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SPECIALLY MODIFIED LOW-PROTEIN FOODS
GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS (GAPMS)
DETERMINATION REPORT WITH RECOMMENDATION

Date: {DATE}

To: Beth Kidder, Deputy Secretary for Medicaid

From: Bureau of Medicaid Policy

Subject: **Specially Modified Low-Protein Foods**

PURPOSE

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

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

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

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

REPORT WITH RECOMMENDATION

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

The analysis described in this report includes:

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

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

HEALTH SERVICE SUMMARY

Phenylketonuria (PKU)

Classified as an inborn error of metabolism (IEM), PKU is a genetic condition present from birth that prohibits the body from metabolizing the protein phenylalanine. When the body cannot break phenylalanine down, the protein accumulates in the bloodstream affecting development of the central nervous system. If left untreated, PKU results in intellectual disability, seizures, and behavior disorders. The condition affects approximately 1 out of every 15,000 newborns in the U.S. (Camp et al, 2012) and 206 Florida Medicaid recipients.

Treatment

PKU is a genetic defect and has no cure. However, early diagnosis immediately following birth and diligent dietary management can prevent the disease's effects. Patients diagnosed with PKU must avoid foods that contain phenylalanine. These consist of those generally high in protein such as poultry, beef, pork, dairy, fish, seafood, legumes, and nuts. Patients should also avoid other staples like bread, pasta, and starches (corn and potatoes) but can eat them in small quantities. This results in the primary components of a PKU patient's diet consisting of fruits and vegetables. Given these restrictions, patients are unable to consume adequate protein to sustain healthy development and nutrition and must use special formulas (medical foods) rich in protein but absent of phenylalanine to meet their needs. When combined with a low-protein diet, the formulas enable PKU patients to lead full, healthy lives. To prevent complications, patients diagnosed with PKU must adhere to this diet for life (Vockley et al, 2014).

Medical Foods

Medical food is a broad term that can lead to confusion and misuse. In 2012, Camp et al used PKU as an example of how to better define the term. In regards to the disease, medical food consists of two categories, products that provide protein along with other essential nutrients and foods that are low in protein. This includes foods such as single amino acids and specific vitamins.

The term "medical foods" is an umbrella label that includes a variety of products used to treat and manage numerous medical or health conditions. According to the Orphan Drug Act of 1988, medical foods are those "formulated to be consumed or administered enterally under the supervision of a physician and which are intended for the specific management of a disease or condition." The U.S. Food and Drug Administration (FDA) further states that "medical foods are foods that are specially formulated and processed for a patient who requires use of the product as a major component of a disease or condition's specific dietary management." (FDA, 2016)

These broad definitions allow for multiple product types to share the classification of medical foods including formulas, supplements, and anything processed specifically for disease management. The label alone is insufficient to determine purpose and medical necessity. One

product categorized as a medical food can be an enteral formula vital to treating a disease, while another is an ordinary food item designed without an ingredient that can be harmful for patients with certain diagnoses or conditions. Understanding the purpose for each medical food requires in-depth investigation beyond the label.

Formulas

Formulas are nutritional drinks designed to provide nutrients for patients who are unable to obtain them from their diet. Depending on the disease, formulas can contain specific proteins and vitamins specially processed to sustain a patient's nutrition while not exacerbating the disease. For example, formulas for PKU patients contain amino acids absent of phenylalanine and serve as a primary source of protein (Van Calcar et al, 2012).

Specially Modified Low-Protein Foods

Used as an adjunct to manage PKU, SMLPFs resemble conventional items such as hamburgers, bread, cheese, and hot dogs but contain ingredients free of phenylalanine. Based on wheat starch recipes, these products' intent is not to provide core nutrients but rather to promote more normal appearing diets and give satiety to patients.

Unlike formulas, SMLPFs are not necessary to treat PKU. They do not provide proteins free of phenylalanine and cannot act as substitutes for formulas. Instead, these foods help to increase dietary variety and normalize the appearance of a low protein diet (Vockley et al, 2013).

Due to the rarity of PKU, patients wishing to acquire these foods must do so directly from the manufacturers as they are not commercially available in local grocery stores. This makes the products more difficult to access due to higher costs and shipping (Camp et al, 2012). The products may cost two to eight times as much as similar (unmodified) products in grocery stores. Additionally, given that some of these items are soft (bread) or frozen (microwaveable entrees), shipping costs can be more expensive (Camp et al 2012).

Intended for use in addition to formula, these products range from basic staples such as low-protein flour to frozen microwaveable dishes. Product examples and their ingredients are listed below (Cambrooke, 2017):

- Baking Mix, 2 lb. bag, $15.49. Ingredients: wheat starch, sugar, canola oil, fully hydrogenated cottonseed oil, and xanthan gum
- Blueberry Scones, 16 oz. package, $12.99. Ingredients: wheat starch, non-dairy creamer, blueberries, tapioca starch, butter, sugar, powdered sugar, xanthan gum, canola oil, fully hydrogenated cottonseed oil, baking powder, cinnamon, and malic acid
- American Cheese Singles, 32 slice package, $12.99. Ingredients: water, food starch, partially hydrogenated soybean oil, modified food starch, milk protein concentrate, salt, natural flavor, sodium phosphate, stabilizers (xanthan, locust bean, guar gums), sorbic acid, lactic acid, and artificial color

Government Regulatory Body Approval

The FDA does not subject medical foods to the same regulatory process as drugs. However, they must meet and follow certain guidelines and are exempt from the nutrient content labeling rule mandated by the Nutrition Labeling and Education Act of 1990. The FDA requires all medical foods to adhere to the following criteria:

- Be specially formulated and processed products
- Be intended for the dietary management of a patient that is unable to digest nutrients
- Provide nutrition specifically for the unique needs caused by a disease or condition
- Be used under a medical professional's supervision

Obtaining medical food does not require a prescription because the FDA does not regulate them as drugs.

LITERATURE REVIEW

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

Dietary Management of PKU

The medical community agrees that the best treatment for PKU is through dietary management and that controlling phenylalanine levels with a combination of formula and low protein foods is the ideal method (Camp et al, 2012). However, available scholarship does not indicate a medical necessity for SMLPFs as opposed to fruits, vegetables, and sugars, as patients are still required to obtain essential nutrients from formulas (Vockley et al, 2014).

To treat PKU, the primary method of controlling dietary intake presents problems such as adherence, malnutrition, and effects on quality of life (Ho et al, 2014). Research notes that 60-80% of patients begin failing to maintain their diets by adolescence and those that do still show impaired cognitive function. Much of the reason why patients struggle with adherence is due to the palatability of a PKU diet. They must avoid all foods high in protein and can only eat starches, fruits, and vegetables in limited quantities. In addition, the phenylalanine-free amino acid formulas have large quantity servings and poor flavor (Santos et al, 2006).

Adding glycomacropeptide (GMP) to PKU patients' diets has improved nutrition and quality of life. Based on a natural by-product of cheese production, GMP has a high protein concentration and contains little phenylalanine. Replacing synthetic amino acids with GMP in formulas results in more satiety, better nutrition, and higher compliance with PKU diets (Strisciuglio et al, 2014). Although GMP is present in formulas, it is not an ingredient in SMLPFs.

Van Calcar et al (2012) provided an analysis evaluating how alternatives were needed for amino acid-based formulas to help patients stay compliant with a PKU diet. They emphasized that persistent hunger was one of the main challenges with PKU diets and that GMP could serve as a better alternative. The analysis noted that GMP provided improved satiety and better taste over amino acid formulas.

MacLeod et al (2010) conducted a study with 11 PKU patients completed over an eight-day period. During the first four days, participants consumed a diet using a synthetic amino acid formula as their primary source of protein. In the last four days, the researchers switched the formula to food containing GMP. Participants gave daily blood samples throughout the study. The conclusions noted that the participants had lower levels of the hunger hormone, ghrelin,

when they consumed a GMP-based diet. This indicated higher rates of satiety because increased ghrelin levels occur when the body is hungry.

When determining the best method for improving satiety while providing essential proteins, research indicates that using foods and formulas with GMP offers an ideal strategy. Van Calcar et al (2012) states "protein is the most satiating nutrient." Low-protein foods based on starches do not have amino acids or GMP and cannot provide basic nutrition (Vockley et al, 2014).

Current Research on PKU Treatments

New research focuses on reinforcing the PKU diet by making it more palatable and satisfying. This includes introducing formulas based on glycomacropeptide but also exploring large neutral amino acids (LNAA). In 2016, Concolino et al conducted a study that evaluated LNAA efficacy and concluded that this method is effective in lowering blood phenylalanine levels. They based this on the findings from 12 participants who also reported that the LNAA based foods tasted better than their traditional formulas. Concolino et al also noted that this method provided an effective means of delivery for other essential vitamins and nutrients. Although LNAAs appear promising, more studies with larger groups are needed to determine their full potential. If LNAAs become a mainstay in treating PKU, they will function as part of the dietary management strategy (Ney et al, 2014).

Another option gaining support is through pharmaceuticals. In 2007, the FDA approved Kuvan (sapropterin dihydrochloride), which can enhance tolerance of phenylalanine in PKU patients. Muntau et al published the results of a trial in 2017 showing that the drug raised acceptable levels but that it should be taken in conjunction with a traditional PKU diet. To reach these conclusions, the researchers placed 27 participants on Kuvan for a 26-week regimen and compared phenylalanine tolerance with a control group that only used the diet. Despite findings like these and those of similar trials, Kuvan cannot become the new mainstay of PKU treatment. The drug's efficacy varies depending on the severity of each patient's condition and is not recommended for cases that are difficult to manage (Ho et al, 2014).

Advancing research for PKU treatment is highly challenging due to the rarity of the disease. The small number of patients and their geographic dispersion do not allow for adequate sample sizes when conducting studies. Because of this, demonstrating effectiveness is difficult and slows progress in comparison to common diseases (Agency for Healthcare Research and Quality, 2012).

Research on Specially Modified Low-Protein Foods

Current research on treating PKU continues to focus on managing the condition through diet with formula as the primary means of obtaining vital nutrients. However, these studies do not examine the efficacy of SMLPFs. Without research and trials, questions remain as to whether these products promote dietary adherence, can be consumed in quantities adequate to achieve satiety, and are necessary to provide complete nutrition in addition to formula.

Evidence-Based Clinical Practice Guidelines

The American College of Medical Genetics and Genomics (ACMG) released a guideline for the management of PKU in 2014. It stated that "dietary therapy with restriction of phenylalanine intake remains the mainstay" of PKU therapy and that without medical foods the disease "will result in inadequate protein to support normal growth and health." However, the ACMG

differentiates between medical foods that are formulas containing glycomacropeptide or amino acids from those that are SMLPFs. In regards to formulas, it asserts that they are the main factor in a PKU diet and are needed to "meet established dietary requirements." The ACMG also considers SMLPFs to be necessary because they "mimic higher protein foods" and increase variety. The guidelines further state that formulas and SMLPFs "should be regarded as medications." Aside from these statements, the ACMG issues no further opinion or guidelines on the use of SMLPFs.

COVERAGE POLICY

This section provides a summary of coverage and policy information from Medicaid, Medicare, and private insurers.

Medicare

Medicare does not cover SMLPFs. The Centers for Medicare and Medicaid Services (CMS) have not issued a national coverage determination and none of its contracted insurers have issued a local coverage determination (CMS, 2017).

Medicaid

Florida Medicaid covers PKU formulas such as Glytactin for patients under 21. These products consist of glycomacropeptide and/or other phenylalanine-free ingredients that provide essential protein and nutrients while improving satiety.

Connecticut offers coverage for SMLPFs only with prior authorization (Connecticut Husky Health, 2015).

Georgia's coverage policy for SMLPFs must have prior authorization and are only available to enrollees age 21 and under (Georgia Department of Community Health, 2017).

Idaho covers SMLPFs but requires prior authorization (Idaho Department of Health and Welfare, 2017).

Indiana covers SMLPFs and reimburses $5.33 per unit (Indiana Medicaid, 2016).

Iowa covers SMLPFs only with prior authorization and for those products that have a National Drug Classification number (Iowa Department of Human Services, 2014).

Maine does not offer coverage for SMLPFs (Maine Department of Health and Human Services, 2017)

Minnesota's Health Care Program covers SMLPFs for up to $525 per month (Minnesota Department of Human Services, 2017).

Kentucky covers SMLPFs, requiring prior authorization and certificate of medical necessity (Kentucky Department of Public Health, 2016).

Nevada covers SMLPFs only with prior authorization and for a six-month period. Patients must acquire their SMLPFs through a pharmacy or durable medical equipment provider (Nevada Department of Health and Human Services, 2015).

New Jersey covers SMLPFs when prescribed by a practitioner (New Jersey Department of Human Services, 2015).

West Virginia does not cover SMLPFs (West Virginia Department of Health and Human Resources, 2016).

Wyoming and Texas cover SMLPFs only with prior authorization and will not reimburse for foods traditionally classified as low in nutritional value such as cakes, cookies, and onion rings (Wyoming Department of Health, 2016 and Texas Department of Health and Human Services, 2016).

Other Insurers

Aetna does not cover specially modified low-protein foods except when state law mandates it.

United Healthcare lists low-protein foods among its coverage exclusions for oral and enteral nutrition and does not cover it unless state law requires it.

Blue Cross Blue Shield (BCBS) of Rhode Island and BCBS of Massachusetts cover low-protein foods when ordered by a physician.

Florida Blue (BCBS) does not cover low-protein foods.

Oregon statutorily requires private insurers to cover low-protein foods using code S9435 (Huntington et al, 2009).

GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS RECOMMENDATION

This report does not recommend specially modified low-protein foods as a health service that is consistent with generally accepted professional medical standards. Such foods are not demonstrated to be an effective treatment option for PKU.

Rationale

The medical profession notes that SMLPFs can assist in the management of PKU by increasing dietary variety and satiety. However, it does not indicate that these foods are necessary for sustaining the health and nutrition of patients. SMLPFs do not provide essential nutrients and can only be used to supplement formula. Using them to treat PKU alone would result in complications and developmental issues for patients. The clinical practice guidelines also do not indicate necessity, noting that SMLPFs help create the appearance of a normal diet.

While research has demonstrated the vitality of formulas for managing PKU, it does not do the same for SMLPFs. The available literature does not cite any studies to support necessity, causing the statement supporting their use to appear as opinion rather than fact. In order for SMLPFs to share the same medically necessary status of formula, research needs to show that PKU patients cannot manage the disease without it. Stating that such food provides “dietary variety” is insufficient to consider it as medication.

Considering the lack of essential nutrition and the limited research supporting its efficacy, specially modified low-protein foods are not consistent with the generally accepted professional medical standards pursuant to Rule 59G-1.035, F.A.C.

____Concur **____Do not Concur**

Comments:

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Deputy Secretary for Medicaid (or designee) *date*

RICK SCOTT
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SCLERAL CONTACT LENS
COVERAGE DETERMINATION REPORT WITH RECOMMENDATION

Date: November 14, 2017

To: Beth Kidder, Deputy Secretary for Medicaid

From: Bureau of Medicaid Policy

Subject: **Scleral Contact Lenses**

PURPOSE

The purpose of this report is to determine whether scleral contact lenses should be covered under the Florida Medicaid program under CPT code V2531.

REPORT WITH RECOMMENDATION

This report represents a summary of information and reliable evidence considered when making the coverage recommendation. The intent is to provide a brief analysis with justification in support of the final recommendation.

The analysis described in this report includes:

- Background on the coverage request
- A review of the literature considered by the relevant medical community or practitioner specialty associations from credible scientific evidence-based literature published in peer reviewed journals
- A review of existing coverage policies for similar health services under the Florida Medicaid program
- A summary of coverage policy from other state Medicaid and commercial insurers
- A fiscal analysis

BACKGROUND

The Agency for Health Care Administration received a request for coverage of scleral contact lenses. This product was determined to be a generally accepted professional medical standard (GAPMS), not requiring a complete GAPMS review. Scleral contact lenses were evaluated for a coverage determination.

Scleral contact lenses are a type of rigid gas permeable lens that rest completely on the sclera and do not touch the cornea. They are composed of three portions: the scleral (haptic) portion that rests on the sclera; the vault, which is responsible for corneal and limbal clearance of the lens; and the optical portion of the lens. When properly fitted, the lenses are stable and do not move on the eye. The diameter of the lenses is 15 mm or larger. Mini-scleral contact lenses

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have diameters between 15 mm – 18 mm, and true scleral contact lenses have diameters greater than 18 mm. The lenses are filled with either unpreserved saline or normal saline fluid before being inserted in the eye (Rathi, Mandathara, Taneja, Dumpati, & Sangwan, 2015). This fluid reservoir masks corneal surface irregularities, thereby improving visual acuity for patients with corneal surface irregularities. The fluid reservoir also serves as a liquid bandage, which can be used to treat ocular surface disorders (Schornack & Patel, 2010).

Sclera and Cornea

The sclera is the white, outer coating of the eye and is made of tough, fibrous tissue that extends from the cornea to the optic nerve at the back of the eye. The cornea is the clear, dome-shaped, outermost layer of the eye. It serves as a barrier to protect the eye from germs, dust, and other harmful matter (Medline Plus, 2017). The cornea also helps the eye focus and accounts for two-thirds of the eye's refractive power (Katzman & Jeng, 2014). Many types of disease processes and irregularities can affect the cornea.

Diseases and Irregularities of the Cornea

Corneal damage is a leading cause of blindness worldwide, with causes including injuries to the outermost layer of the cornea, damage or scars from other eye surgeries, infections, hereditary corneal defects, and inflammation from chronic dry eye (Research to Prevent Blindness, 2017). Corneal diseases and irregularities are also prevalent, occurring in young and old populations alike. In their 2009 report, Shepard, Razavi, Stason, Jacobs, Suaya, Cohen, et al. found that corneal disease ranked fifth among major eye diseases among Medicare recipients in terms of frequency and physical and economic burden. Keratoconus is the most common degenerative disease affecting the cornea and the most common corneal dystrophy in the United States. Keratoconus is a progressive thinning of the cornea that causes the middle of the cornea to thin, bulge outward, and form a rounded cone shape. The abnormal curvature can result in double or blurred vision, nearsightedness, astigmatism, and increased sensitivity to light. Most prevalent among teenagers and adults in their 20's, keratoconus affects one in 2000 Americans (National Eye Institute, 2016).

Ocular surface diseases include severe dry eye syndromes of various etiologies (Alipour, Kheirkhah, & Behrouz, 2012); corneal ectasia disorders such as keratoconus and pellucid marginal degeneration (Rathi, Mandathara, Vaddavalli, Srikanth, & Sangwan, 2012); and persistent epithelial defects (Katzman & Jeng, 2014). These diseases can result in poor visual acuity, ocular discomfort, and decreased quality of life. In addition to ocular surface disease, corneal irregularities also lead to poor visual acuity despite conservative treatment with eyeglasses or conventional soft or rigid gas permeable contact lenses. Irregularities can result from disease processes, can occur after various types corneal surgeries, or can be due to corneal trauma (Romero-Jiménez & Flores-Rodriguez, 2012; Steele & Davidson, 2007; Ye, Sun, & Weissman, 2006).

Mild forms or early stages of corneal diseases can be treated with topical and systemic medications, bandage soft contact lenses, and various other types of contact lenses (such as soft, rigid gas permeable, Rose K, piggy back, or hybrid), depending on the particular disease. Advanced ocular surface diseases and corneal irregularities are quite challenging to treat because of distortions to the corneal shape. Conventional treatments become less and less tolerated and effective as these diseases progress (Shepard et al., 2009; Stason, et al., 2009).

Treatment

Conventional Lenses

There are two common types of contact lenses: soft and standard rigid gas permeable. Soft contact lenses are small in diameter and conform to the shape of the cornea. Certain conditions of the eye may cause the cornea to become warped or severely damaged (e.g., keratoconus, corneal surgery, trauma) and cannot be managed with soft contact lenses due to the fit of the lens on the eye.

Standard rigid gas permeable lenses float on a layer of tears on top of the cornea; because they are rigid, they do not conform to the shape of the cornea like soft contact lenses. The tears accumulated under a standard rigid gas permeable lens fill in the damaged areas, providing greatly improved visual acuity. While results with standard rigid gas permeable lenses may be satisfactory, there are cases in which standard rigid gas permeable lenses are still unable to provide acceptable vision or a comfortable fit. For example, as keratoconus advances and the cornea becomes more irregular in shape, the ocular surface could be damaged if an optimal fit cannot be achieved (Rathi et al., 2013).

Scleral Contact Lenses

If soft contact lenses or standard rigid gas permeable contact lenses are not therapeutically successful, cannot be tolerated, or are otherwise contraindicated, scleral contact lenses may then be evaluated for use. The large diameter of scleral contact lenses (15.5-23 mm) allows them to be supported entirely by the sclera and completely vault the cornea, which creates a fluid-filled space (Rosenthal & Croteau, 2005). The large diameter of these lenses also improves centration, comfort, and corneal health (Romero-Jimenez & Flores-Rodriguez, 2012). Steele and Davidson (2007) reported that scleral contact lenses completely neutralize an irregular corneal surface, making the fitting of such eyes much easier. Scleral contact lenses can also be used to improve vision in patients who have corneal transplants (Schornack & Patel, 2010).

Surgical Interventions

Keratectomies (excising damaged parts of the cornea) and keratoplasty procedures (corneal transplants) are performed on deformed, damaged, and scarred corneas (Blackmore, 2010; Baran, Bradley, Alipour, Rosenthal, Le, & Jacobs, 2012). Surgical options, including repeat keratoplasty, may be delayed or avoided if scleral contact lenses can be effectively utilized (Schornack & Patel, 2010). Furthermore, Rathi et al. (2015) reported the use of scleral contact lenses can reduce the rate of keratoplasty for patients with keratoconus, which in turn reduces the cost, effort, and other issues related to maintaining corneal grafts.

Various surgical interventions, such as punctal occlusion and amniotic membrane transplantation, have been proposed for managing severe dry eye disease refractory to other treatment methods. The use of scleral contact lenses has been shown to be safe and effective in managing dry eye symptoms, which may result in regression of the disease and negate the need for surgical intervention (Alipour et al., 2012). The use of scleral contact lenses for persistent epithelial defects, if successful, can lead to a decreased need for surgical options, such as anterior stromal puncture, diamond burr debridement, and phototherapeutic keratectomy (Blackmore 2010).

Government Regulatory Body Approval

The Food and Drug Administration (FDA), under Subchapter H, Part 886 – Ophthalmic Devices, Subpart D – Prosthetic Devices, identifies a scleral shell as a device "made of glass or plastic that is intended to be inserted for short time periods over the cornea and proximal-cornea sclera for cosmetic or reconstructive purposes. An artificial eye is usually painted on the device. The device is not intended to be implanted."

The device is exempt from the Premarket Notification requirements as a Class II device under special controls.

The Boston Scleral Lens received approval via the premarket approval process on November 30, 1987. The FDA approved the Boston Scleral Lens for managing corneal disorders on March 1, 1994 (Hayes, 2006). The FDA has since approved two additional scleral contact lenses. On February 9, 2016, BostonSight IC Scleral Lens, sold by Boston Foundation for Sight, was approved. On April 27, 2016, the EYEPRINTPRO Scleral GP Lenses, sold by Advanced Vision Technologies, were approved (FDA, 2017).

LITERATURE REVIEW

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

Clinical Indications

Pullum (1999) identified the clinical indications for scleral contact lenses as irregular corneal topography, high refractive errors, iris encapsulation, therapeutic or protective applications, and "other" applications (e.g., working in dusty environments, intolerance to corneal or hydrogel lens wear).

In their research, Rosenthal and Croteau (2005) studied two primary clinical indications for scleral contact lenses: management of severe ocular disease and improvement of optical function. Scleral contact lenses serve as a liquid bandage in the management of various types of severe ocular diseases (e.g., persistent epithelial defects, severe dry eye disease, chronic graft-versus-host disease). The lenses provide a fluid-filled reservoir that bathes the cornea, provides an adequate supply of oxygen, and protects the cornea from friction/shearing from the eyelid, which occurs during blinking. In addition to restoring or maintaining the integrity of the corneal surface, the use of these lenses to manage severe ocular disease has been shown to reduce ocular pain and photophobia and improve visual acuity. Scleral contact lenses can also be utilized to deliver prophylactic and therapeutic topical medications to the cornea (Rosenthal, Cotter, & Baum, 2000).

Clinical Outcomes

To describe the therapeutic benefits of scleral contact lenses in the management of ocular surface diseases, Romero-Rangel et al. (2000) reviewed the medical charts of 49 patients (76 eyes) with a diagnosed ocular surface disease, ages 3 to 87 years. Their diagnosed diseases included Stevens-Johnson syndrome, ocular cicatricial pemphigoid, toxic epidermal necrolysis, several types of keratitis, a congenital deficiency, Sjogren syndrome, and inflammatory corneal

degeneration. In 25 of 76 eyes, other types of contact lenses had been tried unsuccessfully. Visual acuity improved in 40 eyes (53%). Defects were healed in eight of 15 eyes with a corneal epithelial defect at time of lens insertion. Of the eyes with a history of recurrent or persistent epithelial defects, 48% did not experience a recurrence of epithelial defects after lens fitting. Thirty-seven of 49 patients (75%) reported a marked decrease in photophobia. Forty-five of the 49 patients (92%) reported improvement in their quality of life due to a reduction of photophobia and ocular discomfort. Forty-seven of 49 patients (72 of 76 eyes) were able to maintain or improve their visual acuity. The authors concluded gas permeable scleral contact lenses provide an additional effective strategy in the surface management and visual rehabilitation of patients with severe ocular disease.

Rosenthal et al. (2000) conducted a retrospective study of treatment outcomes in 13 patients (14 eyes), ages 16 to 74 years, with persistent epithelial defects fitted with scleral contact lenses. Re-epithelization of the cornea requires a combination of oxygenation, moisture, and protection of the epithelium. The design of scleral contact lenses allows them to avoid suction through a fluid-filled tear interchange. This creates a unique environment for the corneal epithelium, consisting of an adequate oxygen supply, a constant aqueous interface, and the absence of friction, negating the need for surgery. The authors concluded scleral contact lenses were effective in promoting healing in the eyes of eight patients that failed to heal after other therapeutic measures were tried. Healing time varied from 36 hours to 36 days. The lenses used in the study also served as a vehicle for delivering prophylactic and therapeutic topical ocular medications (an antibiotic and a steroid) to the cornea.

Rosenthal and Croteau (2005) conducted a retrospective study involving the record review of 538 patients (875 eyes) fitted for gas permeable scleral contact lenses for whom rigid gas permeable lenses either were not tolerated or were contraindicated in all eyes. Of note, patient age was not indicated. They studied the impact of scleral contact lenses on optical function (501 eyes) and management of severe ocular surface disease (374 eyes). Of the eyes fitted primarily to improve visual functioning, most had corneal ectasia (including keratoconus), abnormal astigmatism after penetrating keratoplasty, or other failed surgical interventions, and eyeglasses were inadequate in correcting their vision. In many of those cases, the scleral contact lenses were effective in providing excellent vision correction. Of the eyes fitted to manage various ocular surface diseases, the scleral contact lenses were used as a corneal bandage. The use of the lenses significantly mitigated ocular pain and disabling photophobia, helped heal persistent epithelial defects and prevent recurrence, and improved vision. This study identified scleral contact lenses as an important palliative and therapeutic tool, especially in regards to relief of pain and photophobia in patients with primary severe dry eye. Scleral contact lenses were also a superior alternative to tarsorrhaphy in managing exposure keratitis. The study did note extended scleral contact lens wear and dry eye disease were risk factors for developing bacterial keratitis, especially when epithelial defects were present. However, this complication did not occur when the fluid reservoir was inoculated with moxifloxacin. Overall, scleral contact lenses were reported to be an important tool for managing many corneal disorders that have not responded to other treatment measures.

E-S. Visser, R. Visser, van Lier, and Otten (2007) published two studies using the same population data, drawn from the authors' practices. One study pertained to the clinical features of modern scleral lenses and the second study examined patient satisfaction. Their study recruited 178 patients (284 eyes), ages 18 to 80 years. Among these patients, 106 were wearing scleral contact lenses in both eyes and 72 were wearing scleral contact lenses in only one eye. These patients were fitted with scleral contact lenses due to failure with other lens types. Among the 284 eyes, 87 eyes were uncorrected with contact lenses prior to their fitting

for scleral contact lenses; 142 eyes were using a standard rigid gas permeable lens; and 55 eyes were using other types of lenses (such as eyeglasses and corneal, piggyback, and soft lenses). The patients were divided into six main groups based on their diagnoses: keratoconus (143 eyes), post-penetrating keratoplasty (56 eyes), primary or secondary irregular astigmatism (36 eyes), keratitis sicca (15 eyes), corneal dystrophy (10 eyes), and "multiple diagnoses" (24 eyes). The authors found significant increases in visual acuity with scleral contact lenses in comparison to best-corrected visual acuity without scleral contact lenses. The highest median increase was seen in eyes with keratoconus. With regards to patient satisfaction, 78.9% of patients reported increased ocular comfort, 78.2% reported improved visual quality, and 87.7% reported overall satisfaction with their scleral contact lenses.

Scleral contact lenses have been shown to provide significant improvements in visual acuity and visual functioning for patients with corneal ectasia, irregular astigmatism, and ocular surface disease for whom other correction methods failed (Baran et al., 2012). In 59 patients (118 eyes) with corneal ectasia, ages 18 to 89 years, 93% were able to achieve visual acuity of 20/40 or better even though 53 of those patients had failed attempts with other correction methods.

Advantages and Disadvantages

Scleral contact lenses can effectively treat a variety of ocular surface diseases and corneal aberrations where other lens types have been unsuccessful. Their large diameter makes them easier to fit over irregular corneas and they provide good centration on the eye. They can also be used to deliver topical medications to the cornea. Noted advantages of scleral contact lenses include improvements in corneal health, improvements in visual acuity and visual functioning, decreases in ocular pain and photophobia, decreased need for surgical interventions, and improvements in quality of life. Developments in lens materials and designs, the use of new technology for making the lenses, and improvements in lens-fitting techniques have resulted in wider acceptance for using scleral contact lenses. Scleral contact lenses are relatively easy to fit. The number of fitting sessions required to successfully fit these lenses is comparable to fitting other rigid gas permeable lenses, and the initial fitting is often times successful. In many instances, standard design lenses can provide an acceptable fit (Schornack, Baratz, Patel, & Maguire, 2008), which reduces cost in comparison to customized lenses.

Shepard et al. (2009) conducted an economic appraisal of the Boston Ocular Surface Prosthesis (a particular brand of scleral contact lenses). They compared the costs of dispensing (manufacturing and professional services) to the benefits of improvements in visual acuity and visual functioning, which, in combination with other information, was converted to quality adjusted life years. The authors determined that the lenses were a cost-effective technology in terms of improving quality adjusted life years. The cost-effectiveness ratio was similar in patients with ectasia/astigmatism and ocular surface disease.

Regarding disadvantages, some studies have shown a risk of keratitis (infection) with the use of scleral contact lenses. Rosenthal et al. (2000) found the risk of bacterial keratitis was high in patients who wore the lenses for an extended period of time, especially if an epithelial defect was present. Rosenthal and Croteau (2005) indicated that dry eye and extended contact lens wear were risk factors for developing bacterial keratitis, but the risk was mitigated when the fluid reservoir was inoculated with moxifloxacin. The risk of keratitis has been shown to be rare in patients with keratoconus. The risk of infection can be reduced by following standard hygiene protocols for scleral contact lenses. Additional contraindications for use of scleral contact lenses include corneal edema, acute hydrops, and post filtration surgery; however, scleral

contact lenses may be resumed after the hydrops heals (Rathi et al., 2013). Corneal vascularization due to hypoxia is a known complication in all forms of contact lens wear, though the cause of hypoxia varies with different lens types. Because of the design of scleral contact lenses, they can be utilized in patients who develop corneal vascularization associated with wearing other types of contact lenses. The design of scleral contact lenses also provides an oxygenated environment for the cornea. The handling and care regimen can be a challenge for some individuals, as there are different insertion and removal techniques utilizing miniature plungers, frequent changing of saline bottles, and the use of multiple solution types for cleaning and disinfecting. However, Vreugdenhil, Geerards, and Vervaet (1998) found that even patients with low visual acuity did not have difficulty handling the lenses. The cost of the specialized equipment to manufacture these lenses is high, which increases manufacturing costs. As noted above, not all patients require custom-made lenses, which should lower overall costs.

Limitations

Studies pertaining to the clinical aspects of scleral contact lenses tend to be retrospective and uncontrolled with small sample sizes and a lack of long-term follow up. Some studies were supported by the Boston Foundation for Sight (the company that manufactures the scleral contact lens evaluated in numerous studies) and/or Bausch & Lomb, or were conducted by authors who are salaried employees of the Boston Foundation for Sight. The articles noted neither Bausch & Lomb nor the authors of the studies had personal financial interest in the scleral contact lens.

Evidence-Based Clinical Practice Guidelines

The American Academy of Ophthalmology (2014) published a retrospective study of patients, ages 6 to 92 years, who utilized scleral contact lenses for a wide range of ocular problems, including undifferentiated dry eye syndrome, neurotrophic keratopathy, exposure keratopathy, chronic graft-versus-host disease, limbal stem cell deficiency, post-refractive surgery dry eye, and Sjogren's syndrome. The findings from this report indicated:

- Commercially available scleral lenses can be successfully used in the management of moderate to severe ocular surface disease
- The scleral lens fitting process can be completed efficiently for most eyes by using diagnostic trial lenses
- In addition to protecting the ocular surface, scleral lenses improve visual acuity in patients whose surface disease has compromised vision
- Therapeutic goals (improved comfort, ocular surface protection, or resolution of keratopathy) were achieved in 113 of 115 patients

COVERAGE POLICY

Medicare

According to the National Coverage Determination (Section 80.1), payment may be made under Section 1861(s)(2) of the Social Security Act for some FDA-approved contact lenses in certain situations. Specifically:

> Some hydrophilic contact lenses are used as moist corneal bandages for the treatment of acute or chronic corneal pathology and for other therapeutic reasons.

The National Coverage Determination (Section 80.4) also states payment may be made under the prosthetic device benefit for hydrophilic contact lenses when prescribed for an aphakic patient.

Additionally, the National Coverage Determination (Section 80.5), pertaining to scleral shells, indicates payment may be made under Section 1861(s)(8) of the Social Security Act under certain circumstances. Specifically:

> Scleral shell (or shield) is a catchall term for different types of hard scleral contact lenses. A scleral shell fits over the entire exposed surface of the eye as opposed to a corneal contact lens, which covers only the central non-white area encompassing the pupil and iris. Where an eye has been rendered sightless and shrunken by inflammatory disease, a scleral shell may, among other things, obviate the need for surgical enucleation and prosthetic implant and act to support the surrounding orbital tissue. In such a case, the device serves essentially as an artificial eye. In this situation, payment may be made for a scleral shell under §1861(s)(8) of the Act.

Scleral shells are occasionally used in combination with artificial tears in the treatment of "dry eye" of diverse etiology. Tears ordinarily dry at a rapid rate, and are continually replaced by the lacrimal gland. When the lacrimal gland fails, the half-life of artificial tears may be greatly prolonged by the use of the scleral contact lens as a protective barrier against the drying action of the atmosphere. Thus, the difficult and sometimes hazardous process of frequent installation of artificial tears may be avoided. The lens acts in this instance to substitute, in part, for the functioning of the diseased lacrimal gland and would be covered as a prosthetic device in the rare case when it is used in the treatment of "dry eye."

Procedure code V2531 was added to Florida's Medicare contractor, First Coast, Part A Medicare fee-for-service Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) fee schedule for dates of service on or after January 1, 2015. The code is considered a DME, prosthetic device, and the maximum reimbursement rate is $522.08 (First Coast Service Options, Inc., 2017).

Florida Medicaid

Florida Medicaid currently covers 33 different procedure/treatment options for management and treatment of ocular issues, including keratectomies, corneal transplant/keratoplasty, implantation of intrastromal corneal ring segments, removal of eye lesions, correction of astigmatism, closure of eyelid by suture, conjunctivoplasty procedures, and contact lens fitting and contact lens prescriptions for the treatment of ocular surface disease.

State Medicaid Programs

Thirty Medicaid programs include coverage for scleral contact lenses on their fee schedules, as outlined in the following table:

State	Fee Schedule
Arizona	$417.07
Colorado	$330.88
Delaware	$421.66
District of Columbia	$405.47
Idaho	$150.00
Illinois	Unspecified
Indiana	$506.52
Iowa	Manual
Kansas	Unspecified
Maine	$201.17
Massachusetts	Individual Consideration
Michigan	Manual
Minnesota	$211.03
Mississippi	$53.45
Missouri	$78.28

State	Fee Schedule
Nebraska (V2530 only)	Individual Consideration
New Hampshire	$309.14
New Jersey	By Report
New Mexico	$177.30
Oklahoma	Manual
Oregon	$160.84
Rhode Island	$239.57
South Dakota	$479.80
Texas	$236.58
Vermont	Unspecified
Virginia	Individual Consideration
West Virginia	$406.67
Wisconsin	Manual
Wyoming	By Report

Missouri, Vermont, and Wyoming Medicaid programs cover scleral contact lenses for recipients 0-20 years of age. Medical necessity documentation and invoice of cost are required. Minnesota manually covers scleral contact lenses without prior authorization for bandage lenses and patients with diagnoses of aphakia, keratoconus, or aniseikonia; all other diagnoses or conditions require authorization for lens services and supplies. Texas covers scleral contact lenses for any age as long as there is no other option to correct visual defect; however, replacement lenses are only covered for recipients 0-20 years of age. Illinois covers scleral contact lenses with prior authorization.

Commercial Insurers

Aetna (2016) considers scleral contact lenses medically necessary for any one of the following indications:

- For the treatment of severe dry eyes (keratoconjunctivitis sicca), such as from Sjogren's syndrome, chronic graft-versus-host disease, radiation, surgery, Meibomian gland deficiency
- Corneal disorders associated with systemic autoimmune diseases
- Congenital etiologies

Replacement lenses are considered medically necessary under medical plans if required because of a change in the member's physical condition (not including refractive changes).

Blue Cross and Blue Shield of Florida (2017) indicates scleral contact lenses meet the definition of medical necessity for patients who have not responded to topical medications or standard spectacle or contact lens fitting for the following conditions:

- Corneal ectatic disorders (e.g., keratoconus, keratoglobus, pellucid marginal degeneration, Terrien's marginal degeneration, Fuchs' superficial marginal keratitis, postsurgical ectasia)
- Corneal scarring and/or vascularization
- Irregular corneal astigmatism (e.g., after keratoplasty or other corneal surgery)
- Ocular surface disease (e.g., severe dry eye, persistent epithelial defects, neurotrophic keratopathy, exposure keratopathy, graft-versus-host disease, sequelae of Stevens

Johnson syndrome, mucus membrane pemphigoid, post ocular surface tumor excision, post-glaucoma filtering surgery) with pain and/or decreased visual acuity

Blue Cross/Blue Shield of Mississippi (no date) considers scleral contact lenses medically necessary when a patient has not responded to topical medications or standard spectacle or contact lens fitting for the following conditions:

- Corneal ectatic disorders (e.g., keratoconus, pellucid marginal degeneration)
- Corneal scarring and/or vascularization
- Irregular corneal astigmatism (e.g., after keratoplasty or other corneal surgery)
- Ocular surface disease (e.g., severe dry eye, graft-versus-host disease, sequelae of Stevens Johnson syndrome)

Blue Cross/Blue Shield of Texas (2016) considers scleral contact lenses medically necessary when the eye has been rendered sightless, shrunken or deformed, or when people are not candidates for corneal transplant. Premature babies or children who did not develop properly or completely may be candidates for medical necessity.

Fallon Health (2016) covers scleral contact lenses for certain medically necessary diagnoses. Prior authorization is required, as defined below:

Corneal contact lenses:

- Post-cataract surgery with insertion of intraocular lenses
- Treatment of aphakia (absent natural lens)
- Treatment of keratoconus (irregular protrusion of cornea)
- As moist bandages for treatment of acute or chronic corneal pathology

Scleral contact lenses:

- To treat eyes rendered sightless and shrunken by inflammatory disease. A scleral shell may obviate the need for surgical enucleation and prosthetic implant and act to support the surrounding orbital tissue.

Fiscal Analysis

During Fiscal Year 2015/2016 (FY15/16), there were 44,463 unique recipients with an associated diagnosed eye disease (see Attachment 1 for a list of diagnosed eye diseases and total number of recipients per disease). When recipients with more than one associated diagnosed eye disease are included, the number of recipients increases to 46,202. The age of diagnosed recipients ranged from 0 – 109 years.

For the purpose of this fiscal analysis, 33 procedure codes (see Attachment 2) currently covered by Florida Medicaid related to the management and treatment of multiple ocular issues were utilized (Agency for Health Care Administration, 2017). The Bureau of Medicaid Data Analytics provided information for fee-for-service claims and managed care encounter data. It should be noted the managed care encounters are low projections because the amount paid listed on the encounter was $0. During FY15/16, the total cost of claims for all analyzed treatment codes under fee-for-service transactions was $255,544.05. The total cost of claims for the same treatment codes under managed care encounters was $1,397,067.28. Combined, these costs totaled $1,652,611.33.

Removal of eye lesions (including keratectomy with grafts) was the costliest treatment during FY15/16, at a combined cost of $698,654.44. Corneal transplant procedures (keratoplasty) were performed at a combined cost of $292,928.01. Ocular surface reconstruction/amniotic membrane transplantations were performed at a combined cost of $231,237.84.

If covered, the Bureau of Medicaid Program Finance recommends that scleral contact lenses be reimbursed at $279.39. These lenses should last approximately 1-3 years.

According to Dalton and Sorbara (2011), 12-26% of patients with keratoconus need surgical intervention, and penetrating keratoplasty is the most commonly performed surgery. Baran et al. (2012) indicate penetrating keratoplasty corrects opacity but often results in post-operative astigmatism or anisometropia, which still requires correction with contact lenses. Contact lens fitting after keratoplasty is difficult. Schornack and Patel (2010) also report that despite a high initial success rate of penetrating keratoplasty, many patients still require rigid contact lenses to achieve their best vision. Additionally, complications such as graft rejection and graft failure occur in approximately 20% and 10% of eyes, respectively, and ectasia can recur in 6-11% of eyes receiving a penetrating keratoplasty for keratoconus. This frequently results in repeat keratoplasty procedures. Consequently, costs associated with treating corneal disorders increase.

During FY15/16, the total combined cost of penetrating keratoplasty (CPT code 65730) for Florida Medicaid was $133,413.88. If 12% of those individuals (using the low end of estimates provided by Dalton and Sorbara, 2012) had been prescribed scleral contact lenses, the cost of lenses would have been $4,392.01. By comparison, the cost of 12% of surgeries was $16,009.67. The use of scleral contact lenses instead of surgery for just 12% of cases would have resulted in a savings of $11,617.26. As mentioned previously, penetrating keratoplasty is not always successful in restoring vision and lenses are still needed. However, the use of scleral contact lenses prior to considering penetrating keratoplasty could result in some patients not requiring surgery, which would reduce the overall cost of treatment over the recipient's lifetime. Research indicates the use of scleral contact lenses can delay or avoid initial or repeat keratoplasty, which in turn reduces the cost, effort, and other issues related to maintaining corneal grafts (Schornack & Patel, 2010; Rathi et al., 2015). Savings would further increase with the use of scleral contact lenses in place of other corneal surgical procedures, such as keratectomy and ocular surface reconstruction. Also of note, scleral contact lens use may not be required throughout a recipient's life, thereby reducing costs associated with replacement lenses. Schornack, Pyle, and Patel (2014) conducted a retrospective study regarding scleral contact lens use in the management of ocular surface disease. Among 83 patients who had 12 or more months of follow-up after scleral contact lens therapy, 9 patients discontinued using the lenses because they found adequate relief with less aggressive intervention. For four patients, their conditions resolved and the lenses were no longer needed.

GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS RECOMMENDATION

This report recommends scleral contact lenses as a health service that has been demonstrated to be an effective treatment option for certain advanced diseases of the cornea whereby no other types of contact lenses have been successful. If scleral contact lenses become a covered service under the Florida Medicaid program, it is recommended that they be prior authorized. Supporting medical documentation must include the recipient's diagnosis, the symptoms associated with the condition, the prescription for each eye, and documentation of all prior treatments attempted.

Rationale

✓ **Concur** ____ **Do not Concur**

Comments:

_____

_____

_____

Deputy Secretary for Medicaid (or designee)

11/17/17
Date

Attachment 1

Recipient Count per Diagnosis

Diagnosis Category	Unique Recipient Count	Percentage
Dry Eye Syndrome	32,131	69.5%
Keratoconjunctivitis	4,417	9.6%
Irregular Astigmatism	4,241	9.2%
Ulcer	2,043	4.4%
Keratoconus	1,286	2.8%
Aphakia	1,216	2.6%
Bullous Keratopathy	427	0.9%
Recurrent Cornea Erosion	324	0.7%
Corneal Ectasia	88	0.2%
Keratopathy (Bullous aphakic)	29	0.1%

Attachment 2

Procedure Codes Reimbursed by Florida Medicaid

Excision
65400 – Excision of Lesion, cornea (keratectomy, lamellar, partial), except pterygium
65420 – Excision or transposition of pterygium, without graft
65426 – with graft

Removal or Destruction
65450 – Destruction of lesion of cornea by cryotherapy, photocoagulation, or thermocauterization

Keratoplasty
65710 – Keratoplasty (corneal transplant); anterior lamellar
65730 – penetrating (except in aphakia or pseudoaphakia)
65750 – penetrating (in aphakia)
65755 – penetrating (in pseduoaphakia)
65756 – endothelial

Other Corneal Procedures of the Anterior Segment
65770 – Keratoprosthesis
65772 – Corneal relaxing incision for correction of surgically induced astigmatism
65775 – Corneal wedge resection for correction of surgically induced astigmatism
65778 – Placement of amniotic membrane on the ocular surface; without sutures
65779 – single layer, sutured
65780 – Ocular surface reconstruction; amniotic membrane transplantation, multiple layers
65782 – limbal conjunctival autograft (includes obtaining graft)
65785 – Implantation of intrastromal corneal ring segments
66999 – Unlisted procedure, anterior segment of eye

Posterior Sclera, Repair
67250 – Scleral reinforcement, without graft
67255 – with graft

Tarsorrhaphy
67875 – Temporary closure of eyelids by suture

Conjunctivoplasty
68320 – Conjunctivoplasty; with conjunctival graft or extensive rearrangement
68325 – with buccal mucous membrane graft (includes obtaining graft)
68326 – Conjunctivoplasty, reconstruction cul-de-sac; with conjunctival graft or extensive rearrangement
68328 – with buccal mucous membrane graft (includes obtaining graft)
68330 – Repair of symblepharon; conjunctivoplasty, without graft
68335 – with free graft conjunctiva or buccal mucous membrane (includes obtaining graft)

Special Ophthalmological Services
92025 – Computerized corneal topography, unilateral or bilateral, with interpretation and report
92071 – Fitting of contact lens for treatment of ocular surface disease

Contact Lenses
V2511 – Contact lens, gas permeable, toric (maximum fee for bilateral fitting = $280; each replacement lens = $59)
V2513 – Contact lens, gas permeable, extended wear (maximum fee for bilateral fitting = $278; each replacement lens = $58.50)
V2521 – Contact lens, hydrophilic, toric (maximum fee for bilateral fitting = $284; each replacement lens = $60)
V2523 – Contact lens, hydrophilic, gas permeable (maximum fee for bilateral fitting = $266; each replacement lens = $55.50)

RICK SCOTT
GOVERNOR

JUSTIN M. SENIOR
SECRETARY

FRACTIONAL EXHALED NITRIC OXIDE MEASUREMENT GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS (GAPMS) DETERMINATION REPORT WITH RECOMMENDATION

Date: June 13, 2017

To: Beth Kidder, Deputy Secretary for Medicaid

From: Bureau of Medicaid Policy

Subject: **Fractional Exhaled Nitric Oxide Measurement Device**

PURPOSE

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

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

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

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

REPORT WITH RECOMMENDATION

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

The analysis described in this report includes:

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

Pl. Trial Ex. 330

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

HEALTH SERVICE SUMMARY

Asthma

Asthma is a chronic lung disease that affects 25 million people, including 7 million children, in the United States. The disease causes the inflammation and narrowing of the airways (bronchial tubes) that carry air into and out of the lungs. People diagnosed with asthma have inflamed airways which are swollen and sensitive. In most cases, inhalation of certain substances causes the muscles to contract around the airways, narrowing them and limiting airflow into the lungs. This can result in an asthma exacerbation marked by wheezing, shortness of breath, and coughing. (National Heart, Lung, and Blood Institute, 2012)

Diagnosing asthma requires evaluating a patient's history, physical examination, and tests such as pulmonary function tests (spirometry). Due to the numerous factors that can cause asthma or asthma symptoms, no standard procedure exists to make a diagnosis. Practitioners base their diagnoses on the likelihood of asthma and treat symptoms accordingly. (National Heart, Lung, and Blood Institute, 2012)

Diagnostic Testing

Spirometry measures lung function and is used in the diagnosis and management of respiratory conditions such as asthma, pulmonary fibrosis, and chronic obstructive pulmonary disease (COPD). (Global Initiative for Chronic Obstructive Lung Disease, 2007)

When administering spirometry, the practitioner has the patient take a deep breath and exhale as hard as possible into an apparatus that measures how much air moves in and out of the lungs. The results consist of two measurement types, forced vital capacity (FVC) and forced expiratory volume (FEV1), and are compared to a predicted result based on age, sex, height, and ethnicity. If the patient's FVC and FEV1 are lower than the predicted result, the test indicates an obstructive airway disease. (Global Initiative for Chronic Obstructive Lung Disease, 2007)

Practitioners also use bronchodilator reversibility testing to determine whether a fixed airway is narrowing. This consists of a comparison and contrast of two spirometry tests, one where the patient performs the test normally and a second conducted 15-20 minutes later following bronchodilator administration. If the second test's results show improved lung function, it indicates that the airway obstruction is reversible and supports a diagnosis of asthma. (Global Initiative for Chronic Obstructive Lung Disease, 2007)

Treatment

Asthma does not have a cure, and the treatment goal is to keep the disease well controlled. To attain this, practitioners instruct patients to avoid factors that trigger exacerbations such as allergens and treat other conditions that provoke asthma symptoms. For patients having difficulty controlling the disease, practitioners prescribe inhaled corticosteroids (ICS). These are the preferred medications to reduce inflammation and achieve long-term control. Other

treatments such as nebulizers (a device that delivers a medication as a fine mist to the lungs) and monthly Omalizumab (anti-inflammatory) injections are used when ICSs are inadequate. (National Heart, Lung, and Blood Institute, 2012)

Fractional Nitric Oxide Measurement (FeNO)

Nitric oxide (NO), a pollutant produced by the lungs, is a highly reactive molecule/free radical that is detectable in exhaled breath. Its oxidant properties and role in lung function cause it to play a key role in the pathophysiology of pulmonary diseases such as asthma.

Patients with asthma diagnoses tend to have elevated levels of NO in their exhaled breath as a result of allergic airway inflammation (Shaw et al, 2007). Research studies have been conducted to determine if measuring the FeNO levels in a patient's breath can assist with the diagnosis of asthma and if adjustments in medication are needed to attain optimal control.

Aerocrine – NIOX Product Line

Aerocrine manufactures FeNO monitoring devices (NIOX) for research and clinical applications. Only trained healthcare professionals may operate the device as directed by the user manual. The latest portable system on the market is the NIOX VERO (Aerocrine, 2014).

To use the device, a patient empties their lungs, takes a deep breath through the patient filter to test capacity, and slowly exhales for 10 seconds. The device measures the NO concentration of the last 3 seconds of the 10 second exhalation and displays the result in approximately 1.5 minutes. According to the manufacturer, the device can last 5.5 years or 15,000 measurements. (Aerocrine, 2014)

Government Regulatory Body Approval

According to Title 21 CFR 862.3080, a breath nitric oxide test system is identified as a "device intended to measure fractional nitric oxide in human breath. Measurement of changes in fractional nitric oxide concentration in expired breath aids in evaluating an asthma patient's response to anti-inflammatory therapy, as an adjunct to established clinical and laboratory assessments of asthma." (U.S. Food and Drug Administration, 2003)

In 2014, the U.S. Food and Drug Administration (FDA) determined that NIOX VERO is approved for use as a prescription device. The FDA further stated that NIOX VERO cannot be used with infants or children under seven years old. (U.S. Food and Drug Administration, 2014)

LITERATURE REVIEW

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

Asthma Exacerbation Reduction and Monitoring

Powell et al (2011) conducted a research trial that assigned 220 non-smoking, pregnant women with asthma into two groups, one to monitor FeNO levels in regards to treatment (111 participants) and the other to continue management without monitoring (109 participants).

During the trial, the participants having their FeNO levels monitored had lower exacerbation rates than those who did not with a mean rate of 0.29 exacerbations per pregnancy in comparison to 0.69. As a result of evaluating their FeNO levels, the participants in the monitoring group received different treatment regimens consisting of higher doses of inhaled corticosteroids (ICS) and long-acting beta-agonists.

Petsky et al (2014) tracked the asthma management of 63 children separated into two groups, 31 receiving FeNO monitoring and 32 continuing management without monitoring. Of the participants who completed the trial (eight did not complete the trial), 6 of the 27 children receiving FeNO monitoring reported having an exacerbation as opposed to 15 of the 28 children in the other group. Petsky et al acknowledged that the FeNO monitoring group used higher doses of ICS and that the strategy is not likely to improve asthma control and a second-larger study is needed.

Shaw et al (2007) conducted a trial with 118 asthma patients divided into two groups, one that used FeNO monitoring to determine ICS treatment (58 participants) and the other to continue management without monitoring (60 participants). The results showed that a treatment strategy using FeNO measurements did not translate into a large reduction of ICS usage or exacerbations over a 12-month period in comparison to current asthma guidelines.

In both the Powell et al and Petsky et al trials, the FeNO monitoring groups experienced fewer significant exacerbation but also took higher doses of medication. The Shaw et al trial noted an 11% increase in ICS used by the FeNO monitoring group but indicated that the group had a smaller daily dose. When determining the methodology, the trials used different cutoffs of FeNO measurements to determine whether or not to increase ICS with a range of 26 ppb (Shaw et al) to 35 ppb (parts per billion) (Petsky et al).

Asthma Diagnosis

Pedrosa et al (2010) conducted a trial with 114 adult patients reporting asthma symptoms but did not have a diagnosis. All of the participants had normal spirometry (pulmonary function test) and negative bronchodilator tests. Prior to undergoing a methacholine challenge test (evaluates the narrowing and tightening of airways), the participants had FeNO measurements taken. The results showed that 35 of the 114 received diagnoses of asthma and that those diagnosed had higher FeNO levels with a cutoff value of 40 ppb.

Schneider et al (2013) conducted a prospective diagnostic study with 393 participants who had reported asthma symptoms. The participants provided FeNO measurements and morning sputum samples. The study resulted in 154 asthma and 5 COPD (chronic obstructive pulmonary disease) diagnoses and concluded that FeNO measurement functioned best as a diagnostic tool when inflammatory patterns are considered. However, Schneider et al noted that FeNO measurements had a low predictive value when the pre-test probability for asthma was also low.

Other studies such as Ciprandi et al (2010), Buslau et al (2014), Woo et al (2012), and Jerzynska et al (2014) showed varying cutoff levels for FeNO measurements when diagnosing asthma with a range of 18.05 ppb (Buslau et al) to 40 ppb (Pedrosa et al). These variances do not allow for a fixed cutoff, making the diagnosis of asthma difficult based on FeNO measurements.

Evidence-Based Clinical Practice Guidelines

The American Thoracic Society (ATS) released a clinical practice guideline (2011) for the interpretation of FeNO levels. It concluded that conventional tests such as spirometry provide limited information regarding airway inflammation and that FeNO measurements can aid in detecting eosinophilic inflammation (allergy driven) and determine ICS responsiveness. The ATS also recommended FeNO measurement cutoffs of >50 ppb in adults and >35 ppb in children to indicate eosinophilic inflammation that is likely to respond to ICS. However, the ATS indicated that FeNO measurements alone cannot serve as a basis for diagnosis or treatment plan and that they need to be applied within the clinical context. The ATS also stated that FeNO values may apply best when compared to a personal baseline as opposed to a normal range and recommended further trials using multiple clinical settings. In 2012, the American Academy of Allergy, Asthma, and Immunology (AAAAI) and the American College of Allergy, Asthma, and Immunology (ACAAI) released a joint statement supporting the ATS's clinical practice guideline.

The National Institute for Health and Care Excellence (NICE), which is based in the United Kingdom, released recommendations (2014) for the use of FeNO measurements in the diagnosis and management of asthma. NICE concluded that FeNO testing is useful as a diagnostic tool for patients who have an intermediate probability of having asthma and must be done in combination with other tests. NICE further determined that FeNO measurements function as a "rule in" test and that a negative or low reading does not rule out asthma. For management, NICE recommended that FeNO testing can serve as support for patients continuing to show symptoms despite ICS use. However, it is not optimal for lowering ICS medication in patients who have well-controlled asthma.

COVERAGE POLICY

Medicare

Medicare does not have a National Coverage Determination (NCD) for FeNO measurement. This does not preclude individual states from making a Local Coverage Determination (LCD) and adding the Current Procedural Terminology (CPT) code 95012 to their fee schedules. Florida's Medicare contractor, First Coast Service Options, covers FeNO testing under CPT code 95012.

Medicaid

Thirty-seven Medicaid programs cover FeNO testing under CPT code 95012. Keystone First's (Pennsylvania's Managed Medicaid Plan) clinical policy (2014) states that FeNO testing is covered only to establish an eosinophilic asthma diagnosis when testing and physical examinations are inconclusive. All other uses for FeNO measurements are not medically necessary.

Other Insurers

Cigna stated in its 2015 coverage policy that it does not cover FeNO measurement for any indication due to insufficient evidence of beneficial health outcomes. The company deemed the test as investigational.

Blue Cross Blue Shield (BCBS) of North Carolina reported in its 2016 corporate medical policy that it considers FeNO measurement to be investigational and does not cover the service.

Regence, the BCBS company for Oregon and Utah, completed a literature review of FeNO measurements in 2016 and concluded that the test was investigational and not eligible for coverage.

WellCare in a position statement (2014) stated that it does not cover FeNO measurement due to its investigational status. However, WellCare does cover the test for Georgia Medicaid which does consider it medically necessary.

Aerocrine reported that United Healthcare and Health Care Service Corporation (HCSC) cover FeNO testing in two press releases from 2012 and 2014 respectively.

GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS RECOMMENDATION

This report does not recommend Fractional Exhaled Nitric Oxide (FeNO) Measurement as a health service that is consistent with generally accepted professional medical standards.

Rationale

The medical profession agrees that measuring FeNO levels can aid in the diagnosis and treatment of asthma. However, the profession differs on how to use those levels appropriately and what thresholds should be established. More conclusive research and trials are necessary to understand the potential benefits of this test. Furthermore, trials already conducted do not make a case for the necessity of FeNO. To control asthma, practitioners prescribe inhaled corticosteroids and can measure the dosage depending on severity. Patients who report exacerbations can have their medications adjusted without having to take an additional test. Regardless of whether FeNO levels are known, physicians can follow the standard treatment and diagnostic testing for asthma while attaining the same results.

Given the need for further research to establish more definite clinical guidelines, FeNO measurements have not been determined to be a generally accepted professional medical standard consistent with Rule 59G-1.035(2), F.A.C. When assessing patient benefit, research and trials indicated that improved results can be attained without measuring FeNO levels and that the test serves as an adjunct to established methods for evaluating asthma.

EPSDT Considerations

The American Thoracic Society's guidelines indicate that measuring FeNO levels can aid in the diagnosis of asthma when other tests prove inconclusive and that it can assist in determining appropriate ICS doses. Florida Medicaid pays for children's services when they protect life and prevent significant disability or harm in accordance with the state's medical necessity definition.

Though, it is not recommended that further analysis be conducted to add FeNO as a covered Medicaid service, consistent with EPSDT requirements, the Agency and its health plans can evaluate individualized requests through its special services processes (as described in Rule 59G-5.020, F.A.C.) to determine if the service is medically necessary and to ensure that this treatment approach presents as the child's best alternative given the pending circumstances.

____Concur **____Do not Concur**

Comments:

_____

_____

_____

_____ 7/3/17

Deputy Secretary for Medicaid (or designee) *date*

RICK SCOTT
GOVERNOR

ELIZABETH DUDEK
SECRETARY

BREAST PUMP
GAPMS DETERMINATION REPORT WITH RECOMMENDATION

Date: May 18, 2015

To: Justin Senior, Deputy Secretary for Medicaid

From: Bureau of Medicaid Policy

Subject: **Breast Pump Coverage**

PURPOSE

In order for a breast pump to be covered under the Florida Medicaid program, it must meet medical necessity criteria as defined in 59G-1.010(166),[A1] Florida Administrative Code. (F.A.C.), and funded through the General Appropriations Act of Chapter 216, Florida Statutes (F.S.).

Pursuant to the criteria set forth in 59G-1.010(166)(a)(3), F.A.C., breast pumps must be consistent with generally accepted professional medical standards (GAPMS) as determined by the Medicaid program, and not experimental or investigational.

In accordance with the determination process established in 59G-1.035,[A2] F.A.C., this GAPMS Determination Report with Recommendation is submitted for review to the Deputy Secretary for Medicaid.

The Deputy Secretary for Medicaid will make the final determination as to whether breast pumps are consistent with generally accepted professional medical standards and not experimental or investigational.

RECOMMENDATION

This report recommends breast pumps as a health service that is consistent with generally accepted professional medical standards. It is further recommended that the following devices be covered:

1. A rent-to-purchase electric breast pump may be considered medically necessary when a nursing mother is experiencing prolonged separation from her infant because of work, school, or a medical reason.

2. Electric hospital grade breast pump rental may be considered medically necessary when a newborn recipient has one of the following conditions:
   - Prematurity (less than 37 weeks gestation),
   - Neurologic disorder,
   - Genetic abnormalities (e.g., Down Syndrome),

Pl. Trial Ex. 330

- Anatomic and mechanical malformation (e.g., cleft lip and palate),
- Congenital malformations requiring surgery (e.g., respiratory, cardiac, gastrointestinal, central nervous system)

An electric hospital grade breast pump rental may also be considered medically necessary when the nursing mother has been diagnosed with and is receiving treatment for mastitis or related infection of the breast.

Coverage of an electric hospital grade breast pump rental would be limited to no more than a three month period. Exceptions can be made on a case by case basis, based upon medical necessity.

REPORT WITH RECOMMENDATION

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

The analysis described in this report includes:

- Background information and pertinent current Medicaid policies
- An overview of the health service
- Information submitted by the requestor
- Confirmation of clearance from the government regulatory body
- Evidence based clinical practice guidelines
- Coverage policies from commercial and other state Medicaid insurers.

HEALTH SERVICE SUMMARY

Breast Pumps – Device Summary

There are three basic types of breast pumps:

- Manual pumps
- Battery-powered pumps
- Electric pumps

These pumps may be offered with single or double pumping actions. Table 1 provides information on different types and descriptions of breast pumps that are available.

Pumping Type	How it works	Types of Breast Pumps
Single	Extracts milk from one breast at a time.	Most manual breast pumps are single pumps. Most battery-powered pumps are single pumps.
Double	Can be used to extract milk from both breasts at the same time.	Some electric pumps are double pumps.

Table 1

GOVERNMENT REGULATORY BODY APPROVAL

Medical devices (including breast pumps) are regulated by the United States Food and Drug Administration (FDA). Breast pumps are often used by breastfeeding women to extract ("express") their breast milk. Breast pumps can also be used to maintain or increase a woman's milk supply, relieve engorged breasts and plugged milk ducts, or pull out flat or inverted nipples so a nursing baby can latch-on to its mother's breast more easily. Many women find it convenient, or even necessary, to use a breast pump to express and store their breast milk once they have returned to work, are traveling, or are otherwise separated from their baby. A breast pump can be used as a supplement to breastfeeding and some pumps are designed to mimic the suckling of a nursing baby. A number of breast pumps have been reviewed and approved by the FDA (U.S. Food and Drug Administration, 2015).[A3]

CLINICAL OUTCOMES

The benefits of breastfeeding are widely acknowledged, and as such, breastfeeding is the infant feeding method recommended by numerous organizations, including the Association of Women's Health, Obstetric and Neonatal Nurses[A4]; the World Health Organization[A5]; the Dietitians of Canada and Breastfeeding Committee for Canada[A6]; the American Dietetic Association[A7]; and the American Academy of Pediatrics (AAP).[A8]

The American Academy of Family Physicians[A9] and most all of the organizations listed above recommends that all babies, with rare exceptions, be breastfed and/or receive expressed human milk exclusively for the first six months of life.

The AAP[A8] reports that breastfeeding is associated with reductions in middle ear infections, gastrointestinal infections, sudden infant death syndrome, and adolescent and adult obesity rates. Therefore, the AAP also recommends exclusive breastfeeding for the first 6 months after birth, and then continued breastfeeding for one year or longer, as other foods are introduced. These benefits are further supported by literature published by the Institute of Child Health and Human Development.

The Institute of Child Health and Human Development (ICHHD)[A10] also proposes certain benefits of breastfeeding for the nursing mother, including:

- Less blood loss following childbirth and improved healing
- Improved postpartum weight loss
- Lower likelihood of experiencing postpartum depression, which is seen more often in new mothers who do not breastfeed
- Less chance of developing certain health conditions, such as rheumatoid arthritis, cardiovascular disease, and certain cancers (for example, breast cancer)
- Physical and emotional benefits of breastfeeding directly from a mother's breast due to skin-to-skin contact with her infant

EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES

Both the ICHHD and in an issue paper regarding Medicaid coverage of lactation services, the Department of Health and Human Services, Centers for Medicare & Medicaid Services, provides that improving the health of the population and reducing preventable causes of poor health, such as obesity, is a priority; and current research indicates that breastfeeding or using

expressed milk for the first 6 to 12 months of life is highly beneficial for both the mother and infant in reducing these and other preventable health conditions. [A11]

On January 20, 2011, the United States Surgeon General released "The Surgeon General's Call to Action to Support Breastfeeding." This report indicates that there is a 32% higher risk of childhood obesity and a 64% higher risk of type 2 diabetes for children who are not breastfed. This report also provides recommended actions to remove some of the obstacles faced by women who want to breastfeed their babies; pointing out the health and economic benefits of breastfeeding, and offering opportunities for women to be supported in the workplace for breastfeeding including access to high-grade electric breast pumps. [A12]

In July, 2014, the National Center for Chronic Disease Prevention and Health Promotion's Division of Nutrition, Physical Activity, and Obesity, which is a division of the Centers for Disease Control and Prevention, published a Breastfeeding Report Card. Florida is within approximately two percentage points of national averages for the number of babies being breastfed with three quarters of all babies born being breastfed at some point, and around half still being breastfed at six months (Table 2). [A13]

Centers for Disease Control and Prevention National Immunization Survey (July 2014)					
Breastfeeding Rates	Ever Breastfed (%)	Breastfeeding at 6 months (%)	Breastfeeding at 12 months (%)	Exclusive breastfeeding at 3 months (%)	Exclusive breastfeeding at 6 months (%)
U.S. National	79.2	49.4	26.7	40.7	18.8
Florida	77.0	48.7	26.9	38.9	18.3

Table 2

An effective electric breast pump is an important tool for the management of breastfeeding challenges such as providing human milk to sick or premature infants. A breast pump is also, in Western culture, critical for breastfeeding mothers who return to work. Obtaining an effective electric breast pump can be difficult for uninsured or impoverished women because of the expense, complicated insurance reimbursements, and scarcity of providers that supply breast pumps to the inner-city community (Chamberlain, McMahon, Philipp, and Merewood, 2006).[A14]

Mothers who work outside the home initiate breastfeeding at the same rate as mothers who stay at home. However, the breastfeeding continuance rate declines sharply in mothers who return to work. While the work environment may be less than ideal for the breastfeeding mother, obstacles can be overcome. Electric piston pumps may be the most suitable type for mothers who work outside the home for more than 20 hours per week; however, when a mother is highly motivated, any pump type can be successful in any situation (Biagioli, 2003). [A15]

COVERAGE POLICY [A16]

Affordable Care Act

The Affordable Care Act (2010) requires most health insurance plans to cover the cost of a breast pump as part of women's preventative health services. These rules apply to health insurance marketplace plans and all other private health insurance plans, except for grandfathered plans. State Medicaid programs are not required by the Affordable Care Act to provide lactation services including breast pumps. [A11]

Florida Women, Infants, and Children (WIC)
Florida's Special Supplemental Nutrition Program covers breast pumps under certain circumstances. However, funding for breast pumps statewide is limited. Of the available pumps, local WIC offices use a priority system to determine who will receive a breast pump, as the resource is limited.

Medicare
Medicare does not cover breast pumps or breast pump supplies.

Aetna
Aetna covers the rental of breast pumps under its DME benefit when either of the following criteria is met:

- The newborn is detained in the hospital after the mother is discharged
- The infant is diagnosed with a congenital disorder that interferes with feeding

Florida Blue (Commercial Insurer Blue Cross/Blue Shield)
Florida Blue covers the following:

- One electrical or manual breast pump per member, per delivery (hospital grade electric breast pumps are excluded except when medically necessary during an inpatient hospital stay)

Minnesota Medicaid
Minnesota Medicaid covers breast pumps when ordered by the treating provider for any nursing mother experiencing separation from her infant because of work, school, illness or any other medical reason.

New York Medicaid
New York Medicaid covers hospital or professional grade breast pump under the following circumstances impacting the newborn:

- Prematurity (including multiple gestation),
- Neurologic disorders,
- Genetic abnormalities (e.g., Down's Syndrome),
- Anatomic and mechanical malformations (e.g., cleft lip and palate),
- Congenital malformations requiring surgery (e.g., respiratory, cardiac, gastrointestinal, CNS),
- Prolonged infant hospitalization.

Oregon Medicaid
Oregon Medicaid covers breast pumps taking into consideration the medical appropriateness for the infant and/or mother.

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FISCAL

Reimbursement rates for electric and hospital grade breast pumps are variable, based on research and review of other states coverage polices (Table 3).

Table 1: Other States' Medicaid Rates

	Electric Pump	Electric Hospital-Grade Pump[1]
Alaska	$1.27	$91.50
Connecticut	$118.75	
Idaho	$394.34	
Illinois	$119.74	
Maryland	$87.90	$56.21
Michigan	$134.32	$61.82
Minnesota	$256.14	$51.31
New Mexico	$49.25	
New York	$173.47	$38.61
Oregon	$80.92	
Texas	$152.88	$39.15
Washington	$65.60	$80.52
Average Mean[2]	**$124.00**	**$58.07**

Table 3

In conducting the fiscal analysis for coverage breast pumps under Florida Medicaid, we utilized the average reimbursement rates, as reflected above for each device.

Electric Breast Pump Purchase

In 2013, Florida Medicaid reimbursed for 111,619 births. In Florida, while 77% of newborns born in 2013 were reported to have ever been breastfed, only about 49% are still being breastfed at six months of age (Table 2). This signals that while a large percentage (the majority) of women in Florida have attempted to breastfeed their newborn/infant, only about half continue to do so for as long as recommended. Therefore, assuming 50% of these newborns were breastfed and there was a need to utilize an electric breast pump, the total cost for Florida Medicaid is expected to be $6,920,378.

Hospital Grade Breast Pumps Rentals

During state fiscal year 2013-2014, there were approximately 60,000 infants diagnosed with prematurity (less than 37 weeks gestation), a neurologic disorder, genetic abnormalities (e.g., Down Syndrome), an anatomic and/or mechanical malformation (e.g., cleft lip and palate), and congenital malformations requiring surgery (e.g., respiratory, cardiac, gastrointestinal, central nervous system).

[1] Per month rental rate
[2] Removed outlier rates

Assuming 50% of these newborns' mothers desired to breastfeed, but due to the child's condition required a hospital grade breast pump, the total cost for Florida Medicaid is expected to be $5,226,300 (based on a maximum rental period of three months). The estimated annual fiscal impact of covering both electric and hospital grade breast pumps is $12,146,678. The cost of this may be partially offset in the short-term by reductions in middle ear and gastrointestinal infections and in the long-term by reduced rates of obesity with its associated chronic disease costs (e.g. diabetes).

GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS RECOMMENDATION

This report recommends breast pumps as a health service that is consistent with generally accepted professional medical standards. It is further recommended that the following devices be covered:

1. A rent-to-purchase electric breast pump may be considered medically necessary when a nursing mother is experiencing prolonged separation from her infant because of work, school, or a medical reason.

2. Electric hospital grade breast pump rental may be considered medically necessary when a newborn recipient has one of the following conditions:
   - Prematurity (less than 37 weeks gestation),
   - Neurologic disorder,
   - Genetic abnormalities (e.g., Down Syndrome),
   - Anatomic and mechanical malformation (e.g., cleft lip and palate),
   - Congenital malformations requiring surgery (e.g., respiratory, cardiac, gastrointestinal, central nervous system).

   An electric hospital grade breast pump rental may also be considered medically necessary when the nursing mother has been diagnosed with and is receiving treatment for mastitis or related infection of the breast.

   Coverage of an electric hospital grade breast pump rental would be limited to no more than a three month period. Exceptions can be made on a case by case basis, based upon medical necessity.

✓ **Concur** ____ **Do Not Concur**

Comments:

_____

_____

_____

_____ 5/28/15

Signature **Date**

Deputy Secretary for Medicaid (or designee)

Attachments

A1. 59G-1.010(166), F.A.C., "Medically Necessary"
A2. 59G-1.035, F.A.C., "Determining Generally Accepted Professional Medical Standards"
A3. FDA. 501(k) Devices: Megna Breast Pumps K142479. U.S. Food and Drug Administration. February 2015.
FDA. 501(k) Devices. Ardo Carum and Calypso Powered Breast Pumps K141742 . U.S. Food and Drug Administration. October 2014
FDA. 501(k) Devices. Expresse and Premier Powered Breast Pumps K973501. U.S. Food and Drug Administration. December 1997
A4. Association of Women's Health, Obstetric and Neonatal Nurses. AWHONN Position Statement: Breastfeeding. *Journal of Obstetric, Gynecologic, & Neonatal Nursing.* 2015. 44(1);145-150.
A5. World Health Organization. Media Centre: Infant and young child feeding Fact Sheet N342. February 2014. http://www.who.int/mediacentre/factsheets/fs342/en/
A6. Infant Feeding Joint Working group. Nutrition for Health Term Infants: Recommendations from Birth to Six Months. *Health Canada* 2014 http://www.hc-sc.gc.ca/fn-an/nutrition/infant-nourisson/recom/index-eng.php#a3.
A7. American Dietetic Association. Promoting and Supporting Breastfeeding. *Journal of the American Dietetic Association.* 2009. 109;1926-1942.
A8. American Academy of Pediatrics. Policy Statement: Breastfeeding and the Use of Human Milk. *Pediatrics*. 2012. 129(3); e827-e841
A9. American Academy of Family Physicians. Breastfeeding, Family Physicians Supporting (Position Paper). *American Family Physician.* 2015. 91(1);56-57
A10. National Institutes of Health. What are the benefits of breastfeeding? Eunice Kennedy Shriver National Institute of Child Health and Human Development. 2015. https://www.nichd.nih.gov/health/topics/breastfeeding/conditioninfo/Pages/benefits.aspx
A11. Center for Medicaid and CHIP Services. Issue Brief: Medicaid Coverage of Lactation Services. 2012. http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Quality-of-Care/Downloads/Lactation_Services_IssueBrief_01102012.pdf
A12. U.S. Department of Health and Human Services. *The Surgeon General's Call to Action to Support Breastfeeding.* U.S. Department of Health and Human Services, Office of the Surgeon General. 2011. http://www.surgeongeneral.gov
A13. Centers for Disease Control and Prevention. *Breastfeeding Report Card United states/2014.* National Center for Chronic Disease Prevention and Health Promotion, Division of Nutrition, Physical Activity, and Obesity. 2014. www.cdc.gov
A14. Chamberlain, L.B., McMahon, M., Philipp, B.L., Merewood, A., Breast pump access in the inner city: a hospital-based initiative to provide breast pumps for low-income women. *Journal of Human Lactation.* 2006. 22(1);94-98
A15. Biagioli, Frances, Returning to work while breastfeeding. *American Family Physician.* 2003. 68(11);2199-2207
A16. *Hardcopy*

From: miriam grossman
Subject: Re: AAP-FCAAP Comment Letter: Medicaid Coverage for Gender Affirming Care (Privileged & Confidential)
To: Andre Van Mol; Jason.Weida@ahca.myflorida.com; Andrew.Sheeran@ahca.myflorida.com
Cc: Weida, Jason; kidendo@comcast.net; Sheeran, Andrew
Sent: July 7, 2022 8:53 PM (UTC-04:00)
Attached: image001 (1).png, image002 (1).png, image003 (1).png, image004 (1).png, image005 (1).png, image006 (1).png, image007 (1).png, AAP-FCAAP Comment Letter_Medicaid Coverage for Gender-Affirming Care (FINAL).pdf

Can't wait to watch you take them apart Andre. Sorry I'm not there in person.

Sent from my iPhone

> On Jul 7, 2022, at 8:46 PM, Andre Van Mol <95andrev@gmail.com> wrote:
>
> Amazing. They don't make it out of the first paragraph without misrepresentation.
> They say "widely accepted standard of care "with reference to "the Endocrine Society ." Page 3895 of side guidelines state specifically these do not establish the standard of care. Furthermore, the first paragraph is already defeated by James Cantor's attachment, which speaks specifically about this kind of misrepresentation of organizational statements. OK, I will keep reading and save my comments for tomorrow.
>
> Andre
>
> Sent from my iPhone
>
> > On Jul 7, 2022, at 7:40 PM, Andre Van Mol <95andrev@gmail.com> wrote:
> >
> > Just now seeing this at Atlanta airport.
> >
> > Andre
> >
> > Sent from my iPhone
> >
> > > On Jul 7, 2022, at 5:25 PM, Weida, Jason <Jason.Weida@ahca.myflorida.com> wrote:
> > >
> > > **PRIVILEGED & CONFIDENTIAL**
> > > **ATTORNEY WORK PRODUCT PROTECTED**
> > >
> > > Andre, Quentin, and Miriam,
> > >
> > > Please see the below and attached. Today, the American Academy of Pediatrics and its Florida Chapter have submitted this white paper responding to the GAPMS report and the proposal rule. I encourage you to read it.
> > >
> > > Thanks,
> > > Jason

Pl. Trial Ex. 330

From: MEDICAID RULE COMMENTS <MEDICAIDRULECOMMENTS@ahca.myflorida.com>
Sent: Thursday, July 7, 2022 5:11 PM
To: Weida, Jason <Jason.Weida@ahca.myflorida.com>
Subject: FW: AAP-FCAAP Comment Letter: Medicaid Coverage for Gender Affirming Care

---

From: Scott Van Deman <communications@fcaap.org>
Sent: Thursday, July 7, 2022 1:59 PM
To: MEDICAID RULE COMMENTS <MEDICAIDRULECOMMENTS@ahca.myflorida.com>
Cc: Hudson, Jeff <JHudson@aap.org>; Alicia E. Adams, Esq. <master@fcaap.org>
Subject: AAP-FCAAP Comment Letter: Medicaid Coverage for Gender Affirming Care

To whom it may concern:

Thank you for the opportunity to provide commentary to the Agency for Healthcare Administration on Medicaid rules currently being considered.

Attached is a joint letter from The American Academy of Pediatrics and the Florida Chapter of the American Academy of Pediatrics pertaining to the proposed rule concerning Medicaid's coverage of gender affirming care. This letter also has been submitted electronically through the feedback form at the Florida Department of State public notice number 25979915.

I am requesting that you please acknowledge receipt of this communication via return email.

Thank you once again, and please let me know if you have any questions.

Sincerely,

Scott VanDeman
Communications Coordinator
Florida Chapter of American Academy of Pediatrics, Inc.
Call: 850-224-3939, ext. 1005 |Text: 850-772-0654| Fax: 912-452-9050
Email: svandeman@fcaap.org | Website: fcaap.org
Mail: 1400 Village Square Blvd., #3-87786, Tallahassee, FL 32312

From: Fenske, Taryn M.
Sent: Monday, August 29, 2022 1:28 PM EDT
To: Juarez, Brock; Strickland, Katie
CC: Smith, Bailey A.
Subject: Re: Medicaid Data Response

I'm good with this!
Get Outlook for iOS
From: Juarez, Brock <Brock.Juarez@ahca.myflorida.com>
Sent: Friday, August 26, 2022 2:33:45 PM
To: Fenske, Taryn M. <Taryn.M.Fenske@eog.myflorida.com>; Strickland, Katie <Katie.Strickland@eog.myflorida.com>
Cc: Smith, Bailey A. <Bailey.A.Smith@eog.myflorida.com>
Subject: Medicaid Data Response

Proposed Response:

Good Afternoon,

Please see the attached data on the treatment of gender dysphoria within Florida's Medicaid population over the last four years. Please note, this data only includes those receiving treatment for gender dysphoria and would not include any other categories for treatment such as intersex, cancer, etc. This data is also limited to only our Medicaid population and is not reflective of the total numbers statewide across all forms of healthcare.

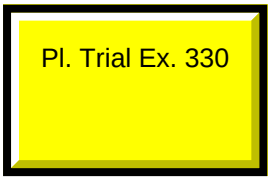
The Agency is providing the number of recipients and procedures for a variety of surgeries for the treatment of gender dysphoria along with the number of recipients and prescriptions for estrogen, testosterone, and puberty blockers for the treatment of gender dysphoria.

As a baseline for comparing data trends we have also included the number of behavioral health therapy visits by recipients and procedures.

What You Should Know

- **From 2017 to 2021 Florida Medicaid saw a 1100% increase in children, even as young as the age of 16, receiving irreversible surgical procedures amongst the Medicaid population compared to only a 63% increase in children receiving therapy for the treatment of gender dysphoria.**
- **From 2017 to 2021 Florida Medicaid saw a 270% increase in children receiving puberty blockers amongst the Medicaid population compared to only a 63% increase in children receiving therapy for the treatment of gender dysphoria.**
- **From 2017 to 2021 Florida Medicaid saw a 110% increase in children receiving estrogen compared to only a 63% increase in children receiving therapy for the treatment of gender dysphoria.**
- **From 2017 to 2021 Florida Medicaid saw a 166% increase in children receiving testosterone amongst the Medicaid population compared to only a 63% increase in children receiving therapy for the treatment of gender dysphoria.**

As you can see, the alarming increase in children receiving pharmaceutical and surgical treatments for gender dysphoria was vastly greater than children receiving behavioral health treatments for gender



dysphoria. This is a concerning statistic and potentially indicative of a medical community increasingly focused on promoting treatments found to be experimental and investigational with the potential for harmful long term effects.

Brock Juarez | Communications Director
Agency for Health Care Administration
850.412.3614 (office) | 850.567.2133 (mobile)

2/24/2020 2:25 PM
Marilyn Burgess - District Clerk Harris County
Envelope No. 41093653
By: Krystle Gibson
Filed: 2/24/2020 2:25 PM
Pgs-2
SDD
QUXWX

NOTICE: THIS DOCUMENT CONTAINS SENSITIVE DATA

NO. 2019-79137

IN THE MATTER OF THE MARRIAGE OF	§	**IN THE DISTRICT COURT**
[redacted]	§	
AND	§	**311TH JUDICIAL DISTRICT**
[redacted]	§	
AND IN THE INTEREST OF	§	
[redacted]	§	**HARRIS COUNTY, TEXAS**
CHILDREN		

ORDER STRIKING EXPERT
DR. QUENTIN L. VAN METER, M.D.

On February 27, 2020, this Honorable Court heard Petitioner [redacted] Motion to Strike the Expert Testimony of Dr. Quentin L. Van Meter, M.D.

Appearances

Petitioner, [redacted], appeared along with his counsel of record, Douglas Ray York and announced ready.

Respondent, [redacted], appeared along with her counsel of record, Deborah L. Thompson and announced ready.

Reporters Record

A record of the testimony was made by Chelsea Allen, the Court Reporter for the 311th Judicial District Court.

Findings and Order

After hearing evidence and argument of Counsel, THE COURT FINDS that Dr. Quentin L. Van Meter, M.D., is discredited as an expert to give testimony in this cause on his opinions regarding the legal question of whether an adolescent transgender child should be administered puberty blockers and whether affirmation of an incongruent gender in a child is harmful or not.

IT IS THEREFORE ORDERED that Dr. Quentin L. Van Meter, M.D. shall not be allowed to give any testimony in this cause as an expert and Dr. Quentin L. Van Meter, M.D. is hereby struck as an expert witness in this cause.

Signed:
2/27/2020

SIGNED: _____
JUDGE

APPROVED AS TO FORM ONLY:

LAW OFFICES OF DOUGLAS RAY YORK, P.C.
1021 Main St., Ste. 1450
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By: /s/ Douglas Ray York
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Attorney for Petitioner,
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By: _____
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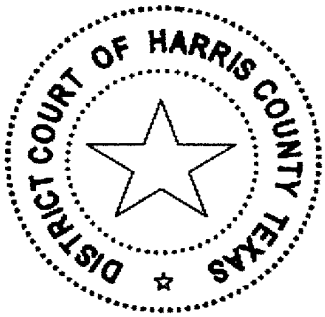
eservice@deborahlthompson.com
Attorney for Respondent,
[redacted]



I, Marilyn Burgess, District Clerk of Harris County, Texas certify that this is a true and correct copy of the original record filed and or recorded in my office, electronically or hard copy, as it appears on this date.
Witness my official hand and seal of office this March 3, 2020

Certified Document Number: 89690098 Total Pages: 2

Marilyn Burgess, DISTRICT CLERK
HARRIS COUNTY, TEXAS

In accordance with Texas Government Code 406.013 electronically transmitted authenticated documents are valid. If there is a question regarding the validity of this document and or seal please e-mail support@hcdistrictclerk.com