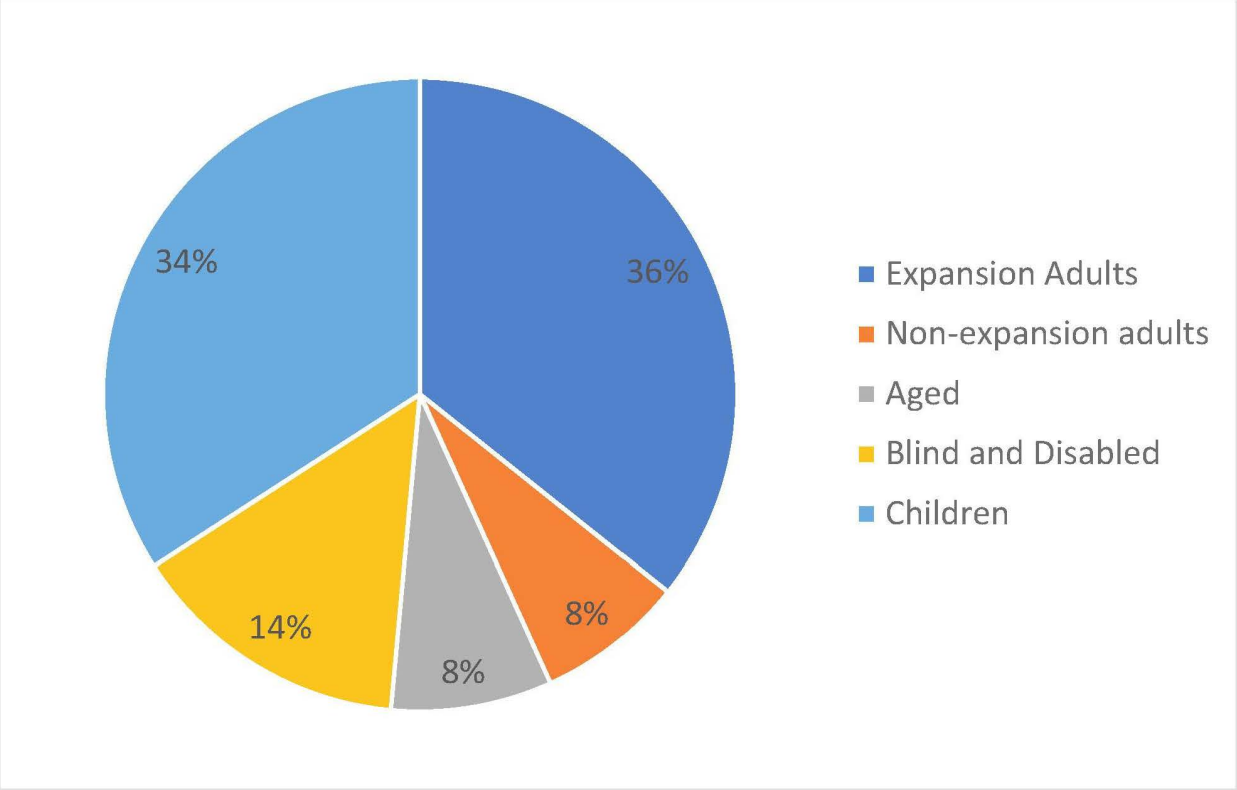
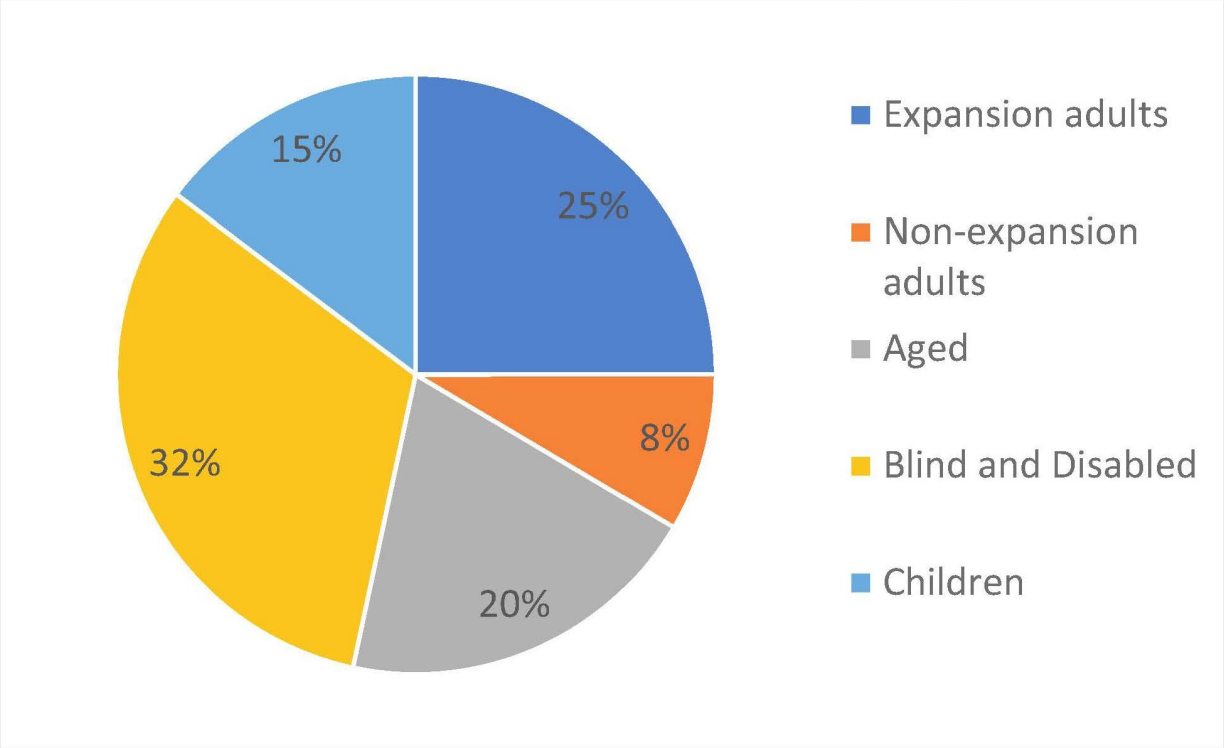


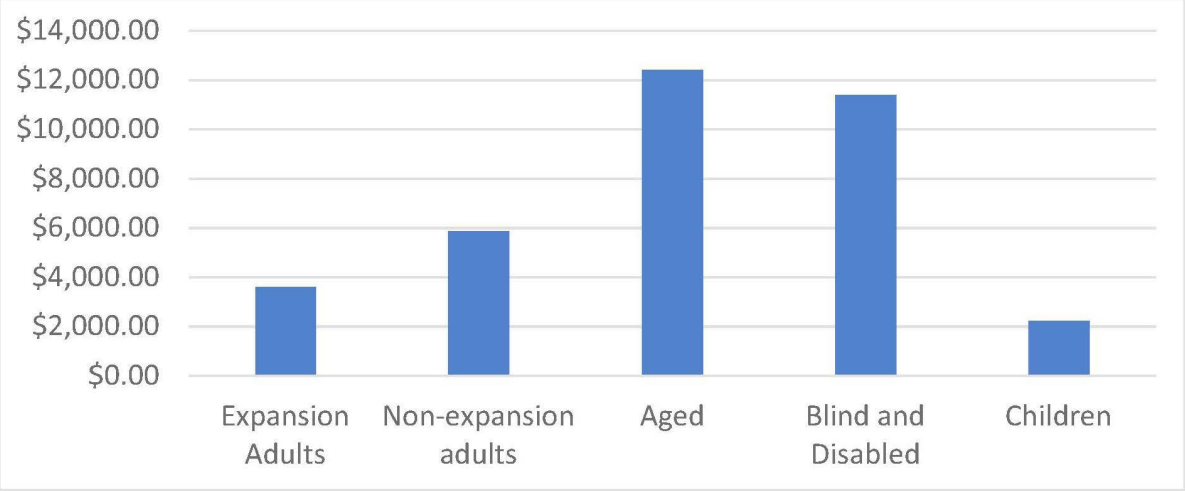
Figure 10B: Percent of Medicaid spending attributable to each eligibility group in 2017



In 2017, more than one-third of Medicaid beneficiaries were part of the adult expansion population, however, these individuals accounted for only about 25% of total Medicaid spending during the calendar year. On the other hand, the aged population and the blind and disabled populations together comprised only about 22% of the Medicaid population in 2017, however they accounted for more than 50% of all Medicaid spending. The aged population and the blind and disabled Medicaid populations tend to have special healthcare needs and require more frequent Medicaid services than other groups. It is understandable that the expansion population accounts for a smaller proportion of Medicaid spending relative to populations with greater healthcare needs.

Figure 11 displays average Medicaid spending per person by eligibility group. Individuals in the aged population and the blind and disabled Medicaid populations account for a much greater share of Medicaid spending than individuals in other eligibility groups. Beneficiaries in the aged population and blind and disabled population accounted for two to four times greater average spending per person relative to beneficiaries in any of the other eligibility groups.

Figure 11: Medicaid spending per person by eligibility group



Medicaid innovations and successes

Innovative approaches to treating Substance Use Disorder

West Virginia has been at the epicenter of the nation's drug crisis. In 2017, West Virginia had the highest drug overdose death rate in the country, with a rate that was greater than double the national average.[9] This crisis has dramatically impacted our Medicaid program, which insures many individuals suffering from Substance Use Disorder (SUD). In the last year, BMS has implemented several innovative policies to improve the quality and availability of SUD treatment for Medicaid beneficiaries. Ultimately, these policies will bolster the SUD care delivery network in the state and improve the health and well-being of West Virginians.

BMS was recently awarded a Medicaid 1115 waiver by the Centers for Medicare and Medicaid Services (CMS) to enhance the continuum of care for beneficiaries with SUD. This waiver is

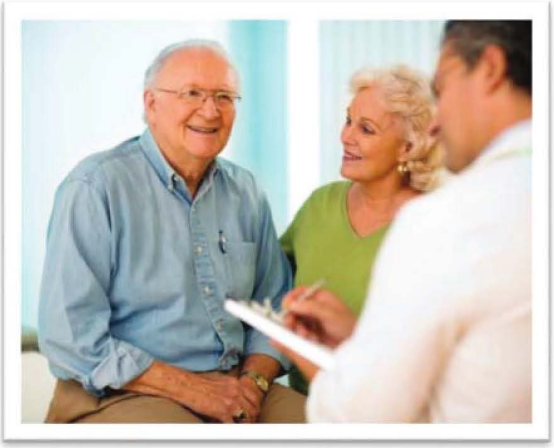
intended to improve the availability, quality, and coverage of SUD treatment services for Medicaid beneficiaries. The waiver allows Medicaid beneficiaries with SUD to receive the full continuum of care for SUD treatment as defined by the American Society of Addiction Medicine. Medicaid enrollees with SUD are now eligible to receive additional behavioral therapies including peer recovery support and withdrawal management services, as well as short-term residential treatment. The 1115 waiver also expands access to medication assisted treatment (MAT) including methadone treatment services from opioid treatment programs. Additionally, emergency medical service providers can now be reimbursed for administration of naloxone to Medicaid beneficiaries suffering an overdose. Importantly, the new services provided under the 1115 waiver are consistent with the industry standard best practices set forth by the American Society of Addiction Medicine.

In addition to the 1115 waiver, BMS is also taking an innovative approach to treating babies born with neonatal abstinence syndrome (NAS). NAS is a disorder caused by prenatal exposure to opioids or other drugs. Babies with NAS experience a host of symptoms including tremors, vomiting, seizures, excessive crying and sensitivity to stimuli, and these infants require around-the-clock care during the first few weeks of life. BMS is the first Medicaid program in the country to have an approved state plan amendment (SPA) specifically to bolster NAS treatment services. The SPA allows health facilities to be recognized as NAS Treatment Centers, and allows them to receive Medicaid reimbursement for providing NAS treatment. Services that can now be reimbursed under the SPA include comprehensive assessment and care plan development; housing in a low or reduced stimuli environment; pharmaceutical withdrawal management; therapeutic swaddling; rocking; newborn massage; and other services.

Home and Community-Based Services for person-centered care

The Medicaid Home and Community-Based Services (HCBS) waiver program allows state Medicaid agencies to provide services to members in their homes or communities to avoid institutionalization. HCBS programs work to create sustainable, person-centered, long-term support systems for people with disabilities, chronic conditions, and the elderly. The goal of HCBS waiver programs is to improve members' independence, health, and quality of life. Within broad federal guidelines, states can develop HCBS programs tailored to the needs of Medicaid beneficiaries who prefer to receive treatment in their home or communities rather than an institutional setting. West Virginia has three HCBS waiver programs:

1. Aged and Disabled Waiver—This program is a long-term care alternative that provides services that enable an individual to remain at or return home rather than receiving nursing home care. The goals and objectives of this program are focused on providing services that are person-centered, promote choice, independence, respect, and community integration.
2. Intellectual/Developmental Disabilities (I/DD) Waiver—This program provides services that instruct, train, support, supervise, and assist individuals who have intellectual and/or developmental disabilities in achieving the highest level of independence and self-sufficiency possible. The I/DD waiver program provides services in natural settings where the member resides rather than in intermediate care facilities.
3. Traumatic Brain Injury (TBI) Waiver—This program provides services to individuals with a documented traumatic brain injury, defined as a non-degenerative, non-congenital injury to the brain resulting in the need for a nursing facility level of care. The purpose of the program is to prevent unnecessary institutionalization by providing services and supports that are person-centered and promote independence and community integration.



Health Homes for at risk populations

The Affordable Care Act gave state Medicaid programs the option of creating the Health Homes program to provide a comprehensive system of care coordination for Medicaid beneficiaries with multiple chronic conditions. The Health Homes program does not act as a place where patients live, but as a system for holistically providing medical, behavioral, and social support services for individuals with complex healthcare needs. Individuals enrolled in Health Homes are assigned a multidisciplinary team of healthcare providers who collaboratively provide services and supports in a coordinated manner. Health Homes services include comprehensive care management, care coordination, health promotion, and community and social support services. Each patient enrolled in the program is also assigned a personal care manager who is required to contact the patient at least bi-weekly to ensure the patient's needs are being addressed. West Virginia currently has two Health Homes. The first Health Home began in July 2014 for members with bipolar disorder who have, or are at risk of having, hepatitis B or C. The second Health Home

began in April 2017 and is designed for Medicaid beneficiaries with pre-diabetes, diabetes or obesity, who are at risk of also having anxiety or depression.

Reducing pharmacy spending and investing in the state

On July 1, 2017, BMS carved out pharmacy services from the managed care program and began delivering these services as part of the fee-for-service delivery model. With this model, pharmacy benefits are managed by the State Pharmacy Services program, which serves as its own Pharmacy Benefits Manager (PBM). This model unbundles incurred costs and creates a more transparent method of payment for pharmacy services. Claims processing is handled by DXC, the fee-for-service medical/dental claims processor, and processing fees are transparent. Supplemental rebates on preferred drugs are negotiated through a multi-state consortium of Medicaid programs. The collection of federal and supplemental rebates is overseen in-house and the entire amount collected is retained by the Medicaid program. So far, this initiative has paid dividends, with significant cost-savings in the first year alone. In addition to savings on administrative costs and increased rebates, BMS increased the dispensing fee to $10.49 per prescription, providing a significant re-investment back into the pharmacy business community.

Looking to the future

BMS is committed to providing innovative, high quality, and accessible healthcare to the citizens of West Virginia. As part of this commitment, BMS recently completed a strategic planning initiative to more formally establish the Bureau's mission, core values, and major strategic initiatives. This plan will be used to guide the overall direction that BMS will take over the next five years. Development of this strategic plan is only the first step in continuing efforts to improve transparency and better serve the citizens of West Virginia. A copy of the BMS strategic plan can be found on the website: dhhr.wv.gov/bms.

Notes

Notes

Appendix

For additional information about the West Virginia Medicaid program, please contact BMS at: 304-558-1700

For additional information pertaining to preparation of this manual, please contact Nathan Pauly at Nathan.J.Pauly@wv.gov.

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