### MEDICAL POLICY



MEDICAL POLICY DETAILS	
<b>Medical Policy Title</b>	Gender Reassignment/Gender Affirming Surgery and Treatments for Commercial
	and Medicare Advantage Members
Policy Number	7.01.84
Category	Contract Clarification
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<b>Committee Approval</b>	12/08/11, 10/25/12, 10/24/13, 10/23/14, 12/10/15, 12/8/16, 04/26/18, 04/24/19, 04/23/20,
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Product Disclaimer	• If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.
	• If a commercial product (including an Essential Plan product) covers a specific service, medical policy criteria apply to the benefit.
	• If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

#### **POLICY STATEMENT**

- I. Based upon our criteria and assessment of the peer-reviewed literature, hormone therapy (i.e., gonadotropin-releasing hormone agents/pubertal suppressants and cross-sex hormones), with the exception of histrelin acetate (*See Policy Statement XI*) has been shown to be a beneficial and effective intervention for gender dysphoria, and, therefore, is considered **medically appropriate** (*refer to Policy Guideline I*).
- II. Based upon our criteria and assessment of the peer-reviewed literature, bilateral mastectomy, with or without chest reconstruction and with or without pectoral implants, including nipple/areola reconstruction and tattooing, for transitioning individuals who were assigned female at birth, has been shown to be a beneficial and effective intervention for gender dysphoria, and, therefore, is considered **medically appropriate** when **ALL** of the following criteria are met:
  - A. The patient has received a letter of referral from a qualified mental health professional (*refer to Policy Guidelines below*).
  - B. The patient has been diagnosed with persistent gender dysphoria, including <u>all</u> of the following:
    - 1. The patient has a desire to live and be accepted as a member of the identified gender, usually accompanied by the wish to make their body as congruent as possible with the preferred gender through surgery and hormone treatment;
    - 2. The gender dysphoria has been present persistently for at least one year;
    - 3. The condition is not a symptom of another mental disorder or a chromosomal abnormality; and
    - 4. The condition causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.
  - C. The patient has the capacity to make a fully informed decision and to consent to treatment, as well as the ability to comply with all aftercare instructions, including recommended medical, surgical, nursing, and/or psychological care recommended by the patient's providers.
  - D. The patient has reached the age of majority (18 years of age or older), or, if under the age of majority, meets all of the following criteria for early intervention:
    - 1. has consent from both parents/guardians for surgery when applicable;
    - 2. has identified as transgender for at least two years;
    - 3. has been living in the desired gender role for at least one year;

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- 4. has been receiving testosterone treatment for at least one year;
- 5. has received an additional letter of referral from a second qualified mental health professional or physician (*refer to Policy Guidelines below*);
- 6. has compelling reasons impacting their physical and/or psychological well-being, as documented by the patient's mental health/adolescent medicine provider(s); and
- 7. has reasonably good control over any significant medical or mental health concerns that are present.

Note: Hormone treatment history is not required for adults seeking chest reconstruction (including mastectomy) surgery.

- III. Based upon our criteria and assessment of the peer-reviewed literature, breast augmentation/implants, including nipple/areola reconstruction and tattooing, for transitioning individuals who were assigned male at birth has been shown to be a beneficial and effective intervention for gender dysphoria, and, therefore, is considered **medically appropriate**, when **ALL** of the following criteria are met:
  - A. The patient has received a recommendation letter from a qualified mental health professional (*refer to Policy Guidelines below*).
  - B. The patient has been diagnosed with persistent gender dysphoria, including all of the following:
    - 1. The patient has a desire to live and be accepted as a member of the identified gender, usually accompanied by the wish to make their body as congruent as possible with the preferred gender through surgery and hormone treatment;
    - 2. The gender dysphoria has been present persistently for at least one year;
    - 3. The condition is not a symptom of another mental disorder or a chromosomal abnormality; and
    - 4. The condition causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.
  - C. The patient has the capacity to make a fully informed decision and to consent to treatment, as well as the ability to comply with all aftercare instructions, including recommended medical, surgical, nursing, and/or psychological care recommended by the patient's providers.
  - D. The patient has reached the age of majority (18 years of age or older).
  - E. If significant medical or mental health concerns are present, they are reasonably well-controlled.
  - F. The patient has completed a minimum of 24 months of hormone therapy, unless hormone therapy is medically contraindicated, or the patient is otherwise unable to take hormones.
- IV. Based upon our criteria and assessment of peer-reviewed literature, <u>gonadectomy</u> (i.e., hysterectomy and oophorectomy in a birth-assigned female in transition, and orchiectomy in a birth-assigned male in transition) has been shown to be effective and, therefore, is considered **medically appropriate** when **ALL** of the following criteria are met:
  - A. The patient has received two recommendation letters submitted by qualified mental health professionals, or has received one letter from a qualified mental health professional and one letter from a physician (MD, DO), as follows:
    - 1. One letter should be submitted by a mental health professional with whom the individual has had ongoing interactions sufficient to:
      - a. establish a diagnosis of severe and persistent gender dysphoria;
      - b. rule out other diagnoses that might confound the diagnosis of gender dysphoria;
      - c. identify pertinent patient strengths, stressors, and supports; and
      - d. diagnose and address other relevant psychological disorders that might otherwise interfere with the individual's success; and
    - 2. The second mental health professional or physician providing a recommendation is not required to have an ongoing relationship with the individual, but should have significant experience assessing individuals with gender dysphoria and/or evaluating decision-making capacity in individuals prior to major medical procedures and surgeries (*refer to Policy Guidelines below for additional information*).

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- B. The patient has an established and well-documented history of gender dysphoria, diagnosed by a mental health professional and present for a minimum of one year, including <u>all</u> of the following:
  - 1. distress with their assigned gender and with the physical attributes or secondary sex characteristics of their assigned gender;
  - 2. a desire to do away with current secondary sexual characteristics and/or a desire to change their secondary sex characteristics in order to bring them more in line with their internally experienced gender;
  - 3. noticeable gender distress that causes clinically significant impairment in social, occupational, or other areas of functioning; and
  - 4. distress and associated symptoms that are not better-explained by another psychological disorder or by a chromosomal abnormality or intersex condition.
- C. The patient has the capacity to make a fully informed decision and to consent to treatment.
- D. The patient has reached the age of majority (18 years or older).
- E. If significant medical or mental health conditions are present, the patient has appropriate medical and psychiatric providers in place, symptoms are under reasonably good control, and a plan for continued follow-up of these conditions is in place.
- F. The patient has a history of 12 months of continuous hormone therapy consistent with the patient's gender goals, unless hormone therapy is medically contraindicated, or the patient has a history of a severe medical or psychiatric adverse effect from hormonal treatments.
- V. Based upon our criteria and assessment of the peer-reviewed literature, genital reconstructive surgery (i.e., vaginectomy, urethroplasty, metoidioplasty, phalloplasty (including hair removal procedures to treat tissue donor sites), scrotoplasty, and placement of a testicular prosthesis and erectile prosthesis in individuals assigned female at birth, in transition; penectomy, vaginoplasty (including hair removal procedures to treat tissue donor sites), labiaplasty, and clitoroplasty in individuals assigned male at birth, in transition) has been medically proven to be effective and, therefore, is considered **medically appropriate** when **ALL** of the following criteria are met:
  - A. The patient has received two recommendation letters submitted by qualified mental health professionals or has received one letter from a qualified mental health professional and one letter from a physician (MD, DO), as follows:
    - 1. One letter should be submitted by a mental health professional with whom the individual has had ongoing interactions sufficient to:
      - a. establish a diagnosis of severe and persistent gender dysphoria;
      - b. rule out other diagnoses that might confound the diagnosis of gender dysphoria;
      - c. identify pertinent patient strengths, stressors, and supports; and
      - d. diagnose and address other relevant psychological disorders that might otherwise interfere with the individual's success; and
    - 2. The second mental health professional or physician providing a recommendation is not required to have an ongoing relationship with the individual, but should have significant experience assessing individuals with gender dysphoria and/or evaluating decision-making capacity in individuals prior to major medical procedures and surgeries (*refer to Policy Guidelines below for additional information*).
  - B. The patient has an established and well-documented history of gender dysphoria, diagnosed by a mental health professional, including all the following characteristics:
    - 1. distress with their assigned gender and with the physical attributes or secondary sex characteristics of their assigned gender;
    - 2. a desire to do away with current secondary sexual characteristics and/or a desire to change their secondary sex characteristics in order to bring them more in line with their internally experienced gender;
    - 3. noticeable gender distress that causes clinically significant impairment in social, occupational, or other areas of functioning; and
    - 4. distress and associated symptoms are not better explained by another psychological disorder or by a chromosomal abnormality or intersex condition.

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- C. The patient has the capacity to make a fully informed decision and to consent to treatment (*refer to Policy Guidelines*).
- D. The patient has reached the age of majority (age 18 years and older).
- E. If significant medical or mental health conditions are present, the patient has appropriate medical and psychiatric providers in place, symptoms are under reasonably good control, and a plan for continued follow-up of these conditions is in place.
- F. The patient has a history of 12 months of continuous hormone therapy consistent with the patient's gender goals, unless hormone therapy is medically contraindicated, or the patient has a history of a severe medical or psychiatric adverse effect from hormonal treatments.
- VI. Based upon our assessment of the peer-reviewed literature, feminizing or masculinizing voice therapy and/or voice training services have been medically proven to be effective and, therefore, are considered **medically appropriate** for the treatment of gender dysphoria, when performed by a state-licensed speech-language pathologist or speech therapist. (*Refer to Corporate Medical Policy # 8.01.13 Speech Pathology and Therapy*).
- VII. Based upon our assessment of the peer-reviewed literature, voice modification surgery has been medically proven to be effective and, therefore, will be reviewed on a case-by-case basis by a Health Plan medical director with experience in treating patients with mental health conditions, and may be considered **medically appropriate** when **ALL** of the following criteria are met:
  - A. The patient has received a recommendation letter from a qualified mental health professional (refer to Policy Guidelines below).
  - B. The patient has been diagnosed with persistent gender dysphoria, including all of the following:
    - 1. The patient has a desire to live and be accepted as a member of the identified gender, usually accompanied by the wish to make their body as congruent as possible with the preferred gender through surgery and hormone treatment;
    - 2. The gender dysphoria has been present persistently for at least one year;
    - 3. The condition is not a symptom of another mental disorder or a chromosomal abnormality; and
    - 4. The condition causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.
  - C. The patient has the capacity to make a fully informed decision and to consent to treatment, as well as the ability to comply with all aftercare instructions, including recommended medical, surgical, nursing, and/or psychological care recommended by the individual's providers.
  - D. The patient has reached the age of majority (18 years of age or older).
  - E. If significant medical or mental health concerns are present, they are reasonably well-controlled.
  - F. The patient has completed a minimum of 24 months of masculinizing hormone therapy prior to seeking voice masculinization surgery, unless hormone therapy is medically contraindicated, or the patient is otherwise unable to take hormones.
  - G. The patient has completed a trial of speech therapy and/or voice training services prior to seeking voice modification surgery.
  - H. The treatment plan includes post-operative voice training.
  - I. The treating physician has determined that the requested procedure is medically necessary to treat the patient's gender dysphoria.
- VIII. Based upon our assessment of the peer-reviewed literature, other surgeries and procedures for the treatment of gender dysphoria, including, but not limited to, facial feminization or masculinization surgery (i.e., blepharoplasty, liposuction of the face or neck, rhinoplasty, facial bone reconstruction, jaw shortening/sculpturing, chin augmentation, cheek augmentation, tracheal shaving/thyroid chondroplasty, hair reconstruction as part of forehead feminization surgery, and electrolysis or laser hair removal of face and/or neck hair (refer to *Policy Guideline IX*)), liposuction, lipofilling, and gluteal augmentation, will be reviewed on a case-by-case basis by a Health Plan medical director with experience in treating patients with mental health conditions and may be considered **medically appropriate** when **ALL** of the following criteria are met:

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- A. The patient has received a recommendation letter from a qualified mental health professional (*refer to Policy Guidelines below*).
- B. The patient has been diagnosed with persistent gender dysphoria, including all of the following:
  - 1. The patient has a desire to live and be accepted as a member of their identified gender, usually accompanied by the wish to make their body as congruent as possible with the preferred gender through surgery and hormone treatment;
  - 2. The gender dysphoria has been present persistently for at least one year;
  - 3. The condition is not a symptom of another mental disorder or a chromosomal abnormality; and
  - 4. The condition causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- C. The patient has the capacity to make a fully informed decision and to consent to treatment, as well as the ability to comply with all aftercare instructions, including recommended medical, surgical, nursing, and/or psychological care recommended by the individual's providers.
- D. The patient has reached the age of majority (18 years of age or older).
- E. If significant medical or mental health concerns are present, they are reasonably well controlled.
- F. The patient has completed a minimum of 24 months of hormone therapy, unless hormone therapy is medically contraindicated, or the patient has a history of a severe medical or psychiatric adverse effect from hormonal treatments.
- G. The treating physician has determined that the requested procedure is medically necessary to treat the patient's gender dysphoria.
- IX. Based upon our criteria and assessment of the peer-reviewed literature, services to reverse gender reassignment/gender affirming surgery are considered **not medically necessary**, except in the case of a serious medical barrier to completing gender-affirming surgery or the development of a serious medical condition necessitating reversal.
- X. Surgery to revise the appearance or function of previous gender-affirming surgery due to dissatisfaction with the outcome will be reviewed on a case-by-case basis by a Health Plan medical director with experience in treating patients with mental health conditions, when the treating physician has determined that the requested procedure is medically necessary to treat the patient's gender dysphoria. Revision surgery will be considered **medically necessary** when there is significant discomfort, functional impairment, or medical complications resulting from the initial surgery.
- XI. Based upon our criteria and the lack of peer-reviewed literature, the histrelin acetate subcutaneous implant is considered **investigational** for suppression of puberty in transgender individuals.

Refer to Corporate Medical Policy #3.01.15 Behavioral Health Treatment for Gender Dysphoria.

Refer to Corporate Medical Policy #4.01.05 Assisted Reproductive Technologies for Infertility.

Refer to Corporate Medical Policy ##7.01.55 Blepharoplasty with or without Levator Muscle Advancement.

Refer to Corporate Medical Policy # 7.01.11 Cosmetic and Reconstructive Procedures.

*Refer to Corporate Medical Policy # 7.01.53 Abdominoplasty and Panniculectomy.* 

Refer to Corporate Medical Policy #8.01.13 Speech Pathology/Therapy for voice therapy requests.

Refer to Corporate Medical Policy # 10.01.01 Breast Reconstruction Surgery for nipple/areola reconstruction and tattooing.

Refer to Corporate Medical Policy #11.01.26 Medical Services for Transgender Individuals.

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#### **POLICY GUIDELINES**

I. Coverage of oral or self-administered hormone therapy and hormone inhibitor agents is dependent upon the prescription drug benefits of the member's subscriber contract.

- II. Two state-licensed health care professionals must recommend gender reassignment/gender-affirming genital surgery. One professional must be a qualified mental health provider with whom the patient has an established and ongoing professional relationship. The recommendation must specify the provider's competency in transgender care. The second professional may be a psychiatrist, psychologist, licensed clinical social worker, or physician. The providers must establish that gender-affirming surgery is medically necessary to treat the patient's gender dysphoria and that the patient demonstrates full capacity for informed decision making, consent, and compliance. Capacity includes: an understanding of common risks and complications, short- and long-term outcomes (e.g., effects on sexual function/fertility), options available to address fertility or sexual function concerns, and the expected benefits associated with surgery. Further, informed decision making requires that an individual have realistic expectations from surgical treatment and have the ability to plan for and comply with the recommendations of their providers with regard to surgical, medical, nursing, and psychological care following surgery. Based on a comprehensive assessment of the patient's capacity, the mental health provider should attest to the patient's readiness and appropriateness for the surgery being proposed. (Note: If breast/chest surgery or surgery/procedures to address secondary sex characteristics is/are the only procedure(s) being requested in an adult patient, only one mental health provider recommendation is required; however, this recommendation must come from a mental health provider with whom the individual has an established and ongoing professional relationship, and must include a comprehensive assessment of capacity as outlined above.)
- III. An established and ongoing professional relationship is defined as one in which the provider has had ongoing interactions with the patient sufficient to:
  - A. establish a diagnosis of severe and persistent gender dysphoria;
  - B. rule out other diagnoses that might confound the diagnosis of gender dysphoria;
  - C. identify pertinent patient strengths, stressors, and supports; and
  - D. diagnose and address other relevant psychological disorders that might otherwise interfere with the patient's success.
- IV. For individuals with considerable comorbidities or a history of severe symptoms (due to gender dysphoria, minority stress, or other mental conditions), the provider may provide a recommendation for surgery that includes an appropriate treatment plan for addressing and mitigating these symptoms, stressors, or conditions in the pre-and post-surgical periods.
- V. The patient should have sufficient medical, nursing, and emotional support to adequately address needs in the post-operative, recovery, and healing period. (For individuals having surgery remotely but returning home less than two weeks following surgery, the patient must have medical providers in place who will be following the surgery both in the home area and/or in the city where surgery is to be performed.)
- VI. In-home medical/nursing supports are required in the post-operative period, which may include family members, partners, or friends; or, if no family member, partner, or friend is involved, sufficient alternative options for aftercare support (e.g., visiting nurse, etc.) must be identified.
- VII. If the patient is to have surgery in an out-of-town location and return home, the medical and/or surgical providers who will be responsible for the patient's post-surgical care and who will manage any complications should be identified. (Note: A plan to use urgent care/emergency care is not sufficient.)
- VIII. The Health Plan recognizes that treatments and services to address gender dysphoria remain limited. In some areas, especially those areas remote from larger cities, finding surgical and/or mental health providers may be more challenging. For this reason, many individuals elect to have gender affirming treatments and surgeries in remote locations where more comprehensive services and providers with more experience are available. Individuals are encouraged to utilize these centers and facilities for mental health assessments and supports, in addition to surgical

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treatments. Assessments performed by mental health providers at such facilities will be considered carefully. Further, for individuals experiencing difficulties in locating medical, surgical, or mental health providers for treatment of gender dysphoria and/or for support in pursuing gender-affirming treatment, care management services are available free of charge to members through the Health Plan.

IX. Up to 12 sessions of electrolysis or laser hair removal of the face or neck, or of tissue donor sites prior to phalloplasty or vaginoplasty, are considered **medically appropriate** when performed by a state-licensed professional.

#### **DESCRIPTION**

Gender dysphoria, previously known as gender identity disorder (GID), involves a conflict between an individual's gender as perceived (or assigned) and the individual's own internal experience of their gender. Gender dysphoria, as defined in the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), requires that there be a noticeable difference between an individual's assigned gender and their gender identity, which is present for at least six months and which causes clinically significant impairments in the individual's functioning. Gender dysphoria is not equivalent to gender non-conformity, gender expansiveness, or to the term "transgender." Not all transgender individuals experience gender dysphoria, although many do. Gender dysphoria occurs when the individual feels significant discomfort and a desire to change their gender socially and/or physically. In addition, the individual may feel an intense need to transform their gender and/or may have severe difficulty coping with their conditions. People with gender dysphoria may report a feeling of being born the wrong sex. The causes of gender dysphoria and the developmental factors associated with it are not well-understood. Gender-affirming surgical options to assist an individual to transition to a gender consistent with their identity are now well-established and are effective interventions for the treatment of extreme cases of gender dysphoria for those with sufficient preparation and readiness. Gender reassignment therapy is an umbrella term for all procedures regarding gender reassignment and usually consists of a real-life experience in the desired role, hormone replacement therapy to modify secondary sex characteristics, and gender reassignment surgery to alter primary sex characteristics. This therapeutic approach is sometimes labeled triadic therapy, due to the three key elements involved. Individuals with gender dysphoria require psychological treatment long before reassignment therapy begins and usually continue it permanently after the "transition."

Gender reassignment or gender-affirming surgery is a permanent change to a patient's sexual identity and is not reversible. Therefore, a careful and accurate diagnosis is essential for treatment and can be made only as part of a long-term diagnostic process involving a multi-disciplinary specialty approach that includes an extensive case history; gynecological, endocrinological, and urological examination; and a clinical psychiatric/psychological examination. The goal of gender reassignment or gender-affirming surgery is to align the individual's physical appearance and genital anatomy with their gender identity. Gender reassignment or gender-affirming surgery involves a series of procedures that will make male genitals into female genitals or vice versa (e.g., penectomy, orchiectomy, vaginoplasty, hysterectomy, salpingo-oophorectomy, colpectomy, metoidioplasty, phalloplasty) and will reshape a male body into a body with female appearances or vice versa (e.g., mastectomy, facial feminization surgery, nose/chin implants, jaw sculpturing, tracheal shaving, voice modification surgery, hair removal).

Gender dysphoria is a DSM-5-recognized medical condition and a pre-requisite for gender-affirming surgery coverage. Many individuals seek mental health treatment to address gender dysphoria; however, gender-affirming treatment (including surgery) is recognized as effective in treating gender dysphoria. At the same time, gender transition is a stressful experience for most individuals, and this is especially true in the post-operative period.

#### **RATIONALE**

A diagnosis of gender dysphoria is based on the DSM criteria. The DSM-5 provides for one overarching diagnosis of gender dysphoria, with separate specific criteria for children and for adolescents and adults. In adolescents and adults, gender dysphoria diagnosis involves a difference between one's experienced/expressed gender and assigned gender, and significant distress or problems functioning. It lasts at least six months and is shown by at least two of the following:

I. a marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics;

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II. a strong desire to be rid of one's primary and/or secondary sex characteristics;

III. a strong desire for the primary and/or secondary sex characteristics of another gender;

IV. a strong desire to be of another gender;

V. a strong desire to be treated as another gender; and/or

VI. a strong conviction that one has the typical feelings and reactions of another gender.

Psychological techniques that attempt to treat gender dysphoria via attempts to alter the individual's gender identity or expression to one considered appropriate for the person's assigned sex (conversion treatments) have typically been shown to be ineffective. Most providers agree (and research supports) that the most effective and reasonable course of treatment for individuals with gender dysphoria is gender transition, which, for many, will eventually involve gender-affirming surgery of some type; and, for individuals with persistent gender dysphoria, this option is considered medically necessary. This conclusion is supported by evidence that individuals with untreated gender dysphoria have higher rates of depression, anxiety, substance abuse problems, and suicide.

The literature related to gender reassignment surgery has numerous limitations (e.g., lack of controlled studies, evidence not collected prospectively, large number of patients lost to follow-up). However, the majority of patients in case series and cohort studies experienced successful outcomes in terms of subjective self-assessment of their surgery, as well as low rates of regret.

The World Professional Association for Transgender Health or WPATH (formerly known as the Harry Benjamin International Gender Dysphoria Association) Standards of Care (SOC) for the Health of Transsexual, Transgender, and Gender Nonconforming People, and the DSM-5 criteria, are widely accepted as definitive documents in the area of gender dysphoria treatment. Per WPATH, the rationale for a preoperative, 12-month experience of living in an identitycongruent gender role is as follows: The criterion noted for some types of genital surgeries—i.e., that patients engage in 12 continuous months of living in a gender role that is congruent with their gender identity—is based on expert clinical consensus that this experience provides ample opportunity for patients to experience and socially adjust in their desired gender role, before undergoing irreversible surgery. The social aspects of changing one's gender role are usually challenging—often more so than the physical aspects. Changing gender role can have profound personal and social consequences, and the decision to do so should include an awareness of what the familial, interpersonal, educational, vocational, economic, and legal challenges are likely to be, so that people can function successfully in their gender role. Support from a qualified mental health professional and from peers can be invaluable in ensuring a successful gender role adaptation (Bockting, 2008). The duration of 12 months allows for a range of different life experiences and events that may occur throughout the year (e.g., family events, holidays, vacations, season-specific work or school experiences). During this time, patients should present consistently, on a day-to-day basis and across all settings of life, in their desired gender role. This includes coming out to partners, family, friends, and community members (e.g., at school, work, other settings).

The criteria in the SOC are supported by evidence-based, peer-reviewed journal publications. Several studies have shown that extensive long-term trials of hormonal therapy and real-life experience living as the other gender, as well as social support and acceptance by peer and family groups, greatly improve psychological outcomes in patients undergoing gender reassignment surgery (Eldh, 1997; Landen, 1998). A study reported by Monstrey and colleagues (2001) described the importance of close cooperation between the many medical and behavioral specialties required for proper treatment of patients with gender dysphoria who wish to undergo gender reassignment surgery.

One study of 188 patients undergoing gender reassignment surgery found that dissatisfaction with surgery was highly associated with sexual preference, psychological co-morbidity, and poor pre-operative body image and satisfaction (Smith, 2005). Other researchers (M.I. Lobato et al. (2006), J.C. Goodard et al. (2007)) reported good overall cosmetic results and high patient satisfaction in studies related to the early and long-term follow-up of patients undergoing gender reassignment surgery (n=19 and n=233, respectively).

Gender-affirming surgeries present significant medical and psychological risks and involve long-term, often-irreversible results. Further, gender transition is a highly stressful process for most, in many cases because of the stress placed upon transgender individuals by others within their families, communities, work sites, and society. Many individuals who

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experience gender dysphoria do benefit from psychological support, if only to allow them a safe environment in which to explore their own minority-stress experience, and to process and plan for a transition that is individualized, safe, and affirming for them. In most cases, a step-wise approach to gender-affirming transition interventions is prudent. In adults for whom secondary sex characteristics are established, a careful approach to transition and to gender-affirming treatment allows for accurate diagnosis and long-term treatment planning by a multi-disciplinary team that includes behavioral, medical, and surgical specialists. Both short-term and long-term outcomes are improved in individuals whose transitions have proceeded according to careful plan and for whom multi-disciplinary services and supports have been put in place. As with the treatment of any condition for which mental health symptoms are present, a thorough psychological analysis by a qualified practitioner is of fundamental importance. Once a diagnosis of gender dysphoria has been established, a trial of hormone therapy is an evidenced-based and helpful treatment intervention that is generally prescribed prior to embarking upon more invasive surgical treatment options. In addition, careful consideration of realistic, safe, and acceptable "real-life" or social transition experiences may be of help for many individuals who are planning for or receiving gender-affirming treatment.

#### Physical effects of hormone therapy

Per WPATH, feminizing/masculinizing hormone therapy will induce physical changes that are more congruent with a patient's gender identity. In individuals assigned female at birth, the following physical changes are expected to occur with masculinizing hormone therapy: deepened voice, clitoral enlargement (variable), growth in facial and body hair, cessation of menses, atrophy of breast tissue, increased libido, and decreased percentage of body fat compared to muscle mass. In patients assigned male at birth, the following physical changes are expected to occur with feminizing hormone therapy: breast growth (variable), decreased libido and erections, decreased testicular size, and increased percentage of body fat compared to muscle mass. Most physical changes, whether feminizing or masculinizing, occur over the course of two years. The amount of physical change and the exact timeline of effects can be highly variable.

#### Facial feminization/masculinization surgery

Raffani et al. (2016) reported outcomes from a retrospective study of 33 male-to-female patients who underwent facial feminization surgery. Patients were evaluated for quality of life outcomes using a nine-question survey at 24 months post-operative. All patient responded positively to the survey. Aesthetic results, assessed objectively by two independent surgeons, were rated "very much improved" (29 of 33 patients, 87.8 percent) or "significantly improved" (four of 33 patients, 12.1 percent).

In a case series of 200 consecutive male-to-female patients in Spain who underwent feminization rhinoplasties, in combination with lip-lift techniques, forehead reconstruction, and other procedures, most patients considered their nose to appear more feminine after the surgery, and the degree of satisfaction after the rhinoplasty was 4 of 5 points (much better) on the Nose Feminization Scale after a mean follow-up of 32 months (Bellinga et al., 2017).

A prospective, international, multi-center, cohort study (Morrison et al., 2019) of 66 male-to-female patients with gender dysphoria who underwent facial feminization surgery reported quality of life outcomes at least six months following surgery. Pre-operative and post-operative measurements included facial feminization outcome scores using a nine-question, validated tool adapted for use in the transgender population, and self-perceived masculinity and femininity. Gender appearance and general aesthetics were rated by reviewers and compared to cisgender women controls. A total of 279 procedures were performed on 66 patients, for an average of 4.2 procedures per patient. Facial feminization outcome scores improved significantly after surgery (pre-operative median score, 47.2; one-week to one-month post-operative median score, 75.0; and six month post-operative median score, 80.6). Likewise, patient satisfaction as measured by a five-point Likert scale remained stable post-operatively (median, 3.0 at both one-week to one-month and six months post-operatively). On a scale of 1 to 5, with 1 being most feminine and 5 being most masculine, mean gender appearance score was 1.83 for the facial feminization surgery cohort (n = 10) and 1.25 for a cohort of five cisgender women controls. Aesthetic outcomes on a scale of 1 to 10 were 6.09 for the facial feminization surgery cohort and 7.63 for cisgender controls. Complications included hypertrophic scarring (five patients), orbital emphysema and hematoma (four patients), nasal hematoma and\_epistaxis (two patients), alopecia (one patient), and iatrogenic jowling or "witches chin" deformity after bony manipulation (two patients).

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While data is limited to case series and cohort studies, the evidence supports that patients who undergo rhinoplasty or facial feminization surgery have a meaningful improvement in net health outcome and are generally pleased with the results.

#### Voice therapy

Voice and communication therapy may help to alleviate gender dysphoria. Specialists include speech-language pathologists, speech therapists, and speech-voice clinicians. The average speaking fundamental frequency (SFF) (F0) of adult males is approximately 107–120 Hz, while the average F0 of females is 189–224 Hz (Hancock and Garabedian, 2013). An F0 greater than 160 Hz-180 Hz is often considered the criterion for a transgender woman's voice to be perceived as female (Kim, 2020; Pasternak and Francis, 2019). Shifting pitch upwards is only one variable in female voice perception. Other variables include resonance, breathiness, intonation, voice quality, pragmatics, and non-verbal communication. Feminizing hormone therapy does not have an impact on the adult transfeminine voice.

In a prospective study of five male-to-female transgender (MTF TG) clients, Gelfer and Tice (2013) examined the outcomes from 16 one-hour sessions of voice therapy immediately after the eight-week treatment course and again 15 months later. Outcomes were based on the evaluation of listeners who provided masculine and feminine ratings. Prior to therapy, 1.9% of the subjects were perceived as female, 50.8% of the time in the immediate post-test, and 33.1% of the time in the long-term post-test. The authors concluded that eight weeks of voice therapy could result in vocal changes in MTF TG individuals that persist, at least partially, for up to 15 months.

#### Voice modification surgery

Surgical techniques for voice feminization include: (1) increasing vocal fold tension through cricothyroid approximation (CTA) or anterior commissure advancement (ACA); (2) shortening the length of the vocal folds through anterior glottal web formation (Wendler glottoplasty); or (3) reducing vocal fold mass through laser-assisted voice adjustment (LAVA) or laser reduction glottoplasty (LRG) (Agana et al., 2019; Kim, 2020). Complications shared among the surgical techniques included dysphonia, reduced maximum phonation time, decreased pitch range, reduced loudness, or the risk of no change in pitch or less than the desired change in pitch (Pasternak and Francis, 2019; Song and Jiang, 2017).

Meister et al. (2017) reported a study of 21 patients in Germany who underwent Wendler's glottoplasty, modified by Hagen, in which the new anterior commissure is stabilized by sutures, and voice rest for several weeks is induced by botox injections into the vocal muscles bilaterally. Four of the patients had previous CTA without satisfaction. The post-operative assessment period ranged from three months to 78 months. Post-procedure, one patient underwent revision surgery and another patient's original anterior commissure persisted, resulting in no elevation of vocal pitch. Comparison of pre- and post- F0 showed elevation in vocal pitch for all other patients. Three patients showed a small elevation of the vocal pitch (less than 20 Hz), four patients showed a moderate elevation (20–39 Hz), five patients showed a strong elevation (40–59 Hz), and eight patients showed a very strong elevation of the fundamental frequency (60 Hz or greater). However, Voice Handicap Index scores showed a persistence of voice handicap and were below control group values. Satisfaction with voice, measured using a 10-cm visual analog scale, resulted in a median of 6.1 cm, and femininity of the voice resulted in a median 5.3 cm. The Life Satisfaction Questionnaire (FLZ) showed a significant reduction in general life satisfaction. The deficiencies in the category "friends, acquaintances, relatives" were significant.

#### Histrelin acetate

Histrelin acetate is a gonadotropin-releasing hormone (GnRH) agonist that is FDA-approved for the treatment of children with central precocious puberty and for palliative treatment of advanced prostate cancer. There is insufficient evidence in the literature to support the use of histrelin in the treatment of gender dysphoria or for the suppression of puberty onset in transgender youth.

#### **CODES**

• Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

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- CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY STATEMENTS AND GUIDELINES CAREFULLY.
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.
- *Code Key: Experimental/Investigational = (E/I).*

#### **CPT Codes**

Code	Description
11920	Tattooing, intradermal introduction of insoluble opaque pigments to correct color
	defects of skin, including micropigmentation; 6.0 sq cm or less
11921	6.1 to 20.0 sq cm
11922	each additional 20.0 sq cm, or part thereof (List separately in addition to code
	for primary procedure)
11950	Subcutaneous injection of filling material (e.g., collagen); 1 cc or less
11951	Subcutaneous injection of filling material (e.g., collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (e.g., collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (e.g., collagen); over 10.0 cc
15775	Punch graft for hair transplant; 1 to 15 punch grafts (as part of forehead feminization
	surgery)
15776	Punch graft for hair transplant; more than 15 punch grafts (as part of forehead
	feminization surgery)
15820	Blepharoplasty, lower eyelid;
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid;
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
15824	Rhytidectomy; forehead
15825	Rhytidectomy; neck with platysmal tightening (platysmal flap, P-flap)
15826	Rhytidectomy; glabellar frown lines
15828	Rhytidectomy; cheek, chin, and neck
15876	Suction assisted lipectomy; head and neck
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity
17380	Electrolysis epilation, each 30 minutes
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue (can be used for
	laser hair removal)
19303	Mastectomy, simple, complete
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19350	Nipple/areola reconstruction
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)

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Code	Description
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes
	obtaining autografts)
21125	Augmentation, mandibular body or angle; prosthetic material
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional
	(includes obtaining autograft)
21137	Reduction forehead; contouring only
21138	Reduction forehead; contouring and application of prosthetic material or bone graft
	(includes obtaining autograft)
21139	Reduction forehead; contouring and setback of anterior frontal sinus wall
21193	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without
	bone graft
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21209	Osteoplasty, facial bones; reduction
21270	Malar augmentation, prosthetic material
21899	Unlisted procedure, neck or thorax (can be used to report voice surgery)
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
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
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
31574	Laryngoscopy, flexible; with injection(s) for augmentation (eg, percutaneous,
	transoral), unilateral
31591	Laryngoplasty, medialization, unilateral
31599	Unlisted procedure, larynx (can be used for reduction of thyroid cartilage)
40500	Vermilionectomy (lip shave), with mucosal advancement
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	second stage
53430	Urethroplasty, reconstruction of female urethra
54125	Amputation penis, complete
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
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis,
5-5	scrotal or inguinal approach

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Code	Description
54660	Insertion testicular prosthesis (separate procedure)
54690	Laparoscopy, surgical, orchiectomy
55175	Scrotoplasty; simple
55180	Scrotoplasty, complicated
55970	Intersex surgery, male to female
55980	Intersex surgery, female to male
56625	Vulvectomy simple; complete
56800	Plastic repair introitus
56805	Clitoroplasty for intersex state
57110	Vaginectomy, complete removal of vaginal wall;
57111	with removal of paravaginal tissue (radical vaginectomy)
57291	Construction of artificial vagina; without graft
57292	with graft
57335	Vaginoplasty for intersex state
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	for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
58275	with total or partial vaginectomy;
58290	for uterus greater than 250 g;
58291	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	for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58543	for uterus greater than 250 g;
58544	for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58550-58554	Laparoscopy, surgical, with vaginal hysterectomy, with or without removal of ovaries
	and/or tubes (code range)
58570-58573	Laparoscopy, surgical, total hysterectomy with or without removal of ovaries and/or
	tubes (code range)
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total
	oophorectomy and/or salpingectomy)
58700	Salpingectomy, complete or partial, unilateral or bilateral (separate procedure)
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral (separate
	procedure)
58940	Oophorectomy, partial or total, unilateral or bilateral;
58953	Bilateral salpingo-oophorectomy with omentectomy, total abdominal hysterectomy
	and radical dissection for debulking;
58999	Unlisted procedure, female genital system (nonobstetrical)

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Code	Description
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
92508	Treatment of speech, language, voice, communication, and/or auditory processing disorder; group, 2 or more individuals

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#### **HCPC Codes**

Code	Description
J1950	Injection, leuprolide acetate (for depot suspension), per 3.75 mg
J3316	Injection, triptorelin, extended-release, 3.75 mg
J9225 (E/I)	Histrelin implant (Vantas), 50 mg
J9226 (E/I)	Histrelin implant (Supprelin LA), 50 mg

#### **ICD10 Codes**

Code	Description
F64.0-F64.9	Gender identity disorders (code range)
Z87.890	Personal history of sex reassignment

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\*Key Article

#### **KEY WORDS**

Gender dysphoria, Gender identity disorder, GID, gender reassignment surgery, genital correction surgery, genital reassignment surgery, genital reconstruction, gender realignment surgery, gender confirmation surgery, intersex, transsexualism, transsexual surgery.

#### CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Gender Dysphoria and Gender Reassignment Surgery. Please refer to the following NCD website for Medicare Members. https://www.cms.gov/medicare-coverage-database/details/ncd-

details.aspx?NCDId=368&ncdver=1&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&s=41&KeyWord=gender+dysphoria&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAACAAAAA&

A final decision memo was issued in August 2016 by CMS for Gender Dysphoria and Gender Reassignment Surgery. The memo is located at: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=282&CoverageSelection=National&KeyWord=gender+reassignment+surgery&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAACAAAAA%3d%3d&

Per CMS Manual, Pub 100-03, Medicare National Coverage Determinations, Transmittal 194, change request 9981 was issued 03/03/17 with implementation 04/04/2017. Effective for claims with dates of service on or after August 30, 2016, coverage determinations for gender reassignment surgery, under section 1862(a)(1)(A) of the Social Security Act and any other relevant statutory requirements, will continue to be made by the local Medicare Administrative. Contractors (MACs) on a case-by-case basis. This transmittal is located at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R194NCD.pdf