RICK SCOTT
GOVERNOR

JUSTIN M. SENIOR
SECRETARY

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

Date: July 19, 2017

To: Beth Kidder, Deputy Secretary for Medicaid

From: Bureau of Medicaid Policy

Subject: **Gender Confirmation Surgery**

PURPOSE

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

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

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

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

REPORT WITH RECOMMENDATION

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

The analysis described in this report includes:

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

Pl. Trial Ex. 263

2727 Mahan Drive • Mail Stop # 20
Tallahassee, FL 32308
AHCA.MyFlorida.com

Facebook.com/AHCAFlorida
Youtube.com/AHCAFlorida
Twitter.com/AHCA_FL
SlideShare.net/AHCAFlorida

- 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
- Evidence based clinical practice guidelines

HEALTH SERVICE SUMMARY

Gender identity, the sense of being male or female (Dhejne, Lichtenstein, Boman, Johansson, Långström, & Landén, 2011), is experienced by everyone. Gender identity develops in early childhood and is thought to be firmly established by the age of four in most people (American Academy of Pediatrics, 1999, as cited in World Professional Association for Transgender Health [WPATH], 2016). The American Psychological Association (2015) further elaborates, stating that although gender identity is established in young toddlerhood, an individual's awareness that their gender identity is not fully aligned with their assigned sex can occur during childhood, adolescence, or adulthood. Gender dysphoria is the discomfort or distress a person feels due to the discrepancy between their experienced gender and their sex assigned at birth. Individuals with gender dysphoria have a strong, persistent desire to live and be accepted as a member of the opposite sex (Bizic, Kojovic, Duisin, Stanojevic, Vujovic, Milosevic, et al., 2014). These individuals often feel they are members of the opposite sex "trapped" in the wrong body (Jarolím, 2000). "Transgender" is a broad term used to describe people whose gender identity or gender expression differs from their assigned sex at birth (The American College of Obstetricians and Gynecologists, 2011). Currently, the United States is home to approximately 1.4 million transgender adults (0.6% of the population) and 150,000 transgender adolescents age 13-17 years (Baker, 2017). The prevalence of male-to-female (MtF) transgender persons is greater than that of female-to-male (FtM) individuals (Barrett, 2014; Bizec et al., 2014; Jarolím, 2000; Selvaggi, Dhejne, Landen, & Elander, 2012). It is important to note that not all transgender individuals experience gender dysphoria or seek treatment.

Transsexualism, first described as a "syndrome" in 1953, was classified as a disorder of sexual identification (Jarolím, 2000). Currently, the International Classification of Diseases, 10th Edition (ICD-10) classifies transsexualism as a disorder of personality and behavior (Barrett, 2014), and a formal diagnosis is made when gender dysphoria reaches a significant level of distress (Selvaggi et al., 2012). In the Diagnostic and Statistical Manual of Mental Disorders (DSM), previous editions used the term "gender identity disorder." In 2013, the latest edition (DSM-5) updated the terminology to "gender dysphoria" to reflect the consensus that gender nonconformity is not a psychiatric disorder, as previously categorized, while also recognizing that access to medical treatment requires a diagnosis (Costa & Colizzi, 2016; Hayes, 2014). Additionally, gender dysphoria has its own chapter in the DSM-5 and is no longer listed under Sexual Dysfunctions and Paraphilic Disorders (American Psychiatric Association, 2013). Multiple professional and government entities, including the WPATH (2016), the European Parliament (Jokić-Begić, Korajlija, & Jurin, 2014), the American Psychological Association (2015), and the World Health Organization (2017), believe gender dysphoria should not be viewed as a psychiatric disorder. Rather, they view gender identity as a continuum and gender nonconformity as a gender variation (Jokić-Begić et al., 2014) that should not be considered negative or pathological (Hess, Rossi Neto, Panic, Rübben, & Senf, 2014).

Minority stress theory is a prominent theoretical framework for health risks of sexual minorities and proposes that stressors encountered in hostile and homophobic or transphobic environments can explain health disparities. The stressors are not experienced by other populations, are chronic, and are socially based (American Public Health Association, 2016).

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

Treatment

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

Hormone Therapy

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

maintain normal physiology (Endocrine Society, 2009; Rotondi, Bauer, Scanion, Kaay, R. Travers, & A. Travers, 2013; Meriggiola, Jannini, Lenzi, Maggi, & Manieri, 2010). According to Fernandez and Tannock (2016), research on these risks has been inconsistent, as some studies show no metabolic changes and other studies show significant metabolic changes. The authors examined transgender individuals receiving cross-sex hormone therapy at an endocrinology clinic and concluded this therapy is safe. They also agreed with established guidelines recommending that this population be monitored for changes in lipid parameters, body mass index, and hemogram parameters. The Endocrine Society recommends regular clinical and laboratory monitoring every three months during the first year and then once or twice yearly thereafter.

Non-medical, Non-surgical, and Non-genital Surgical Treatment Options

Non-medical and non-surgical treatments include, but are not limited to, legal name and sex or gender change on identity documents (WPATH, 2016), mental health services (Baker, 2017), vocal training, body hair removal (Dhejne et al., 2011), and lifestyle coaching. There are non-genital surgical procedures, such as facial feminization surgeries, voice surgeries, (Selvaggi et al., 2012), body contouring, gluteal or pectoral implants, and other cosmetic procedures, to assist individuals with their transition.

Gender Confirmation Surgery

Gender confirmation surgery (also referred to as sex reassignment surgery in the literature) consists of removing and/or altering the primary and secondary sex characteristics to make them congruent with a person's gender identity. The following surgical procedures are utilized for FtM transitions (Monstrey, Ceulemans, & Hoebeke, 2011; Hayes, 2014):

- Mastectomy
- Hysterectomy
- Salpingo-oophorectomy or ovariectomy
- Vaginectomy
- Urethroplasty
- Metoidioplasty or phalloplasty
- Scrotoplasty
- Insertion of testicular and/or erection prostheses

The following surgical procedures are utilized for MtF transitions (Selvaggi et al., 2012; Hayes, 2014):

- Penectomy
- Orchiectomy
- Vaginoplasty
- Clitoroplasty
- Labiaplasty
- Breast augmentation

Government Regulatory Body Approval

The United States Food and Drug Administration (FDA) does not regulate surgical procedures. However, prosthetic devices/implants commonly utilized in gender confirmation surgeries, such as testicular, penile/erectile, and breast prostheses, require premarket approval prior to being placed in commercial distribution per Title 21 of the Code of Federal Regulations. The FDA also regulates new (initiated after May 28,1976) surgical instruments, such as laparoscopic and endoscopic instruments and accessories. New surgical instruments must go through premarket

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

LITERATURE REVIEW

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

Psychological Outcomes

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

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

may delete

including puberty suppression leads to improved psychological functioning on transgender adolescents.

Jokić-Begić et al. (2014) assessed the psychosocial adjustment of six transgender individuals (3 FtM and 3 MtF). All participants expressed very high satisfaction with their decision to undergo surgery. Almost all participants reported satisfaction with sexual functioning following surgery. Assessments of mood variations fell within normal range. Participants reported increased self-esteem due to having a physical body that matched their gender identities. The authors concluded that their results are consistent with other reports confirming the generally stable and favorable function of transgender individuals following gender confirmation surgery. They reference a meta-analysis by Murad et al. (2010) that indicated transition led to a significant increase in quality of life for 80% of transgender people and a decrease in psychological disturbances in cases where such disturbances were present prior to transition. In contrast, Dhejne et al. (2011) found that individuals who underwent gender confirmation surgery between 1973-2003 had a higher risk of psychiatric inpatient care (for conditions other than gender identity disorder) than controls matched on birth year and birth sex. However, they did not compare rates between transgender females and biological females or transgender males and biological males. Additionally, there have been advances in ~~psychological~~ medical healthcare among this population since that time. Meridle

Several studies have shown decreased risk for suicidal ideation, suicide attempt, and suicide after gender confirmation surgery. Bauer et al. (2015) stated recent longitudinal studies have demonstrated reductions in psychological distress following medical transition, though suicide attempts and deaths among individuals who received hormonal treatment and/or gender confirmation surgery remained elevated compared to the general population. They posit the reason for this is that the transgender population almost universally experiences some degree of social exclusion and transphobia, and certain social exclusions and victimization are key factors in suicide disparities across marginalized populations. They identified intervenable factors and categorized them into three major constructs: social inclusion, transphobia, and sex/gender transition. They found that suicidal ideation was significantly reduced for those in the process of medically transitioning versus those who were planning but had not yet begun to transition; however, individuals with suicidal thoughts were at greater risk of attempting suicide during transition in comparison to those who were planning. There was no increased risk of suicide among individuals who completed a medical transition; completing a medical transition had beneficial individual and population effects. The authors extrapolated the data and found that facilitating completion of a medical transition would equate to a 44% reduction in suicidal ideation and a 69% reduction in suicide attempts, preventing an estimated 240 attempts per 1,000 transgender individuals. These results suggest the need for supports for those who may feel suicidal while in the process of transition, and call into question the safety of clinical and procedural practices that delay transition treatments until depressive symptoms or suicidality are well-controlled or otherwise result in long delays in the medical transition process.

put last in P

Dhejne et al. (2011) found that death from suicide was much higher in sex-reassigned individuals compared to matched controls. Specifically, MtF individuals displayed a significantly increased risk of suicide compared to male controls but not female controls. These results suggest that MtFs are at higher risk for suicide attempt after surgery, but the rate is comparable to biological females; FtMs maintained a biological female pattern of suicide attempt after surgery. Kaplan, Nehme, Aunon, de Vries, and Wagner (2016) found that history of attempted suicide was significantly associated with lower general social support, lower social integration, lower support from peers, greater openness about transgender identity in public, and any use of hormones (past or present). Although depression was not significantly related to suicide

noted earlier, study mentioned is based on data from collected between 1973-2003, & it has significantly evolved since that time

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

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

Surgical Outcomes

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

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

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

- Necrosis
- Abscess formation
- Urinary fistulae and/or stenosis (Monstrey et al., 2011)
- Poor erogenous sensation
- Postoperative bleeding (Bogliolo et al., 2014)
- Inadequate final or cosmetic outcome
- Infection (Garaffa, Sansalone, & Ralph, 2013)
- Herniation
- Thrombo-embolic complications
- Intestinal fistulae
- Incontinence of urine and stool (Jarolím, 2000)

Complications specifically associated with MtF gender confirmation surgeries include:

- Neovaginal prolapse (Bucci, Mazzon, Liguori, Napoli, Pavan, Bormioli, et al., 2014
- Absence of natural lubrication (Bizic et al., 2014)
- Peritoneal perforation and rectal laceration (De Stefani, Trombetta, Raber, Savoca, Moro, & Belgrano, 2004)

Complications specifically associated with FtM gender confirmation surgeries include:

- Donor site morbidity and significant scarring (Garaffa, Ralph, & Christopher, 2010)
- Poor graft take (Garaffa et al., 2013)

Although no particular surgical procedures have been identified as the "gold standard," consensus in the literature is that the radial artery-based forearm free flap (RAFFF) is the preferred method for penile reconstruction and results in the best cosmetic and functional outcomes. As many as 99% of patients are able to void while standing and 97% are fully satisfied with cosmesis and size (Garaffa et al., 2010; Garaffa et al., 2013; Monstrey et al., 2011). Penile inversion vaginoplasty (with or without scrotal flaps) in combination with glans-derived sensate clitoroplasty is the preferred method in MtF gender confirmation surgery, as it allows for adequate sensation, good depth, good erotic sensitivity of the neoclitoris, and aesthetically acceptable labia minora and majora. Intestinal pedicled transplants are considered the best choice for those who have previously undergone total penectomy and orchiectomy, those with previously failed skin vaginoplasty, or for patients with Mayer-Rokitansky syndrome (Rossi Neto et al., 2012; Bizic et al., 2014). Flip around to make clearer

Rossi Neto et al. (2012) reported on 13-year surgical outcomes among 332 MtF individuals who underwent surgery from 1995-2008. Due to technique modifications introduced in 2008, individuals who had operations after that time were not included in the study so as to not bias results. All recipients underwent the same vaginoplasty procedure. They categorized surgical complications into five main groups: genital region, urinary tract, gastrointestinal events, wound healing disorders, and unspecific events. The main complication was progressive obstructive voiding disorder due to meatal stenosis, occurring in 40% of patients. Minor wound healing disorders occurred in 33% of patients. Other complications included stricture of vaginal introitus (15%), vaginal stenosis (12%), loss of vaginal depth (8%), and rectal injury (3%). Loss of depth complaints were frequently related to patients' low compliance with post-surgical vaginal dilation. Additional surgeries were needed to correct some complications, whereas other complications were transient and required no treatment. Despite complications, functionality remained intact. The authors stated their findings on complication rates did not indicate permanent, limiting adverse events that could decisively influence functionality after gender confirmation surgery.

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

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

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

Cost Effectiveness

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

issue of coverage for transgender care can be compared to patients with rare diseases, such as cystic fibrosis, who have access to necessary health technology due to the Orphan Drug Act of 1983. The cost of medication to treat cystic fibrosis is neither affordable nor efficient, but treatment is available because of the Act and absorption of cost across the U.S. population, with a budget impact of approximately $0.05 per member per month. The authors also point out that other costly surgeries, procedures, and health technologies (such as spinal fusion for chronic back pain, in vitro fertilization, and drugs for erectile dysfunction) that consensus dictates are not medically necessary are still covered by payers. They concluded that provider coverage of gender confirmation surgery is affordable, efficient, and equitable.

Baker (2017) provided a ~~summary of the history~~ historical summary of coverage for transgender care. Until recently, most payers categorically excluded coverage of any service or procedure related to gender transition. A shift occurred in 2012 when the California Department of Insurance promulgated a regulation prohibiting categorical exclusions of coverage for health care services related to gender transition if the services were covered for other conditions. Services typically a part of gender transition, such as hormone therapy, breast reconstruction, hysterectomy, vaginoplasty, or phalloplasty, are regularly covered for indications such as endocrine disorders, cancer treatment or prevention, intersex conditions, and treatment after traumatic injury. Changes in federal regulations (as discussed ~~below~~ later) have led to increased coverage for transgender care. While challenges to those regulations have left state and federal courts trying to figure out the degree to which federal sex-nondiscrimination laws expressly protect transgender people, ~~Nonetheless,~~ private-sector employers are increasingly providing coverage for transgender issues. No Fortune 500 company offered employee coverage for gender transition in 2002, but 50% did by the end of 2016. Many public employers, including public universities, counties, states, and the Federal Employees Health Benefits Program, now cover transition-related care. Since 2012, 18 states and the District of Columbia have interpreted their own laws as prohibiting private plans from discriminating against transgender people, and 12 states and the District of Columbia have updated their Medicaid rules to affirmatively cover transition-related care. Baker asserts that to date, these reforms have imposed minimal or no new costs. Massachusetts conducted a cost-utility analysis on the expansion of transgender-inclusive coverage and determined that covering transition-related services is cost-effective, especially given the high financial and human costs associated with untreated gender dysphoria. California conducted an economic-impact analysis of their regulation removing transgender exclusions and found an "immaterial" effect on premium costs. They concluded, "The benefits of eliminating discrimination far exceed the insignificant costs," the benefits being improved health outcomes (reduced suicide risk, lower rates of substance use, increased adherence to HIV treatment).

The present form of gender confirmation surgery has been practiced for over 50 years and is the internationally recognized treatment to relieve gender dysphoria in transgender individuals. However, research on outcomes is limited or flawed for a variety of reasons. Methodologically, randomized controlled trials are not feasible given the nature of this issue. The population is small and follow-up is even more challenging due to high dropout rates; individuals decline to participate for various reasons or relocate after surgery. Follow-up periods also tend to be of short duration. Generalizability of results is limited because different studies utilize different surgical techniques and different assessments to measure outcomes. Several authors conclude that although there have been significant advances in this field and current surgical techniques are effective with minimal complications, there remains a need to improve upon surgical techniques to further reduce risk of complications. ~~Nonetheless~~, Overall research indicates gender confirmation surgery is safe, effective in treating gender dysphoria, improves health outcomes,

Despite these limitations

They also have spanned multiple decades, during which awareness & TG issues have led to improvements in mental & medical health care.

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

Evidence-Based Clinical Practice Guidelines

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

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

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

The American Psychiatric Association's Position Statement on Access to Care for Transgender and Gender Variant Individuals, published in 2012, indicates the American Psychiatric Association:

1. Recognizes that appropriately evaluated transgender and gender variant individuals can benefit greatly from medical and surgical gender transition treatments.
2. Advocates for removal of barriers to care and supports both public and private health insurance coverage for gender transition treatment.
3. Opposes categorical exclusions of coverage for such medically necessary treatment when prescribed by a physician.

The American Psychiatric Association also issued a Position Statement on Discrimination Against Transgender and Gender Variant Individuals in 2012, which states the American Psychiatric Association:

1. Supports laws that protect the civil rights of transgender and gender variant individuals.
2. Urges the repeal of laws and policies that discriminate against transgender and gender variant individuals.
3. Opposes all public and private discrimination against transgender and gender variant individuals in such areas as health care, employment, housing, public accommodations, education, and licensing.
4. Declares that no burden of proof of such judgment, capacity, or reliability shall be placed upon these individuals greater than that imposed on any other persons.

The American College of Obstetrics and Gynecology (ACOG) issued a committee opinion regarding health care for transgender individuals in December 2011. The ACOG opposes discrimination on the basis of gender identity and urges public and private health insurance plans to cover the treatment of gender identity disorder. They discuss hormone therapy, surgery, and necessary screenings for FtM and MtF transgender individuals in order to facilitate quality health care by assisting with transition, if desired, and providing long-term preventive health care.

The American Medical Association (AMA) has published several statements regarding transgender care. The AMA opposes the use of "reparative" or "conversion" therapy for sexual orientation and gender identity and supports public and private health insurance coverage for treatment of gender dysphoria as recommended by the patient's physician (2016). The AMA also affirms "there is no medically valid reason to exclude transgender individuals from service in the U.S. military and affirms transgender service members be provided care as determined by patient and physician according to the same medical standards that apply to non-transgender personnel" (2015).

The American Society of Plastic Surgeons published their Guiding Principles regarding gender confirmation surgery in 2017 to provide a template for use in establishing standardized methods for surgical training in transgender care. The article was unanimously approved by the WPATH Board of Directors as the framework for surgical training for gender confirmation procedures. The article indicates no single discipline can satisfy all treatment needs for transgender persons and recommends a multidisciplinary approach including mental health professionals, primary care providers, endocrinologists, plastic surgeons, urologists, gynecologists, colorectal (or general) surgeons, otolaryngology/head and neck (voice) surgeons, and midlevel practitioners. Additional practitioners, including speech and physical therapists, social workers, and case managers are also desirable.

move to end

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

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

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

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

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

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

COVERAGE POLICY

Federal Regulations

Section 1557 is the nondiscrimination provision of the Affordable Care Act, enacted in 2010. The law prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs or activities. Section 1557 builds on long-standing federal civil rights laws; in particular, sex discrimination protections are based on Title IX of the Education Amendments of 1972 and apply to all health system entities that receive federal funds, including Medicare, Medicaid, or health insurance marketplaces. The HHS Office for Civil Rights has enforced provisions of Section 1557 since its enactment. On May 13, 2016, HHS issued a regulation interpreting this provision as encompassing discrimination based on gender identity. Although federal regulation does not require health plans to cover any specific service, plans are prohibited from excluding a service related to gender transition for transgender individuals when the same service is covered for others. However, on December 31, 2016, the U.S. District court for the Northern District of Texas issued an opinion in Franciscan Alliance, Inc., et al. v. Burwell, enjoining the Section 1557 regulation's prohibitions against discrimination on the basis of gender identity and termination of pregnancy on a nationwide basis. Accordingly, HHS' Office for Civil Rights may not enforce these two provision of the regulation while the injunction is in place (U.S. Department of Health and Human Services, n.d.; Baker, 2017). court date?

Medicare

The Centers for Medicare and Medicaid Services (CMS) published an initial national coverage determination (NCD) on August 1, 1989, denying coverage for all transsexual surgery. On May 30, 2014, the HHS Departmental Appeals Board ~~(DAB)~~ determined the NCD was not valid. CMS no longer has a NCD on gender confirmation surgery. Currently, coverage for gender confirmation surgery is determined by Medicare Administrative Contractors (MACs) on a case-by-case basis (CMS, 2016). A search of the CMS website on July 19, 2017 did not reveal any LCDs for "gender confirmation surgery," "gender reassignment surgery," "sex reassignment surgery," or "transsexual surgery."

Florida Medicaid

Florida Medicaid does not expressly cover or deny coverage of gender confirmation surgery but does reimburse for procedures typically performed during gender confirmation surgeries, such as tissue transfer or rearrangement, autologous fat transfer, blepharoplasty, lipectomy, mastectomy, mastopexy, mammoplasty, nipple/areola reconstruction, genioplasty, facial reconstruction, rhinoplasty, urethroplasty, penectomy, orchiectomy, scrotoplasty, prostatectomy, metoidioplasty, phalloplasty, vulvectomy, clitoroplasty, vaginectomy, colpectomy, vaginoplasty, hysterectomy, and salpingo-oophorectomy. Some procedures require prior authorization.

State Medicaid Programs

Fourteen states explicitly deny coverage ~~of~~ for gender confirmation surgery procedures. Twenty-three states (including Florida) do not explicitly deny or proclaim ~~coverage for gender confirmation surgery~~, as their policies do not reference gender dysphoria, transsexualism, or associated treatments. Illinois' administrative code indicates medical or surgical transsexual treatment, for dates of service prior to April 1, 2015 are not covered; however, a formal policy specifying coverage could not be found.

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

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

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

Commercial Insurers

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

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

GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS RECOMMENDATION

This report recommends gender confirmation surgery as a health service that is consistent with generally accepted professional medical standards. Gender confirmation surgery is demonstrated to be an effective treatment option for gender dysphoria. Numerous well-respected professional medical societies endorse gender confirmation surgery as a safe and effective ~~treatment~~. Research in this field, though difficult to conduct given the constraints in studying this population, also supports gender confirmation surgery as a safe and effective treatment for gender dysphoria. Additionally, research has shown that lack of care for this population results in greater health disparities, including poorer long-term outcomes for medical and mental health, increased risk of HIV infection, and increased rates of suicidal ideation, suicide attempt, homelessness, incarceration, and engagement in survival sex. These significant health disparities result in increased societal and medical costs. ~~Furthermore,~~ analyses regarding cost-effectiveness demonstrate that gender confirmation surgery is a cost-effective treatment option that improves quality of life and reduces health disparities.

Rationale

____**Concur** ____**Do not Concur**

Comments:

_____

_____

_____

_____ _____

Deputy Secretary for Medicaid (or designee) *Date*