Gender Affirmation Services
Clinical Coverage Criteria

Overview

Gender Dysphoria is defined as discomfort or distress that is caused by a discrepancy between a person's gender identity and the person's assigned sex at birth. Treatment of Gender Dysphoria is often individualized with a variety of treatments producing varied results in individuals.

Gender affirmation services include hormone replacement therapy, evaluation and treatment for side effects of hormone replacement therapy, genital (male-to-female or female-to-male) surgical procedures, and non-genital (male-to-female or female-to-male) surgical procedures, which take place in a stepwise fashion.

Fallon Health monitors and follows the treatment standards published in the most recent version of The Harry Benjamin International Gender Dysphoria Association's Standards of Care for Gender Identity Disorders, Seventh Version, available at the World Professional Association for Transgender Health website: WPATH

Policy

This Policy applies to the following Fallon Health products:

☒ Commercial
☒ Medicare Advantage
☒ MassHealth ACO
☒ NaviCare
☒ PACE

Gender affirmation services require prior authorization. Additionally, services outside of the member's specific plan network require prior authorization. Please note hormone therapy is a pharmacy benefit and coverage of hormone therapy is dependent upon the member's pharmacy benefit.

Medicare Advantage plan members

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare has an NCD for Gender Dysphoria and Gender Reassignment Surgery (140.9). CMS conducted a National Coverage Analysis on the topic of gender reassignment surgery. After examining the medical evidence, CMS determined that no national coverage determination is appropriate at this time for gender reassignment surgery for Medicare beneficiaries with gender dysphoria. To clarify further, the result of this analysis is not national non-coverage rather it is that no national policy will be put in place for the Medicare program. CMS determined that there was not enough high quality evidence to determine whether gender reassignment surgery

improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical interventions can be identified prospectively. In the absence of national policy, the Medicare Administrative Contractors (MACs) will make determinations on whether or not gender reassignment surgery is reasonable and necessary for beneficiaries in Original Medicare. 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 plans (CAG-00446N) (MCD search 01/24/2022).

NaviCare and PACE plan members

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health will follow guidance published by MassHealth. When there is no Medicare or MassHealth guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members.

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.

MassHealth ACO plan members

Fallon Health follows MassHealth Guidelines for Medical Necessity Determination for MassHealth members. Please use the following links to access the MassHealth Medical Necessity Guidelines:
Gender-Affirming Surgery
Hair Removal

Fallon Health Clinical Coverage Criteria

Puberty Suppression Hormone Therapy:
Adolescents with gender non-conformity or diagnosed gender dysphoria often begin hormone therapy at the onset of puberty. Given puberty suppression is reversible it allows an adolescent the ability to fully explore their gender non-conformity and make informed decisions regarding future treatment. Puberty Suppression hormone treatments are overseen by a Pediatric Endocrinologist and often a Mental Health professional.

In accordance with WPATH the below minimal criteria must be met

1. The adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed);
2. Gender dysphoria emerged or worsened with the onset of puberty;
3. Any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment;
4. The adolescent has given informed consent and, particularly when the adolescent has not reached the age of medical consent, the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process.

Masculinization/Feminization Hormone Therapy:
Hormone therapy designed to masculinize or feminize is done when there is a clear, documented diagnosis of gender dysphoria. This type of hormone therapy results in physical changes to align with the patients desired gender and can carry potential health risks. Changes vary over time from patient to patient though most changes occur over the course of two years.

In accordance with WPATH Standards the below criteria must be met.

Persistent, well-documented gender dysphoria;
Capacity to make a fully informed decision and to consent for treatment;
Age of majority in a given country as such 18. (Medical Directors will review on a case by case basis any clinical exceptions to the age requirement)
If significant medical or mental health concerns are present, they must be reasonably well-controlled.

Surgical Procedures:
Prior Authorization is required and is dependent on coverage under the member's particular plan's benefits. This specific criteria set applies to mastectomies for Female to Male, breast augmentations for Male to Female, and all genital surgeries. Fallon Health may authorize the coverage of transgender surgery procedures when all of the following criteria are met, the request must be supported by the treating provider(s) medical records:

1. The member is 18 years of age or older;
2. Has a definitive diagnosis of persistent Gender Dysphoria that has been made and documented by a qualified licensed mental health professional such as a licensed psychiatrist, psychologist or other licensed physician experienced in the field. Fallon Health reserves the right to request the credentials of this mental health professional.
3. The member has received continuous hormone therapy for 12 months or more under the supervision of a physician with documentation of the member's compliance and the type, frequency, and route of administration;
4. The member has lived as their chosen or reassigned gender full-time for 12 months or more; (3 and 4 may occur concurrently)
5. For gender reassignment surgery, the member's medical and mental health providers document that there are no contraindications to the planned surgery and agree with the plan.

*In accordance with the WPATH SOC, hormone therapy is not required for a Female to Male breast/chest surgery (mastectomy/creation of a male chest).

There are various other procedures commonly associated with Gender Affirmation Surgery. Fallon Health recognizes these procedures bring patients into a wide range of accepted appearances of their desired gender. While Fallon Health maintains a Cosmetic Surgery Clinical Coverage Criteria policy that applies to these procedures consideration will be given to how the procedure will affect gender identity.

Infertility procedures are addressed in Fallon Health's Infertility Clinical Coverage Criteria.

Exclusions

- The reversal of any of the procedures listed above.
- Voice therapy lessons.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

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

Male to Female

Code	Description
19324	Mammaplasty, augmentation; without prosthetic implant
19325	Mammaplasty, augmentation; with prosthetic implant

19350	Nipple/areola reconstruction
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

Female to Male

Code	Description
19303	Mastectomy, simple, complete
19304	Mastectomy, subcutaneous
19316	Mastopexy
53430	Urethroplasty, reconstruction of female urethra
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

References

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Policy history

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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).

02/01/2022 (Added clarifying language related to Medicare Advantage, NaviCare, PACE and MassHealth ACO under policy section; added references).

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.