

## Transgender Services

**Effective:** December 1, 2018

**Next Review:** September 2019

**Last Review:** November 2018

### IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### DESCRIPTION

Medical and surgical treatments of gender dysphoria in transgender individuals involves psychotherapy, hormonal therapy and, in some cases, gender affirmation surgery.

### MEDICAL POLICY CRITERIA

**Note:** Member contracts for covered services vary. Member contract language takes precedence over medical policy.

- I. Medical treatments of gender dysphoria
  - A. Psychotherapy may be considered **medically necessary** as a treatment of gender dysphoria
  - B. Continuous hormone therapy may be considered **medically necessary** as a treatment of gender dysphoria when all of the following criteria are met:
    1. Clinical records document that the patient has the capacity to make fully informed decisions and consent for treatment; and
    2. Clinical records document that a licensed mental health professional has diagnosed gender dysphoria; and

3. At least one of the following criteria must be met for a period of 3 or more months prior to the initiation of hormone therapy:
  - a. Documentation of living as the desired gender; and/or
  - b. Psychotherapy with a licensed mental health professional.

II. Surgical treatments of gender dysphoria may be considered **medically necessary** when either A. or B. are met:

A. Gender affirmation surgery (see Policy Guidelines) may be considered **medically necessary** in the treatment of gender dysphoria when all of the following criteria are met:

1. Age at least 18 years (Note: *age requirement will not be applied to mastectomy with documented provider determination of medical necessity of earlier intervention*); and
2. Clinical records document that the patient has the capacity to make fully informed decisions and consent for treatment, and that any other mental health condition, if present, is adequately controlled; and
3. At least 2 licensed mental health professionals have diagnosed gender dysphoria, and recommend surgical treatment (Note: *only 1 mental health professional referral is required for mastectomy*); and
4. Documentation of continuous hormonal therapy for at least 12 months, unless there is a documented contraindication to hormonal therapy (Note: *hormonal therapy is not required prior to mastectomy*); and
5. Twelve months of living in a gender role that is congruent with the patient's gender identity.

B. When the criteria in II.A. above are met or have been met, the following procedures may be considered **medically necessary** when clinical information is submitted expressly documenting that the particular requested procedure would improve otherwise documented significant gender dysphoria:

1. Breast augmentation
2. Hair removal
3. Hair transplantation
4. Nipple/areola reconstruction in the absence of concurrent or prior subcutaneous or simple/total mastectomy
5. Mastopexy

III. Other than gender affirmation surgeries listed in the Policy Guidelines, and/or surgeries in criteria II above, additional treatments to change specific appearance characteristics are considered **not medically necessary** as treatments of gender dysphoria including, but not limited to the following:

- A. Abdominoplasty
- B. Blepharoplasty
- C. Brow lift

- D. Calf implants
  - E. Cheek/malar implants
  - F. Chin/nose implants
  - G. Collagen injections
  - H. Face-lift
  - I. Facial bone reduction
  - J. Forehead lift
  - K. Lip reduction
  - L. Liposuction
  - M. Neck tightening
  - N. Pectoral implants
  - O. Reduction thyroid chondroplasty
  - P. Rhinoplasty
  - Q. Suction-assisted lipoplasty of the waist
  - R. Voice modification surgery
  - S. Voice therapy/lessons
- IV. Reversal of gender affirmation surgery is considered **not medically necessary** as a treatment of gender dysphoria.

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

## POLICY GUIDELINES

### SUBMISSION OF DOCUMENTATION

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and Physical/Chart Notes
- Documentation of therapy requested if applicable
- Documentation of patient capacity to make decisions/consent to treatment

For medical treatment or mastectomy:

- Documentation that a licensed mental health professional has diagnosed gender dysphoria
- Documentation of length of time living as desired gender
- Documentation of length of time therapy occurred including licensure of therapist

For surgical treatment:

- Documentation that at least 2 licensed mental health professionals have diagnosed

gender dysphoria and recommend surgical treatment

For surgical treatment (excluding mastectomy):

- Documentation of hormonal therapy including length of time administered
- Documented treatment plan including if planned procedures are reversals

## **GENDER AFFIRMATION SURGERY**

Surgical treatment for gender dysphoria differs depending upon the birth gender of the individual. The World Professional Association for Transgender Health (WPATH) indicated that, “(p)hysicians who perform surgical treatments for gender dysphoria should be urologists, gynecologists, plastic surgeons, or general surgeons, and board-certified as such by the relevant national and/or regional association. Surgeons should have specialized competence in genital reconstructive techniques as indicated by documented supervised training with a more experienced surgeon.”<sup>[1]</sup>

The following procedures may be included as part of gender affirmation surgery:<sup>[1,2]</sup>

- Clitoroplasty
- Hysterectomy
- Labiaplasty
- Mastectomy (subcutaneous mastectomy [CPT code 19304] or simple/total mastectomy [CPT code 19303], which may include related nipple/areola reconstruction [CPT code 19350]). Note: The use of CPT code 19318 (reduction mammoplasty) is incorrect coding.
- Metoidioplasty
- Nipple/areola reconstruction related to subcutaneous or simple/total mastectomy with nipple/areola excision or repositioning
- Orchiectomy
- Penectomy
- Penile prostheses implantation
- Phallic reconstruction/Phalloplasty
- Salpingo-oophorectomy
- Scrotoplasty
- Testicular prostheses implantation
- Urethroplasty
- Vaginectomy
- Vaginoplasty

### Definitions:

Subcutaneous mastectomy: skin-sparing mastectomy which removes tissue through an incision under the breast, leaving the skin, areola, and nipple intact.

Simple/total mastectomy: removal of the entire breast and commonly any excess skin, including the areola and nipple.

## CROSS REFERENCES

1. [Endometrial Ablation](#), Surgery, Policy No. 01
2. [Cosmetic and Reconstructive Surgery](#), Surgery, Policy No. 12
3. [Reconstructive Breast Surgery/Mastopexy, and Management of Breast Implants](#), Surgery, Policy No. 40
4. [Reduction Mammoplasty](#), Surgery, Policy No. 60
5. [Autologous Fat Grafting to the Breast and Adipose-derived Stem Cells](#), Surgery, Policy No. 182
6. [Medication Policy Manual](#), Do a find (Ctrl+F) and enter drug name in the find bar to locate the appropriate policy.

## BACKGROUND

This policy supports applicable professional association statements,<sup>[1,3-6]</sup> and is also intended to support the Affordable Care Act (ACA) Section 1557 final implementing regulations published on May 18, 2016, and applicable state requirements<sup>[7]</sup>.

### MEDICAL AND SURGICAL TREATMENT OF GENDER DYSPHORIA

A clinical diagnosis of gender dysphoria is required prior to treatment of the disorder. Treatments typically include psychotherapy, hormone therapy and in some cases surgical gender affirmation procedures. Psychotherapy followed by hormone therapy is often the first medical treatment sought, although not all transgender individuals on hormone therapy choose to undergo gender-affirming surgery.<sup>[4]</sup>

#### Gender Dysphoria

Gender dysphoria is defined by the Diagnostic and Statistical Manual of Mental Disorders DSM-5 Diagnostic Criteria as follows:<sup>[8]</sup>

#### Gender Dysphoria in Children 302.6 (F64.2)

- A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least six of the following (one of which must be Criterion A1):
  1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender, different from one's assigned gender).
  2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to wearing of typical feminine clothing.
  3. A strong preference for cross-gender roles in make-believe play or fantasy play.
  4. A strong preference for toys, games, or activities stereotypically used or engaged in by the other gender.
  5. A strong preference for playmates of the other gender.
  6. In boys (assigned gender), a strong rejection of typically masculine toys, games and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games and activities.
  7. A strong dislike of one's sexual anatomy.
  8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.

- B. The condition is associated with clinically significant distress or impairment in social, school, or other important areas of functioning.

*Specify if:*

**With a disorder of sex development** (e.g., a congenital adrenogenital disorder such as 255.2 [E25.0] congenital adrenal hyperplasia or 259.0 [E34.50] androgen insensitivity syndrome).

**Coding note:** Code the disorder of sex development as well as gender dysphoria.

### **Gender Dysphoria in Adolescents and Adults 302.85 (F64.1)**

- A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:
1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics).
  2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).
  3. A strong desire for the primary and /or secondary sex characteristics of the other gender.
  4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
  5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
  6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).
- B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

*Specify if:*

**With a disorder of sex development** (e.g., a congenital adrenogenital disorder such as 255.2 [E25.0] congenital adrenal hyperplasia or 259.0 [E34.50] androgen insensitivity syndrome).

**Coding note:** Code the disorder of sex development as well as gender dysphoria.

*Specify if:*

**Posttransition:** The individual has transitioned to full-time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one cross-sex medical procedure or treatment regimen- namely regular cross-sex hormone treatment or gender reassignment surgery confirming the desired gender (e.g., penectomy, vaginoplasty in the natal male; mastectomy or phalloplasty in the natal female).

### **Psychotherapy**

Psychotherapy provided by a mental health professional typically includes an initial

assessment of gender identity and dysphoria, the historical development of gender dysphoric feelings, and severity of resulting stress caused by the condition.<sup>[1]</sup> The goal of therapy is to assess, diagnose, and discuss treatment options, if needed, and is typically required prior to hormone therapy and/or surgical treatment.

## Hormone Therapy

Hormone therapy is undertaken in order to feminize or masculinize individuals' bodies to conform to their desired gender identities. For transgender individuals, hormone replacement therapy (HRT) causes the development of many of the secondary sexual characteristics of their gender identity. Prescribed hormones differ depending upon the natal gender of the individual. For individuals seeking to feminize, hormone treatment may include estradiol, finasteride, and spironolactone. For individuals seeking to masculinize, hormone treatment may include androgenic hormones such as testosterone.

## Surgical Treatment

Surgical treatment for gender dysphoria differs depending upon the natal gender of the individual. For individuals who are feminizing, surgery may involve removal of the testicles and penis and the creation of a pseudo vagina, clitoris, and labia. Complications of feminizing genital surgery may include necrosis of the vagina and labia, neovaginal prolapse, fistulas from the bladder or bowel into the vagina, stenosis of the urethra, and small or short vaginas.<sup>[1,9]</sup>

For individuals who are masculinizing, surgery may involve removal of the uterus, ovaries, and vagina, and creation of a neophallus and scrotum with scrotal and/or penile prostheses. The creation of a neophallus for these patients is a multistage reconstructive procedure. Currently, techniques for penile reconstruction procedures vary and complications may include frequent urinary tract stenoses and fistulas, donor site scarring and necrosis of the neophallus.<sup>[1,2]</sup> In addition, breast size does not significantly decrease with hormonal therapy and as a result, masculinizing patients may choose to undergo mastectomy to remove breast tissue. For many patients this may be the only surgery undertaken.<sup>[1]</sup> Mastectomy may involve a complete resection of all breast tissue; however, the nipple/areola sparing technique is typically performed to preserve the nipple/areola.

There are various additional aesthetic surgical procedures which may be sought in order to complete the physical gender transformation and align an individual to their gender identity. However, conflicting opinions exist regarding whether these procedures are essential in treating gender dysphoria.

The WPATH recommends that patients, “engage in 12 continuous months of living in a gender role that is congruent with their gender identity...” prior to gender reassignment surgery so that patients may socially adjust to their desired gender role.<sup>[1]</sup> WPATH notes that changing a gender role may have personal and social consequences which should be adequately explored prior to undergoing an irreversible surgery.

## EVIDENCE SUMMARY

Evidence regarding the treatment of gender dysphoria in transgender individuals primarily consists of systematic reviews consisting of small cohort studies. Randomized clinical trials (RCTs) comparing gender dysphoria treatments with the non-treatment are ideal, however, there are challenges in conducting RCTs to evaluate treatments of gender dysphoria due to

several factors, such as small patient populations, and ethical concerns regarding the high morbidity and mortality rates associated with non-treatment. Therefore, large RCTs are not anticipated. This policy relies on the following systematic reviews and non-randomized studies, as well as professional association recommendations to support applicable federal and state requirements.

## **SYSTEMATIC REVIEWS**

Berli (2017) published a review of the available literature regarding facial gender confirmation surgery (FGCS).<sup>[10]</sup> The literature search went through December, 2016. The evidence was evaluated using the Oxford Centre for Evidence-Based Medicine suggestions for levels of evidence. Based on their findings, Berli and colleagues recommended that the next World Professional Association for Transgender Health (WPATH) Standards of Care version should include specific FGCS procedures. The authors also recommended replacing the historical term, facial feminization surgery (FFS) with more inclusive terminology – facial gender confirmation surgery. The body of evidence regarding FGCS is limited to case reports and case series. The authors found most data did not include quality-of-life outcome measures, and when reported, standardized instruments were not utilized. FGCS procedures were categorized by the authors as structural (e.g., forehead reconstruction, rhinoplasty), and secondary nonstructural procedures (e.g., blepharoplasty, upper lip shortening techniques). The review was limited by the paucity of data on FGCS as a treatment for gender dysphoria. In addition, methodological limitations of the review included but were not limited to, lacks of transparent study selection and a transparent, comprehensive assessment of study quality and risk of bias. These limitations prohibit conclusions about overall health outcomes.

In 2009, Murad assessed quality of life and other psychosocial outcomes of transgendered individuals with GID, receiving hormonal therapy as part of gender affirmation surgery.<sup>[11]</sup> Twenty-eight cohort studies were included in the review which included pooled data from 1,833 patients with GID (1,093 male-to-female [MTF] and 801 female-to-male [FTM]). Significant improvements were reported after gender affirmation compared to pre-treatment status: 80% of patients reported improvement in gender dysphoria (95% CI = 68-89%; 8 studies) 78% reported significant improvement in psychological symptoms (95% CI = 56-94%; 7 studies) 80% reported significant improvement in quality of life (95% CI = 72-88%; 16 studies); and 72% reported significant improvement in sexual function (95% CI = 60-81%; 15 studies). Significant study heterogeneity was reported for all outcomes. Although the authors acknowledge the low quality of evidence used in the analysis, gender affirmation that included hormonal interventions in patient with GID was thought to likely improve symptoms of gender dysphoria and overall quality of life.

In 2009, Elamin evaluated the use of sex steroids on cardiovascular risk in transgender individuals.<sup>[12]</sup> A total of 16 studies were included in the review with a total of 1,471 male-to-female (MTF) patients and 651 female-to-male (FTM) patients. Steroid use was associated with increased serum triglycerides in both MTF and FTM patients and a nonsignificant effect on HDL-cholesterol and systolic blood pressure in FTM patients. Authors noted that the quality of evidence was low due to methodological limitations of included studies, including but not limited to, heterogeneity of patient population and variable follow-up periods and uncontrolled study design.

## **Nonrandomized Studies**



Primary evidence is limited to cohort studies with a variety of methodological limitations, including but not limited to small sample size, short-term follow-up, lack of comparison group, and varied treatment methods. Despite these limitations, significant improvements in quality of life, psychological comorbidities, and sexual functioning were consistently reported in patients who received gender-confirming medical treatments.<sup>[13]</sup>

Imbimbo evaluated the clinical and psychosocial profile of male-to-female transgendered individuals who had undergone reconstructive surgery.<sup>[14]</sup> The average age of patients was 31 years old, 72% had high educational levels, half of patients' contemplated suicide at some point prior to surgery and 4% had attempted suicide. Improved sex life satisfaction was reported in 75% of patients, with almost all patients' reporting satisfaction with their new sexual status. Additional studies sought to evaluate the sociodemographic profile of transgender individuals with GID in an effort to better characterize and provide treatment for this population.<sup>[15]</sup>

Heylens assessed comorbidities and psychosocial factors at various phases of the gender affirmation process in 57 patients with GID.<sup>[16]</sup> The Symptom Checklist-90 (SCL-90) was administered at three time points: baseline, after the start of hormone therapy, and after sex reassignment surgery (SRS) (also known as [aka] gender affirmation surgery). Psychopathological parameters include overall psychoneurotic distress, anxiety, agoraphobia, depression, somatization, paranoid ideation/psychoticism, interpersonal sensitivity, hostility, and sleeping problems and the psychosocial parameters consist of relationship, living situation, employment, sexual contacts, social contacts, substance abuse, and suicide attempt. The greatest improvement in psychoneurotic distress was observed after the initiation of hormone therapy ( $p < 0.001$ ). In addition, significant decreases in anxiety, depression, interpersonal sensitivity and hostility were reported after hormone therapy. No significant differences were observed in pre- and postoperative assessments.

Fisher described clinical and sociodemographic features of 140 transmen ( $n=48$ ) and transwomen ( $n=92$ ) with GID and without affirmation surgery.<sup>[17]</sup> The following assessment tests were administered: the Body Uneasiness Test (a self-rating scale exploring different areas of body-related psychopathology), Symptom Checklist-90 Revised (a self-rating scale to measure psychological state), and the Bem Sex Role Inventory (a self-rating scale to evaluate gender role). Authors reported that transmen displayed significantly better social functioning than transwoman.

Gorin-Lazard reported a case series which assessed a variety of gender dysphoria symptoms with hormonal treatment preceding gender affirmation surgery. Pre- and post- hormone treatment self-esteem (Social Self-Esteem Inventory), mood (Beck Depression Inventory), QoL (Subjective Quality of Life Analysis), and global functioning (Global Assessment of Functioning) scores were compared in 49 patients.<sup>[18]</sup> Hormone therapy was reported to be an independent factor in greater self-esteem, a reduction in depression, and improved QoL scores.

Gomez-Gil evaluated symptoms of social distress, anxiety and depression in 187 transgendered individuals.<sup>[19]</sup> Of those included in the study, 120 had undergone hormonal sex-reassignment (SR) (aka gender affirmation) treatment and 67 had not. Social anxiety was assessed with the Social Anxiety and Distress Scale (SADS) and depression and anxiety were assessed with the Hospital Anxiety and Depression Scale (HADS). The non-hormone group was reported to be significantly younger than the treatment group (mean age 25.9 vs. 33.6

years,  $p=0.001$ ) and was less likely to have undergone surgical interventions ( $p<0.001$ ). After adjusting for confounding factors, the authors reported that patients who were receiving hormone treatment had significantly lower prevalence of depression, anxiety, and social anxiety than those not receiving hormones.

Johansson reported long-term (five-year) outcomes of transgendered individuals ( $n=42$ ) with GID who had completely transitioned ( $n=32$ ), were in progress ( $n=5$ ) or who were on hormone therapy ( $n=5$ ).<sup>[20]</sup> Authors reported that no patient regretted affirmation and clinicians rated the global outcome as favorable in 62% of the cases, compared to 95% according to the patients themselves, with no differences between the subgroups. At follow-up, more than 90% of patients reported stable or improved work situations, partner relations and sex-life. However, 5-15% of patients reported dissatisfaction with hormonal treatment, results of surgery, total gender affirmation procedure, or their present general health.

Asscheman evaluated the long-term (one-year) effects of cross-sex hormones in 966 male-to-female (MTF) and 365 female-to-male (FTM) transgendered individuals.<sup>[21]</sup> MTF patients received different doses of estrogen and cyproterone acetate and FTM patients received parenteral/oral testosterone esters or testosterone gel. Hormone treatment levels varied at pre- and post-surgical affirmation time points. High mortality rates were reported in the MTF group when compared to the general population (51%); however, this increased rate was due to non-hormone-related causes such as suicide, acquired immunodeficiency syndrome (AIDS), cardiovascular disease, drug abuse and other unknown causes. No significant increase in mortality was observed in FTM patients compared to the general population.

## PRACTICE GUIDELINE SUMMARY

### WORLD PROFESSIONAL ASSOCIATION FOR TRANSGENDER HEALTH

The World Professional Association for Transgender Health (WPATH) is a multidisciplinary professional society representing the specialties of medicine, psychology, social sciences and law that has published clinical guidelines regarding health services for patients with gender disorders. In 2011, WPATH approved the update of their evidence and consensus-based guideline regarding, the *Standards of Care (SOC) for the Health of Transsexual, Transgender, and Gender Nonconforming Peoples, 7<sup>th</sup> Version*.<sup>[1]</sup> The 8<sup>th</sup> version is anticipated in 2019. WPATH listed the following options for individuals seeking treatment for gender dysphoria:

- Changes in gender expression and role (which may involve living part time or full time in another gender role, consistent with one's gender identity);
- Hormone therapy to feminize or masculinize the body;
- Surgery to change primary and/or secondary sex characteristics;
- Psychotherapy (individual, couple, family, or group) for purposes such as exploring gender identity, role, and expression; addressing the negative impact of gender dysphoria and stigma on mental health; alleviating internalized transphobia; enhancing social and peer support; improving body image; or promoting resilience.

WPATH guidelines describe surgical procedures as “irreversible changes to the body.” Therefore, WPATH guidelines recommend the appropriate care should be taken to ensure patients have sufficient time (at least 24 hours) to consider all the information and can provide informed consent. WPATH notes, “(t)hese surgeries may be performed once there is written documentation that this assessment has occurred and that the person has met the criteria for a

specific surgical treatment. By following this procedure, mental health professionals, surgeons, and patients share responsibility for the decision to make irreversible changes to the body.”

## **Physical Interventions for Adolescents**

WPATH guidelines state that physical interventions for adolescents fall into three categories or stages:

1. Fully reversible interventions. These involve the use of GnRH analogues to suppress estrogen or testosterone production and consequently delay the physical changes of puberty. Alternative treatment options include progestins (most commonly medroxyprogesterone) or other medications (such as spironolactone) that decrease the effects of androgens secreted by the testicles of adolescents who are not receiving GnRH analogues. Continuous oral contraceptives (or depot medroxyprogesterone) may be used to suppress menses.
2. Partially reversible interventions. These include hormone therapy to masculinize or feminize the body. Some hormone-induced changes may need reconstructive surgery to reverse the effect (e.g., gynaecomastia caused by estrogens), while other changes are not reversible (e.g., deepening of the voice caused by testosterone).
3. Irreversible interventions. Reversible and irreversible interventions are outlined in the standards of care, specifying intervention sequencing in adolescents. It is also stated that “[t]wo goals justify intervention with puberty suppressing hormones: (i) their use gives adolescents more time to explore their gender nonconformity and other developmental issues; and (ii) their use may facilitate transition by preventing the development of sex characteristics that are difficult or impossible to reverse if adolescents continue on to pursue sex reassignment.”

## **Referral for Surgery**

WPATH guidelines indicate that surgical treatments can be initiated by a referral from a qualified mental health professional. One or two referrals may be required depending upon the type of surgery requested. “The mental health professional provides documentation—in the chart and/or referral letter—of the patient’s personal and treatment history, progress, and eligibility.” WPATH guidelines specifically recommend the following:

- One referral from a qualified mental health professional is needed for breast/chest surgery (e.g., mastectomy, chest reconstruction, or augmentation mammoplasty).
- Two referrals—from qualified mental health professionals who have independently assessed the patient—are needed for genital surgery (i.e., hysterectomy/salpingo-oophorectomy, orchiectomy, genital reconstructive surgeries).

## **Criteria for Breast/Chest Surgery (One Referral)**

WPATH lists the following criteria for mastectomy and creation of a male chest in FTM patients:

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to consent for treatment;
3. Age of majority in a given country;
4. If significant medical or mental health concerns are present, they must be reasonably well controlled.

Hormone therapy is not a prerequisite.

### Criteria for Genital Surgery (Two Referrals)

WPATH lists the following criteria for genital surgery:

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to consent for treatment;
3. Age of majority in a given country;
4. If significant medical or mental health concerns are present, they must be reasonably well controlled.
5. 12 continuous months of hormone therapy as appropriate to the patient's gender goals (unless hormones are not clinically indicated for the individual).

In addition, WPATH made specific recommendations regarding breast augmentation procedures:

### Breast Augmentation

The WPATH guideline recommends MTF patients undergo hormone therapy for a minimum of 12 months prior to augmentation surgery and lists specific criteria for breast augmentation (implants/lipofilling).

## THE ENDOCRINE SOCIETY

In 2017, the Endocrine Society in conjunction with American Association of Clinical Endocrinologists, American Society of Andrology, European Society for Pediatric Endocrinology, European Society of Endocrinology, Pediatric Endocrine Society, and World Professional Association for Transgender Health published updated guidelines for the treatment of gender-dysphoric/gender-incongruent persons.<sup>[22]</sup> The guideline employed transparent methods for evidence review and for rating the quality of evidence. Guidelines were referenced as *recommendations* or *suggestions*, by the numbers 1 and 2, respectively. Evidence was ranked as very low-quality |⊕○○○; low quality |⊕⊕○○; moderate quality |⊕⊕⊕○; and high quality |⊕⊕⊕⊕. The consortium made the following statements:

### 1.0 Evaluation of Youth and Adults

- 1.1 We advise that only trained mental health professionals (MHPs) who meet the following criteria should diagnose gender dysphoria (GD)/ gender incongruence in adults: (1) competence in using the Diagnostic and Statistical Manual of Mental Disorders (DSM) and/or the International Statistical Classification of Diseases and Related Health Problems (ICD) for diagnostic purposes, (2) the ability to diagnose GD/ gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (3) training in diagnosing psychiatric conditions, (4) the ability to undertake or refer for appropriate treatment, (5) the ability to psychosocially assess the person's understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) a practice of regularly attending relevant professional meetings. (Ungraded Good Practice Statement)
- 1.2. We advise that only MHPs who meet the following criteria should diagnose GD/gender incongruence in children and adolescents: (1) training in child and adolescent developmental psychology and psychopathology, (2) competence in using the DSM

and/or the ICD for diagnostic purposes, (3) the ability to make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (4) training in diagnosing psychiatric conditions, (5) the ability to undertake or refer for appropriate treatment, (6) the ability to psychosocially assess the person's understanding and social conditions that can impact gender-affirming hormone therapy, (7) a practice of regularly attending relevant professional meetings, and (8) knowledge of the criteria for puberty blocking and gender-affirming hormone treatment in adolescents. (Ungraded Good Practice Statement)

- 1.3. We advise that decisions regarding the social transition of prepubertal youths with GD/gender incongruence are made with the assistance of an MHP or another experienced professional. (Ungraded Good Practice Statement).
- 1.4. We recommend against puberty blocking and gender-affirming hormone treatment in prepubertal children with GD/gender incongruence. (1 | ⊕ ⊕ ○ ○)
- 1.5. We recommend that clinicians inform and counsel all individuals seeking gender-affirming medical treatment regarding options for fertility preservation prior to initiating puberty suppression in adolescents and prior to treating with hormonal therapy of the affirmed gender in both adolescents and adults. (1 | ⊕ ⊕ ⊕ ○)

## **2.0 Treatment of Adolescents**

- 2.1. We suggest that adolescents who meet diagnostic criteria for GD/gender incongruence, fulfill criteria for treatment, and are requesting treatment should initially undergo treatment to suppress pubertal development. (2 | ⊕ ⊕ ○ ○)
- 2.2. We suggest that clinicians begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty. (2 | ⊕ ⊕ ○ ○)
- 2.3. We recommend that, where indicated, GnRH analogues are used to suppress pubertal hormones. (1 | ⊕ ⊕ ○ ○)
- 2.4. In adolescents who request sex hormone treatment (given this is a partly irreversible treatment), we recommend initiating treatment using a gradually increasing dose schedule after a multidisciplinary team of medical and MHPs has confirmed the persistence of GD/gender incongruence and sufficient mental capacity to give informed consent, which most adolescents have by age 16 years. (1 | ⊕ ⊕ ○ ○).
- 2.5. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years in some adolescents with GD/ gender incongruence, even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years. As with the care of adolescents 16 years of age, we recommend that an expert multidisciplinary team of medical and MHPs manage this treatment. (1 | ⊕ ○ ○ ○)
- 2.6. We suggest monitoring clinical pubertal development every 3 to 6 months and laboratory parameters every 6 to 12 months during sex hormone treatment. (2 | ⊕ ⊕ ○ ○)

## **3.0 Hormonal Therapy for Transgender Adults**

- 3.1. We recommend that clinicians confirm the diagnostic criteria of GD/gender incongruence and the criteria for the endocrine phase of gender transition before beginning treatment. (1 | ⊕ ⊕ ⊕ ○)
- 3.2. We recommend that clinicians evaluate and address medical conditions that can be exacerbated by hormone depletion and treatment with sex hormones of the affirmed gender before beginning treatment. (1 | ⊕ ⊕ ⊕ ○)

- 3.3. We suggest that clinicians measure hormone levels during treatment to ensure that endogenous sex steroids are suppressed and administered sex steroids are maintained in the normal physiologic range for the affirmed gender. (2 |⊕⊕○○)
- 3.4. We suggest that endocrinologists provide education to transgender individuals undergoing treatment about the onset and time course of physical changes induced by sex hormone treatment. (2 |⊕○○○)**

#### **4.0 Adverse Outcome Prevention and Long-term Care**

- 4.1. We suggest regular clinical evaluation for physical changes and potential adverse changes in response to sex steroid hormones and laboratory monitoring of sex steroid hormone levels every 3 months during the first year of hormone therapy for transgender males and females and then once or twice yearly. (2 |⊕⊕○○)
- 4.2. We suggest periodically monitoring prolactin levels in transgender females treated with estrogens. (2 |⊕⊕○○)
- 4.3. We suggest that clinicians evaluate transgender persons treated with hormones for cardiovascular risk factors using fasting lipid profiles, diabetes screening, and/or other diagnostic tools. (2 |⊕⊕○○)
- 4.4. We recommend that clinicians obtain bone mineral density (BMD) measurements when risk factors for osteoporosis exist, specifically in those who stop sex hormone therapy after gonadectomy. (1 |⊕⊕○○)
- 4.5. We suggest that transgender females with no known increased risk of breast cancer follow breast-screening guidelines recommended for non-transgender females. (2 |⊕⊕○○)
- 4.6. We suggest that transgender females treated with estrogens follow individualized screening according to personal risk for prostatic disease and prostate cancer. (2 |⊕○○○)
- 4.7. We advise that clinicians determine the medical necessity of including a total hysterectomy and oophorectomy as part of gender-affirming surgery. (Ungraded Good Practice Statement)**

#### **5.0 Surgery for Sex Reassignment and Gender Confirmation**

- 5.1. We recommend that a patient pursue genital gender-affirming surgery only after the MHP and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being. (1 |⊕⊕○○)
- 5.2. We advise that clinicians approve genital gender affirming surgery only after completion of at least 1 year of consistent and compliant hormone treatment, unless hormone therapy is not desired or medically contraindicated. (Ungraded Good Practice Statement)
- 5.3. We advise that the clinician responsible for endocrine treatment and the primary care provider ensure appropriate medical clearance of transgender individuals for genital gender-affirming surgery and collaborate with the surgeon regarding hormone use during and after surgery. (Ungraded Good Practice Statement)
- 5.4. We recommend that clinicians refer hormone treated transgender individuals for genital surgery when: (1) the individual has had a satisfactory social role change, (2) the individual is satisfied about the hormonal effects, and (3) the individual desires definitive surgical changes. (1 |⊕○○○)
- 5.5. We suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country. (2 |⊕⊕○○)

5.6. We suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement. (2 | ⊕○○○)

## **AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGY**

In 2017 and 2011, the American College of Obstetricians and Gynecology (ACOG) published committee opinions regarding care for transgender adolescents, and health care services for transgendered individuals, respectively.<sup>[23,24]</sup> Although these guidelines are not based on evidence, ACOG does make the following statements:

“Obstetrician–gynecologists should be prepared to assist or refer transgender individuals for routine treatment and screening as well as hormonal and surgical therapies. Hormonal and surgical therapies for transgender patients may be requested, but should be managed in consultation with health care providers with expertise in specialized care and treatment of transgender patients.”

Regarding adolescents, ACOG highlights age-specific concerns with a focus on medical management.

“Consensus guidelines support initiating medical therapy after an adolescent has an established diagnosis of transgender identity and has reached Tanner stage II development.”

In addition, ACOG guidelines made specific recommendations regarding hormone therapy, surgery and screening for both female-to-male and male-to-female patients:

### **Female-to-Male Transgender Individuals**

#### Hormones

Methyltestosterone injections every 2 weeks are usually sufficient to suppress menses and induce masculine secondary sex characteristics. Before receiving androgen therapy, patients should be screened for medical contraindications and have periodic laboratory testing, including hemoglobin and hematocrit to evaluate for polycythemia, liver function tests, and serum testosterone level assessments (goal is a mid-normal male range of 500 microgram/dL), while receiving the treatment.

#### Surgery

Hysterectomy, with or without salpingo-oophorectomy, is commonly part of the surgical process. An obstetrician–gynecologist who has no specialized expertise in transgender care may be asked to perform this surgery, and also may be consulted for routine reasons such as dysfunctional bleeding or pelvic pain. Reconstructive surgery should be performed by a urologist, gynecologist, plastic surgeon, or general surgeon who has specialized competence and training in this field.

#### Screening

Age-appropriate screening for breast cancer and cervical cancer should be continued unless mastectomy or removal of the cervix has occurred. For patients using androgen therapy who have not had a complete hysterectomy, there may be an increased risk of endometrial cancer and ovarian cancer.

## Male-to-Female Transgender Individuals

### Hormones

Estrogen therapy results in gynecomastia, reduced hair growth, redistribution of fat, and reduced testicular volume. All patients considering therapy should be screened for medical contraindications. After surgery, doses of estradiol, 2–4 mg/d, or conjugated equine estrogen, 2.5 mg/d, are often sufficient to keep total testosterone levels to normal female levels of less than 25 ng/dL. Nonoral therapy also can be offered. It is recommended that male-to-female transgender patients receiving estrogen therapy have an annual prolactin level assessment and visual field examination to screen for prolactinoma.

### Surgery

Surgery usually involves penile and testicular excision and the creation of a neovagina. Reported complications of surgery include vaginal and urethral stenosis, fistula formation, problems with remnants of erectile tissue, and pain. Vaginal dilation of the neovagina is required to maintain patency. Other surgical procedures that may be performed include breast implants and nongenital surgery, such as facial feminization surgery.

### Screening

Age-appropriate screening for breast and prostate cancer is appropriate for male-to-female transgender patients. Opinion varies regarding the need for Pap testing in this population. In patients who have a neocervix created from the glans penis, routine cytologic examination of the neocervix may be indicated. The glands are more prone to cancerous changes than the skin of the penile shaft, and intraepithelial neoplasia of the glans is more likely to progress to invasive carcinoma than is intraepithelial neoplasia of other penile skin.

## SUMMARY

The research lacks well-designed studies comparing the safety and effectiveness of non-treatment for gender dysphoria with treatments such as hormone therapy and gender affirmation surgery. However, there are challenges in conducting large studies to evaluate existing treatments, and such studies are not expected in the near future. Although additional research is needed, the research has consistently suggested significant improvement in symptoms and overall quality of life in those who have received treatment for gender dysphoria. Therefore, treatment of gender dysphoria in transgender individuals may be considered medically necessary when specified policy criteria are met.

The World Professional Association for Transgender Health (WPATH) Standards of Care (SOC) for the Health of Transsexual, Transgender, and Gender Nonconforming Peoples describe reversible and irreversible interventions, and the ideal order and timing of these approaches. Surgery as an intervention is considered irreversible by WPATH. Therefore, reversal of gender affirmation surgery is considered not medically necessary as a treatment of gender dysphoria.



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## CODES

### NOTES:

- Codes 31552, 31554, 31580, 31584, 31587, and 31591 are not appropriate to use to represent voice modification. Unlisted code 31599 should be reported instead.
- Codes 55970 and 55980 are non-specific. The specific procedure code(s) must be requested in place of these non-specific codes.

Codes	Number	Description
CPT	11970	Replacement of tissue expander with permanent prosthesis
	11971	Removal of tissue expander(s) without insertion of prosthesis
	15775	Punch graft for hair transplant; 1 to 15 punch grafts
	15776	Punch graft for hair transplant; more than 15 punch grafts
	15820	Blepharoplasty, lower eyelid
	15821	;with extensive herniated fat pad
	15822	Blepharoplasty, upper eyelid
	15823	;with excessive skin weighting down lid

17380	Electrolysis epilation, each 30 minutes
19303	Mastectomy, simple, complete
19304	Mastectomy, subcutaneous
19316	Mastopexy
19318	Reduction mammoplasty
19324	Mammoplasty, augmentation; without prosthetic implant
19325	Mammoplasty, augmentation; with prosthetic implant
19350	Nipple/areola reconstruction
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	;complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	;including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	;intermediate revision (bony work with osteotomies)
30450	;major revision (nasal tip work and osteotomies)
31599	Unlisted procedure, larynx
53400	Urethroplasty; first stage, for fistula, diverticulum, or stricture (eg, Johanssen type)
53405	Urethroplasty; second stage (formation of urethra), including urinary diversion
53410	Urethroplasty, 1-stage reconstruction of male anterior urethra
53415	Urethroplasty, transpubic or perineal, 1-stage, for reconstruction or repair of prostatic or membranous urethra
53420	Urethroplasty, 2-stage reconstruction or repair of prostatic or membranous urethra; first stage
53425	Urethroplasty, 2-stage reconstruction or repair of prostatic or membranous urethra; second stage
53430	Urethroplasty, reconstruction of female urethra
54125	Amputation of penis; complete (Penectomy)
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
54660	Insertion of testicular prosthesis
54690	Laparoscopy, surgical; orchiectomy
55175	Scrotoplasty; simple
55180	Scrotoplasty; complicated
55899	Phallic reconstruction/Phalloplasty (Unlisted procedure, male genital system)
55970	intersex surgery; male to female
55980	intersex surgery; female to male
56625	Vulvectomy simple; complete
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
57106	Vaginectomy, partial removal of vaginal wall
57110	Vaginectomy, complete removal of vaginal wall;
57291	Construction of artificial vagina; without graft
57292	Construction of artificial vagina; with graft
57295	Revision (including removal) of prosthetic vaginal graft; vaginal approach
57296	Revision (including removal) of prosthetic vaginal graft; open abdominal approach
57335	Vaginoplasty for intersex state - the physician uses various plastic surgery techniques to correct a small, underdeveloped vagina due to the overproduction of male hormones
57426	Revision (including removal) of prosthetic vaginal graft, laparoscopic approach
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)

58180	Supracervical abdominal hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)
58260	Vaginal hysterectomy, for uterus 250 g or less
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
58270	Vaginal hysterectomy, for uterus 250 g or less; with repair of enterocele
58275	Vaginal hysterectomy, with total or partial vaginectomy;
58290	Vaginal hysterectomy, for uterus greater than 250 g
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58550	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral (separate procedure)
HCPCS C1813	Prosthesis, penile, inflatable
L8039	Breast prosthesis, not otherwise specified
L8600	Implantable breast prosthesis, silicone or equal

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