



Gender Affirming Surgery Clinical Coverage Criteria

Description

Gender-affirming surgery refers to a surgical procedure or a series of surgical procedures designed to align a person's sex characteristics with their gender identity.

Policy

This Policy applies to the following Fallon Health products:

- Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
- MassHealth ACO
- NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
- NaviCare SCO (MassHealth-only)
- PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
- Community Care (Commercial/Exchange)

Gender-affirming surgery requires prior authorization.

Medicare Advantage

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for Gender-Affirming Surgery. Medicare has an [NCD for Gender Dysphoria and Gender Reassignment Surgery \(140.9\)](#), Version Number 1, Effective Date of this Version 08/30/2016. After examining the medical evidence, CMS determined that no national coverage determination is appropriate at this time for gender reassignment surgery. To clarify, this is not national non-coverage determination, rather it is that no national policy will be put in place for the Medicare program. In the absence of an NCD, coverage determinations for gender reassignment surgery under section 1862(a)(1)(A) of the Social Security Act will continue to be made by the Medicare Administrative Contractors (MACs) for beneficiaries in Original Medicare on a case-by-case basis. For Medicare beneficiaries enrolled in Medicare Advantage (MA) plans, the determination of whether or not gender reassignment surgery would be reasonable and necessary will be made by the MA plan (CAG-00446N, 08/30/2016) (MCD search 12/11/2023).

Coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, therefore, Fallon Health Clinical Coverage Criteria are applicable.

MassHealth

Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity

Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth has [Guidelines for Medical Necessity Determination for Gender-Affirming Surgery](#). Fallon Health will make medical necessity determinations for gender-affirming surgery for MassHealth members using coverage criteria in the MassHealth Guidelines for Gender-Affirming Surgery. Requests for prior authorization for gender-affirming surgery for MassHealth members must be submitted by the surgeon performing the procedure and must be accompanied by clinical documentation that supports the medical necessity for the procedure as outlined in the MassHealth Guidelines.

Per Guidelines for Medical Necessity Determination for Gender-Affirming Surgery (Effective September 1, 2023), MassHealth presumes that certain procedures and surgeries are not medically necessary for the treatment of gender dysphoria. Examples of such procedures and surgeries include, but are not limited to, the following:

- Chemical peels
- Collagen injections
- Dermabrasion
- Hair transplantation
- Implants: calf, gluteal, or pectoral
- Isolated blepharoplasty
- Lip reduction or enhancement
- Neck lift
- Panniculectomy or abdominoplasty (see MassHealth Guidelines for Medical Necessity Determination for Excision of Excessive Skin and Subcutaneous Tissue)
- Reversal of previous gender affirming surgery
- Revisions of previous gender affirming surgery other than for complications (infections or impairment of function)
- Rhytidectomy
- Vocal cord surgery

MassHealth has [Guidelines for Medical Necessity Determination for Hair Removal](#) as treatment of gender dysphoria. Fallon Health will make medical necessity determinations for hair removal of the face and neck as part of the treatment of gender dysphoria for MassHealth members using coverage criteria in the MassHealth Guidelines for Hair Removal. Requests for prior authorization for hair removal for MassHealth members must be submitted by the clinician performing the procedure and accompanied by clinical documentation that supports the medical necessity for the procedure as outlined in the MassHealth Guidelines.

Per Guidelines for Medical Necessity Determination for Hair Removal (Effective September 1, 2021), MassHealth does not consider hair removal to be medically necessary under certain circumstances. Examples of such circumstances include but are not limited to hair removal for cosmetic purposes.

NaviCare HMO SNP, NaviCare SCO

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria

Requests for prior authorization for gender affirming surgery must be submitted by the surgeon performing the procedure. The request must be accompanied by clinical documentation that supports the medical necessity of the procedure, including but not limited to the following:

- A copy of the assessment made by the qualified licensed behavioral health professional, including date of onset and history resulting in a diagnosis of gender dysphoria meeting DSM-5 criteria.
- A copy of the referral/recommendation for surgery made by the qualified licensed behavioral health professional who assessed and diagnosed the member.
- If hormone therapy is a required criterion, medical records must document, the prescribed regimen, patient compliance with the prescribed regimen and clinical response over the course of hormone therapy.
- If living as the gender that is congruent with the member's identity is a required criterion, the member's medical records must document the date the member started living as this gender and the member's experience living as this gender.
- If there are any co-existing behavioral health and/or medical conditions, documentation must show they are appropriately managed and are reasonably controlled.

Fallon Health reserves the right to request documentation so as to assure that surgeons performing these procedures are adequately experienced.

Effective September 9, 2021, requests for gender affirmation surgical procedures for commercial plan members < 18 years of age will be considered on an individual case-by-case basis, in accordance with [Massachusetts Division of Insurance Bulletin 2021-11](#).

Procedures for Members Assigned Female at Birth (AFAB)

Bilateral subcutaneous mastectomy, reduction mammoplasty, and/or chest reconstruction/contouring may be considered medically necessary for plan members AFAB when all of the following criteria are met:

1. The plan member is 18 years of age or older; and
2. The plan member has a diagnosis of gender dysphoria meeting DSM-V criteria¹, made by a qualified licensed behavioral health professional who is experienced in the assessment and diagnosis of gender dysphoria (Fallon Health reserves the right to request the credentials of the diagnosing behavioral health professional). This diagnosis must have been present for at least 6 months; and
3. The qualified licensed behavioral health professional who assessed and diagnosed the member (in 2. above) recommends the requested surgery for the plan member; and
4. The plan member has lived as the gender that is congruent with the member's identity, full-time for 12 months or more.

¹ Criteria for the DSM-5 and DSM-5-TR classification of gender dysphoria in adolescence and adulthood denote "a marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration" (criterion A, fulfilled when 2 of 6 subcriteria are manifest; DSM-5, APA, 2013; DSM 5-TR, APA, 2022).

Hysterectomy/salpingo-oophorectomy, metoidioplasty or phalloplasty, vaginectomy, vulvectomy, urethroplasty, and scrotoplasty with implantation of a testicular prostheses may be considered medically necessary for plan members AFAB when all of the following criteria are met:

1. The plan member is 18 years of age or older; and
2. The plan member has a diagnosis of gender dysphoria meeting DSM-V criteria, made by a qualified licensed behavioral health professional who is experienced in the assessment and diagnosis of gender dysphoria (Fallon Health reserves the right to request the credentials of the diagnosing behavioral health provider). This diagnosis must have been present for at least 6 months; and
3. The qualified licensed behavioral health professional who assessed and diagnosed the member (in 2. above) recommends the requested surgery for the plan member; and
4. The plan member has received 12 continuous months of hormone therapy, unless hormone therapy is medically contraindicated, under the supervision of a physician, with documentation of the member's compliance and the type, frequency, and route of administration; and
5. The plan member has lived as the gender that is congruent with the member's identity, full-time for 12 continuous months (4 and 5 may occur concurrently). Exceptions may be provided on a case-by-case basis when the request documents that compliance with this requirement would jeopardize the health, safety, or well-being of the member.

Removal of hair on a skin graft donor site before its use in genital gender affirming surgery using a method that will result in permanent hair removal and performed by a qualified licensed professional is considered medically necessary. Requests for hair removal for must be submitted by the clinician performing the procedure and accompanied by clinical documentation that supports the medical necessity for the procedure.

Procedures for Members Assigned Male at Birth (AMAB)

Augmentation mammoplasty² with implantation of breast prostheses may be considered medically necessary for plan members AMAB when all of the following criteria are met:

1. The plan member is 18 years of age or older; and
2. The plan member has a diagnosis of gender dysphoria meeting DSM-V criteria made by a qualified licensed behavioral health professional who is experienced in the assessment and diagnosis of gender dysphoria (Fallon Health reserves the right to request the credentials of diagnosing provider). This diagnosis must have been present for at least 6 months; and
3. The qualified licensed behavioral health professional who assessed and diagnosed the plan member (in 2. above) recommends the requested surgery for the plan member; and
4. The plan member has no or minimal breast development after receiving continuous hormone therapy for 12 months or more, unless hormone therapy is medically contraindicated, under the supervision of a physician, with documentation of the member's compliance and the type, frequency, and route of administration; and
5. The plan member has lived as the gender that is congruent with the member's identity, full-time for 12 months or more (4 and 5 may occur concurrently). Exceptions may be provided on a case-by-case basis when the request documents that compliance with this requirement would jeopardize the health, safety, or well-being of the member.

Penectomy, orchiectomy, vaginoplasty, clitoroplasty, labiaplasty and vulvoplasty may be considered medically necessary for plan members AMAB when all of the following criteria are met:

1. The plan member is 18 years of age or older; and
2. The plan member has a diagnosis of gender dysphoria meeting DSM-V criteria made by a qualified licensed behavioral health professional who is experienced in the assessment and diagnosis of gender dysphoria (Fallon Health reserves the right to request the credentials of diagnosing provider). This diagnosis must have been present for at least 6 months; and

² de blok et al. J Clin Endocrinol Metab. 103: 532–538, 2018.

3. The qualified licensed behavioral health professional who assessed and diagnosed the plan member (in 2. above) recommends the requested surgery for the plan member; and
4. The plan member has received 12 continuous months of hormone therapy, unless hormone therapy is medically contraindicated, under the supervision of a physician, with documentation of the member's compliance and the type, frequency, and route of administration; and
5. The plan member has lived as the gender that is congruent with the member's identity, full-time for 12 months or more (4 and 5 may occur concurrently). Exceptions may be provided on a case-by-case basis should the request for PA document that compliance with this requirement would jeopardize the health, safety, or well-being of the member.

Removal of hair on a skin graft donor site before its use in genital gender affirming surgery using a method that will result in permanent hair removal and performed by a qualified licensed professional is considered medically necessary. Requests for hair removal for must be submitted by the clinician performing the procedure and accompanied by clinical documentation that supports the medical necessity for the procedure.

Facial Gender Affirming Surgery

The following surgical procedures may be considered medically necessary when all of the criteria listed below are met:

- Forehead contouring and reduction
- Rhinoplasty and septoplasty
- Genioplasty
- Blepharoplasty (only as needed in conjunction with a covered facial feminization or masculinization procedure)
- Brow lift
- Cheek augmentation
- Suction-assisted lipectomy (only as needed in conjunction with a covered facial feminizing/masculinizing procedure)
- Tracheoplasty (thyroid cartilage reduction)
- Hairline advancement
- Lateral canthopexy
- Lip lift
- Lysis intranasal synechia
- Osteoplasty

1. The plan member is 18 years of age or older;
2. The plan member has a diagnosis of gender dysphoria meeting DSM-V criteria made by a qualified licensed behavioral health professional who is experienced in the assessment and diagnosis of gender dysphoria (Fallon Health reserves the right to request the credentials of diagnosing provider). This diagnosis must have been present for at least 6 months; and
3. The qualified licensed behavioral health professional who assessed and diagnosed the plan member (in 2. above) recommends the requested surgery for the plan member; and
4. The plan member has received 12 continuous months of hormone therapy, unless hormone therapy is medically contraindicated, under the supervision of a physician, with documentation of the member's compliance and the type, frequency, and route of administration; and
5. The plan member has lived as the gender that is congruent with the member's identity, full-time for 12 months or more (4 and 5 may occur concurrently). Exceptions may be provided on a case-by-case basis should the request for PA document that compliance with this requirement would jeopardize the health, safety, or well-being of the member.

Hair Removal of the Face and Neck

Hair removal of the face and neck as part of treatment for gender dysphoria may be considered medically necessary when all of the following criteria are met and documented:

1. The plan member is 18 years of age or older; and
2. The plan member has a diagnosis of gender dysphoria meeting DSM-V criteria made by a qualified licensed behavioral health professional who is experienced in the assessment and diagnosis of gender dysphoria (Fallon Health reserves the right to request the credentials of diagnosing provider). This diagnosis must have been present for at least 6 months; and
3. The qualified licensed behavioral health professional who assessed and diagnosed the plan member (in 2. above) recommends hair removal for the plan member; and
4. The plan member has received 12 continuous months of hormone therapy, unless hormone therapy is medically contraindicated, under the supervision of a physician, with documentation of the member's compliance and the type, frequency, and route of administration; and
5. The plan member has lived as the gender that is congruent with the member's identity, full-time for 12 months or more (4 and 5 may occur concurrently). Exceptions may be provided on a case-by-case basis should the request for PA document that compliance with this requirement would jeopardize the health, safety, or well-being of the member.

Electrolysis and laser hair removal are the only two methods of hair removal that are covered by Fallon Health.

Electrolysis is currently the only US Food and Drug Administration (FDA)-approved method of permanent hair removal, whereas laser hair removal is approved for permanent hair reduction (Zhang et al., 2016). Evidence supports the use of electrolysis for permanent hair removal in localized areas and lasers (particularly alexandrite and diode lasers) for permanent hair reduction.

Board-certified dermatologists can provide safe and effective hair removal for the treatment of gender dysphoria.

Requests for hair removal of the face and neck must be submitted by the clinician performing the procedure and accompanied by clinical documentation that supports the medical necessity for the procedure.

Other

Fallon Health recognizes the gender-affirming surgical procedures covered under this policy bring patients into a wide range of accepted appearances of their desired gender. Fallon Health maintains a Cosmetic, Reconstructive and Restorative Services Clinical Coverage Criteria policy that applies to cosmetic, reconstructive, and restorative procedures generally; consideration will be given as to how the procedure will affect gender identity.

Infertility services are addressed in Fallon Health's Infertility Services Clinical Coverage Criteria policy.

Exclusions

- Reversal of any gender-affirming surgery
- Revision of any gender affirming surgery other than for impaired of function
- Vocal cord surgery including procedures for raising voice pitch (e.g., glottoplasty) and for lower voice pitch (e.g., thyroplasty)
- Hair removal, except as described as covered in this Clinical Coverage Criteria policy
- Fallon Health considers the following procedures to be cosmetic (refer to Cosmetic, Reconstructive and Restorative Services Clinical Coverage Criteria for additional information):
 - Otoplasty
 - Abdominoplasty
 - Buttock lift
 - Implants: calf, gluteal, pectoral

- Hair transplantation
- Lip reduction or enhancement

Summary of Evidence

DSM-5-TR Criteria for Gender Dysphoria

Gender dysphoria is designated in the *DSM-5-TR* as clinically significant distress or impairment related to gender incongruence, which may include desire to change primary and/or secondary sex characteristics. Not all transgender or gender diverse people experience gender dysphoria.

The *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR)* provides for one overarching diagnosis of gender dysphoria with separate specific criteria for children and for adolescents and adults.

The *DSM-5-TR* defines gender dysphoria in adolescents and adults as a marked incongruence between one's experienced/expressed gender and their assigned gender, lasting at least 6 months, as manifested by at least two of the following:

- 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)
- 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)
- A strong desire for the primary and/or secondary sex characteristics of the other gender
- A strong desire to be of the other gender (or some alternative gender different from one's assigned gender)
- A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender)
- 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)

In order to meet criteria for the diagnosis, the condition must also be associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

The *DSM-5-TR* defines gender dysphoria in children as a marked incongruence between one's experienced/expressed gender and assigned gender, lasting at least 6 months, as manifested by at least six of the following (one of which must be the first criterion):

- 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)
- 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 the wearing of typical feminine clothing
- A strong preference for cross-gender roles in make-believe play or fantasy play
- A strong preference for the toys, games or activities stereotypically used or engaged in by the other gender
- A strong preference for playmates of the other gender
- 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
- A strong dislike of one's sexual anatomy
- A strong desire for the physical sex characteristics that match one's experienced gender

As with the diagnostic criteria for adolescents and adults, the condition must also be associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Guidelines

Standards of Care for the Health of Transgender and Gender Diverse People, Version 8

The World Professional Association for Transgender Health (WPATH) is an international, multidisciplinary, professional association whose mission is to promote evidence-based care, education, research, advocacy, public policy, and respect in transgender health. One of the main functions of WPATH is to promote the highest standards of health care for transgender and gender diverse (TGD) people through the Standards of Care (SOC). The SOC are based on the best available science and expert professional consensus. The SOC were initially developed in 1979 and the previous version (SOC-7) was published in 2012. In view of the increasing scientific evidence, WPATH commissioned a new version of the Standards of Care, the SOC-8, which was published in 2022. SOC-8 is based upon a more rigorous and methodological evidence-based approach than previous versions. This evidence is not only based on the published literature (direct as well as background evidence) but also on consensus-based expert opinion.

Recognizing the diverse and heterogeneous community of individuals who identify as TGD, gender-affirming surgical procedures may be categorized as procedures for individuals assigned male at birth (AMAB) and assigned female at birth (AFAB). In TGD individuals with gender dysphoria, the current literature supports the benefits of gender-affirming surgery.

The WPATH SOC recommend health care professional assessing transgender and gender diverse adults for gender-affirming treatments are licensed by their statutory body and hold, at a minimum, a master's degree or equivalent training in a clinical field relevant to this role and granted by a nationally accredited statutory institution. In some settings, statutorily regulated health care professionals with lower levels of qualification may practice under the clinical supervision of a qualified health care professional who takes ultimate clinical responsibility for the quality and accuracy of the completed gender affirming medical and/or surgical treatment assessment. Established practice requires the competence to identify and diagnose gender incongruence (Hembree et al., 2017; Reed et al., 2016; T'Sjoen et al., 2020) and the ability to identify differentials or conditions that may be mistaken as gender incongruence (Byne et al., 2018; Dhejne et al., 2016; Hembree et al., 2017). Established practice also strongly emphasizes the need for ongoing continuing education in the assessment and provision of care of TGD people

In individuals AFAB, results of gender-affirming chest surgery or "top surgery" (i.e., subcutaneous mastectomy) have been reported in 5 prospective studies, 8 retrospective and 4 cross-sectional cohort studies published between 2015 and 2019. The efficacy of top surgery has been demonstrated in multiple domains, including a consistent and direct increase in health-related quality of life, a significant decrease in gender dysphoria, and a consistent increase in satisfaction with body and appearance. Additionally, rates of regret remain very low, varying from 0 to 4%. While the effect of top surgery on additional outcome measures such as depression, anxiety, and sexual function also demonstrated a benefit, the studies were of insufficient strength to draw definitive conclusions. Although further investigation is needed to draw more robust conclusions, the evidence demonstrates top surgery to be a safe and effective intervention (WPATH SOC-8, p. S128).

In individuals AMAB, fewer studies have been published regarding gender-affirming breast surgery ("breast augmentation"). Studies include two prospective studies, one retrospective cohort and 3 cross-sectional cohort studies. All the studies reported a consistent and direct improvement in patient satisfaction, including general satisfaction, body image satisfaction, and body image following surgery. Owen-Smith et al. (2018) demonstrated that depression, and especially anxiety, were lower among individuals who received a more extensive gender affirming treatments compared to those who received less treatment or no treatment at all. However, there was no statistical comparison between individuals who underwent top surgery and any other

group (WPATH SOC-8 p. S128). Historically, standard clinical practice has been to first treat any comorbid psychological conditions such as depression and anxiety prior to referring a transgender individual for gender affirming treatments. Withholding hormone therapy or gender-affirming surgery until depression or anxiety have been treated may not be the optimal treatment course given the benefits of reduced levels of distress after undergoing gender affirming treatments.

External genital surgery procedures include but are not limited to vulvoplasty, metoidioplasty, and Phalloplasty. Hair removal is generally necessary before performing external genital procedures (Marks et al., 2019).

Gender-affirming vaginoplasty for individuals AMAB is one of the most frequently reported gender-affirming surgical interventions with 8 prospective, 15 retrospective cohort and 3 cross-sectional cohort studies published in recent years (2015-2018). Although different assessment measurements were used, the results from all studies consistently reported both a high level of patient satisfaction (78–100%) as well as satisfaction with sexual function (75–100%). This was especially evident when using more recent surgical techniques. Gender-affirming vaginoplasty was also associated with a low rate of complications and a low incidence of regret (0–8%).

Recent literature reflects the increased clinical interest in metoidioplasty and phalloplasty as reflected by 3 prospective cohort, 6 retrospective cohort and 4 cross-sectional studies which reviewed the risks and benefits of these procedures. In terms of urinary function, between 75 and 100% of study participants were able to void while standing. In terms of sexual function, between 77 and 95% of study participants reported satisfaction with their sexual function. Most of these studies report high overall levels of postoperative satisfaction (range 83–100%), with higher rates of satisfaction in studies involving newer surgical techniques. Two prospective and two retrospective cohort studies specifically assessed regret following surgery and found no transgender men experienced regret. While study limitations were identified, the reported results were consistent and direct.

Multiple procedures are available for facial gender-affirming surgeries. In recent years, facial gender-affirming surgery has received increased attention, and current literature supports its benefits. Gender-affirming facial surgery aligns an individual's appearance with their gender identity with the goal of alleviating gender dysphoria. Eight recent publications include 1 prospective cohort, 5 retrospective cohort, and 2 cross-sectional studies. All 8 studies clearly demonstrated individuals were very satisfied with their surgical results (between 72% and 100% of individuals). Additionally, individuals were significantly more satisfied with the appearance of their face compared with individuals who had not undergone surgery. One prospective, international, multicenter, cohort study found facial gender-affirming surgery in individuals AMAB significantly improves both mid- and long-term quality of life (Morrison et al., 2020). The results were direct and consistent, but somewhat imprecise because of certain study limitations. While gender-affirming facial surgery for AFAB individuals is an emerging field, current limited data points toward equal benefits in select patients. Future studies are recommended.

Estrogen treatment in AFAB individuals has not been associated with measurable voice changes, while testosterone treatment in AMAB individuals has been found to result in voice deepening. Desired changes associated with testosterone treatment include lowered voice pitch, increased male attributions to voice, and increased satisfaction with voice production. Reported dissatisfaction with testosterone treatment include lack of or insufficient lowering of voice pitch, dysphonia, weak voice, restricted singing pitch range, and vocal instability. These areas can be assessed and addressed in voice training by a voice and communication specialist (WPATH SOC-8 p. S139).

Two types of laryngeal surgeries are relevant for TGD populations: those for raising voice pitch (e.g., glottoplasty with retrodisplacement of the anterior commissure, cricothyroid approximation

(CTA), feminization laryngoplasty, laser-assisted voice adjustment (LAVA)) and for lowering voice pitch (e.g., thyroplasty type III, vocal fold injection augmentation). The number and quality of research studies evaluating pitch-lowering surgeries are currently insufficient, particularly with regard to comparing outcomes with and without other interventions (i.e., testosterone). There are more techniques and studies of pitch-raising surgeries, but the quality of the evidence is still low. Outcomes from pitch-raising surgeries have been compared to outcomes from having no surgery, another type of surgical technique, voice training alone, and surgery in conjunction with voice training. In the 11 studies reporting whether participants had voice training prior to pitch-raising surgery, most participants had prior voice training, but remained dissatisfied with voice and sought surgical intervention. Thus, most studies of surgical outcomes reflect the combined effects of voice training and surgical intervention. Attributes predicting which clients will pursue surgery after training are unknown (WPATH SOC-8, p. S141-S142).

It is important the surgeon and the patient participate in a shared decision-making approach that includes 1) a multidisciplinary approach; 2) an understanding of the patient's goals and expectations; 3) a discussion regarding the surgical options and associated risks and benefits; and 4) an informed plan for aftercare. These recommendations are designed to facilitate an individualized approach to care.

Appropriate aftercare is essential for optimizing outcomes, and it is important patients are informed about postoperative needs (including local wound care, activity restrictions, time off from work or school, etc.). In addition, it is important the surgeon is available to provide and facilitate postoperative care, refer to specialty services, or both as needed. This may include the need for ongoing support (i.e., both from the caregiver as well as the primary care provider, mental health professionals, or both), as well as the need for routine primary care (i.e., breast/chest cancer screening, urologic/gynecologic care, etc.).

There is strong evidence demonstrating the benefits in quality of life and well-being of gender-affirming treatments, including hormone therapy and surgical procedures, are safe and effective at reducing gender incongruence and gender dysphoria, properly indicated and performed as outlined by the WPATH SOC-8, in TGD people in need of these treatments (WPATH SOC-8, p. S18).

Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline

Although hormone therapy is not within the scope of this policy, TGD persons may require medically necessary gender-affirming hormone therapy to achieve changes consistent with their goals, gender identify or both. The treating clinician must ensure that the desire for transition is appropriate; the consequences, risks, and benefits of treatment are well understood; and the desire for transition persists. In most cases, gender-affirming hormone therapy is maintained throughout life.

The two major goals of hormonal therapy are (1) to reduce endogenous sex hormone levels, and thus reduce the secondary sex characteristics of the individual's designated gender, and (2) to replace endogenous sex hormone levels consistent with the individual's gender identity by using the principles of hormone replacement treatment of hypogonadal patients. (Hembree et al., 2017, p. 3885-3886).

Surgery that affects fertility is irreversible. If the social transition has not been satisfactory, if the person is not satisfied with or is ambivalent about the effects of sex hormone treatment, or if the person is ambivalent about surgery, then the individual should not be referred for surgery (Hembree et al., 2017, p. 3893).

Breast surgery is a good example of gender-confirming surgery that does not affect fertility. In all females, breast size exhibits a very broad spectrum. Breast development and a female-typical

fat distribution are among a number of physical changes that occur in response to estrogen treatment. For AMAB individuals to make the best-informed decision, clinicians should delay breast augmentation surgery until the patient has completed at least 2 years of estrogen therapy, because the breasts continue to grow during that time. Breast development is generally maximal at 2 years after initiating hormones. There is a great deal of variability among individuals, as evidenced during pubertal development (Hembree, et al., 2017, p. 3888).

Breast size only partially regresses with hormone therapy in AFAB individuals. In adults, discussions about mastectomy usually take place after hormone therapy has started (Hembree et al., 2017 3894).

- We advise that clinicians approve genital gender-affirming surgery only after completion of at least one year of consistent and compliant hormone treatment, unless hormone therapy is not desired or medically contraindicated (Recommendation 5.2; Ungraded, Good Practice Statement).
- 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 (Recommendation 5.4; Strong Recommendation, Very Low Quality Evidence).

De Blok et al. (2021) conducted a prospective cohort study to examine breast development during the first 3 years of gender affirming hormone therapy. Participants were excluded if they ever used female sex hormones before. Hormone treatment consisted of anti-androgen treatment with cyproterone acetate (a progestogenic antiandrogen, 25 mg daily), combined with either estradiol valerate (4-6 mg daily) or estradiol patches (50-150 mcg/24 hours twice a week). Participants were evaluated at baseline, and after 3, 6, 9, 12, 18, 24, and 36 months of hormone treatment. Breast growth and development was evaluated with 3D imaging and compared with tape measure measurements. At time of the visits, participants filled out 2 questionnaires. The first questionnaire contained questions about the satisfaction with the gained breasts and used a four point Likert scale. The second questionnaire used was the Rosenberg perceived self-esteem scale. This questionnaire was used as general estimator of self-esteem. Laboratory testing was performed at baseline, after 3, 12, 24, and 36 months. A total of 69 transwomen with a median age of 26 years (range 21-38 years) were enrolled. Most (n = 44, 69%) had a normal BMI, and 42 (61%) had average self-esteem at baseline. During follow-up, 25 transwomen underwent vaginoplasty after median 24 months of hormone treatment. Breast volume increased in the right breast by 72 cc (95% CI, 48-96) to 101 cc (SD 48) and in the left breast by 72 cc. (95% CI, 48-97) to 100 cc (SD 48). Mean breast development was comparable between the right and left breast and no difference in breast size was observed. After 36 months, most trans women (71%) had a breast volume corresponding to a bra cup-size smaller than an A-cup. Only 9% had an A-cup (130-150 cc), 16% a B-cup (150-300 cc), 3% a C-cup (300-450 cc), and 1% an E-cup (600-750 cc). Most transwomen in this study (58%) were satisfied with the size of their breasts after treatment. Moreover, most transwomen were satisfied with the symmetry of their breasts (ranging from 63% after 3 months of treatment to 92% after 36 months), and the shape of the breasts (ranging from 51% to 83%). During follow-up, approximately three-quarters of the trans women in this study were satisfied with the size (range, 73% to 83%) and shape (range, 75% to 86%) of their nipples. Perceived self-esteem remained average in most of the transwomen (range, 48 % to 73%) during follow-up. Breast development with hormone treatment was satisfactory to most trans women in this study. Moreover, in 6 individuals, perceived self-esteem increased during treatment from low self-esteem to average self-esteem. In this study, breast development measured with 3D imaging appears to be a better reflection of hormone treatment-induced breast development compared with breast-chest differences measured with a tape measure. As in previous studies, these authors observed breast development during the entire follow-up time of this study. This study was the first with a follow-up up until 36 months after the start of hormone treatment. This shows that breast development in transwomen receiving hormone treatment may take more time than previously thought following the estimations in the Endocrine Society guidelines. This is also supported by the study of Fisher et al., (2016) who showed that mean breast development in trans women reached a Tanner stage 3 after 24 months of treatment,

suggesting that breast development has not reached maximum growth after 2 years of hormone treatment. These observations are in line with breast development during typical cis female puberty which may take up to 5 to 7 years. Most transwomen in this study were satisfied with their gained breast size, irrespective of the gained breast volume. As described earlier, a single ideal breast size does not exist and is dependent on the size of the chest, the height of the person, and cultural influences. The literature on breast size satisfaction in cis women is limited.

Reversal surgery in regretful male-to-female transsexuals after sexual reassignment surgery represents a complex, multistage procedure with satisfactory outcomes. Further insight into the characteristics of persons who regret their decision postoperatively would facilitate better future selection of applicants eligible for sexual reassignment surgery. More studies with appropriate controls that examine long-term quality of life, psychosocial outcomes, and psychiatric outcomes to determine the long-term benefits of surgical treatment are needed. When a transgender individual decides to have gender affirming surgery, both the hormone prescribing clinician and the mental health professional must certify that the patient satisfies criteria for gender-affirming surgery. It is important that the person requesting surgery feels comfortable with the anatomical changes that have occurred during hormone therapy. Dissatisfaction with social and physical outcomes during the hormone transition may be a contraindication to surgery (Hembree et al., 2017, p. 3895).

Ethically Navigating the Evolution of Gender Affirmation Surgery

As the turn of the millennium approached, policy makers set their sights on destigmatizing and depathologizing the treatment for gender incongruence, as gender affirmation surgery continued to grow and become an accepted treatment modality. The WPATH published 8 editions of the SOC between 1979 and 2022, the terminology for transgender and gender diverse identities was changed numerous times, new surgical advancements were made. These changes happened as research studies validated the beneficial effects of gender affirmation surgery and the Endocrine Society and other national organizations published clinical practice guidelines, all of which developments contributed to the practice's acceptance as the official standard of care. "We have now reached a tipping point in the field of gender affirmation surgery wherein the focus has largely shifted from fighting for its acceptance as a treatment modality and increasing patients' access to it toward ethical stewardship of this now validated and accessible set of procedures, although challenges remain, as access to surgical and medical care for adolescents remains politically fraught. This issue of *AMA Journal of Ethics* considers these challenges for the field and offers views of clinicians and advocates as protectors of patient autonomy and patient-centered, inclusive care (Mumford K., 2023)."

Analysis of Evidence (Rationale for Determination)

Fallon Health's clinical coverage criteria for gender-affirming surgery are derived from recommendations in evidence-based guidelines, including WPATH SOC-8 and the Endocrine Society Clinical Practice Guideline, and adapted to align with the local context (WPATH SOC-8, p. S8).

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Coding

One of following ICD-10-CM diagnosis codes must be included on claims for gender affirmation surgical procedures.

ICD-10-CM Codes	Description
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified
Z87.890	Personal history of sex reassignment

The DSM-5 and DSM-5-TR classification of gender dysphoria in adolescence and adulthood denote “a marked incongruence between one’s experienced/expressed gender and assigned gender.” Gender dysphoria replaces gender identity disorder which is no longer be used in the DSM. However, ICD-10 codes continue to use the term gender identity disorder, and providers will need to submit claims for coverage using these diagnosis codes.

Intersex Surgery

When reporting CPT code 55970 (Intersex surgery; male to female), the following staged procedures to remove portions of the male genitalia and form female external genitals are included:

- The penis is dissected, and portions are removed with care to preserve vital nerves and vessels in order to fashion a clitoris-like structure.
- The urethral opening is moved to a position similar to that of a female.
- A vagina is made by dissecting and opening the perineum. This opening is lined using pedicle or split- thickness grafts.
- Labia are created out of skin from the scrotum and adjacent tissue.
- A stent or obturator is usually left in place in the newly created vagina for three weeks or longer.

When reporting CPT code 55980 (Intersex surgery; female to male), the following staged procedures to form a penis and scrotum using pedicle flap grafts and free skin grafts are included:

- Portions of the clitoris are used, as well as the adjacent skin.
- Prostheses are often placed in the penis to create a sexually functional organ.
- Prosthetic testicles are implanted in the scrotum.
- The vagina is closed or removed.

CPT Codes	Code Description
55970	Intersex Surgery, male to female
55980	Intersex Surgery, female to male

Assigned Male at Birth (AMAB)

CPT Codes	Code Description
19324	Mammoplasty, augmentation; without prosthetic implant
19325	Mammoplasty, augmentation; with prosthetic implant
19350	Nipple/areola reconstruction
19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s)
53410	Urethroplasty, 1-stage reconstruction of male anterior urethra
53420	Urethroplasty, 2-stage reconstruction or repair of prostatic or membranous urethra; first stage
53430	Urethroplasty, reconstruction of female urethra
54120	Amputation of penis, partial
54125	Amputation of penis, complete
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach

54690	Laparoscopy, surgical orchiectomy
56800	Plastic repair introitus
56805	Clitoroplasty for intersex state
67291	Construction of artificial vagina; without graft
67292	Construction of artificial vagina; with graft
57335	Vaginoplasty for intersex state

Assigned Female at Birth (AFAB)

CPT Codes	Code Description
19303	Mastectomy, simple, complete
19304	Mastectomy, subcutaneous
19316	Mastopexy
19350	Nipple/areola reconstruction
53430	Urethroplasty, reconstruction of female urethra
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
56625	Vulvectomy simple; complete
57110	Vaginectomy, complete removal of vaginal wall
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 grams or less
58262	Vaginal hysterectomy, for uterus 250 grams or less; with removal of tube(s), and/or ovary(s)
58275	Vaginal hysterectomy, with total or partial vaginectomy
58290	Vaginal hysterectomy, for uterus greater than 250 grams
58291	Vaginal hysterectomy, for uterus greater than 250 grams; 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 grams or less;
58552	Laparoscopy surgical, with vaginal hysterectomy, for uterus 250 grams 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 grams; with removal of tube(s), and/or ovary(s)
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
57572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g;
57573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s), and/or ovary(s)
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral (separate

	procedure)
58940	Oophorectomy, partial or total, unilateral or bilateral

Electrolysis or laser hair removal

Covered for the removal of hair on a skin graft donor site before its use in genital gender affirmation surgery

CPT Code	Code Description
17380	Electrolysis epilation, each 30 minutes
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue Use when billing for laser hair removal

Facial Procedures

14301	Adjacent tissue transfer or rearrangement, any area; defect 30.1 sq cm to 60.0 sq cm
14302	Adjacent tissue transfer or rearrangement, any area; each additional 30.0 sq cm, or part thereof (List separately in addition to code for primary procedure)
20912	Cartilage graft; nasal septum
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)
21137	Reduction forehead; contouring only
21139	Reduction forehead; contouring and setback of anterior frontal sinus wall
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21209	Osteoplasty, facial bones; reduction
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
21296	Reduction of masseter muscle and bone (eg, for treatment of benign masseteric hypertrophy); intraoral approach
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30465	Repair of nasal vestibular stenosis (e.g., spreader grafting, lateral nasal wall reconstruction)
31750	Tracheoplasty; cervical
64716	Neuroplasty and/or transposition; cranial nerve (specify)
64771	Transection or avulsion of other cranial nerve, extradural

Suction-assisted lipectomy

Covered when required as part of a covered facial feminizing/masculinizing procedure

CPT Codes	Code Description
15876	Suction assisted lipectomy; head and neck

Policy history

Origination date: 10/01/2013
Approval(s): Benefit Oversight Committee: 11/13/2013
Technology Assessment Committee: 07/23/2014 (adopted as Clinic Coverage Criteria); 12/03/2014 (updated language surrounding Cosmetic Procedures); 01/27/2016 (updated references, added clarification language surrounding hormone therapy, female to male breast/chest surgeries no longer require hormone therapy as pre-requisite)
10/26/2016 (clarified which criteria applies to breast surgeries, updated references); 10/25/2017 (updated references); 10/11/2018 (updated references); 10/23/2019 (policy name changed from Transgender Services to Gender Affirmation Services, updated references);
09/28/2021 (added covered facial feminizing/masculinizing surgical

procedures, added coverage for commercial plan members < 18 years of age, on a case-by-case basis, in accordance with DOI Bulletin 2021-11, updated references); 06/27/2023 and 12/12/2023 (changed title to Gender Affirming Surgery, removed hormone therapy coverage criteria as hormone therapy is covered under the prescription drug benefit and managed by Pharmacy Services, added coverage for hair removal of the face and neck as part of treatment of gender dysphoria, clarified that the diagnosis of gender dysphoria must have been present for at least 6 months prior to any gender affirming surgery.

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans