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| <b>Medical Benefit</b>  |     | <b>Effective Date:</b> 05/01/15          | <b>Next Review Date:</b> 03/18 |
| <b>Preauthorization</b> | Yes | <b>Review Dates:</b> 03/15, 03/16, 03/17 |                                |

***Preauthorization is required.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

### **Description**

The term Gender Dysphoria describes a severe level of discomfort or distress an individual may experience when the gender that is assigned at birth is in conflict with the gender that they most closely associate with. Expression of gender dysphoria may manifest as a strong belief that one's feelings are typical of the desired gender, as well as a need to be rid of one's sex characteristics (and acquire the sex characteristics of the desired gender) and a desire to be treated as a person of the other gender. Gender reassignment surgery is the irreversible component of a treatment regime which also includes psychotherapy and hormone therapy. A variety of surgical procedures may be directed at altering an individual's physical appearance and function to align with that of the desired gender (i.e., male to female or female to male). The permanency of surgical intervention necessitates that medical and psychological evaluations, behavioral trials, and medical treatment precede this final step.

### **Policy**

Gender reassignment surgery may be considered **medically necessary** when *all* of the following criteria are met:

1. The individual is 18 years of age or older or 21 years of age or older if the surgery will result in sterilization; and
2. The individual has capacity to make fully informed decisions and consent for treatment; and
3. The individual has a documented diagnosis of gender dysphoria and has been an active participant in a recognized gender dysphoria treatment program for at least two years duration, including the following:
  - a. The intense and persistent desire to live and be accepted as a member of the desired gender including the desire to align physical function and appearance with that of the desired gender; and
  - b. The disorder causes clinically significant distress or impairment in social, occupational, or other important areas of functioning; and
4. The individual has undergone a minimum of 12 months of continuous hormonal therapy when recommended by a mental health professional and provided under the supervision of a physician, unless medically contraindicated or the individual is otherwise unable or unwilling to take hormones; and

5. Any significant medical or mental health diagnosis or substance use disorder that is present including severe psychiatric disorders and impaired reality testing (e.g., psychotic episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder) which may require psychotropic medications and/or psychotherapy, must be reasonably well controlled before surgery is contemplated; and
6. Two referrals from qualified mental health professionals who have independently assessed the individual are documented. The first referral must be from the individual's psychiatrist or psychologist, and the second referral should be from a person who has only had an evaluative role with the individual. (see Policy Guidelines) and
7. Documentation (including the start date) that the individual has maintained participation in regular psychotherapy sessions while completing a minimum of 12 months of successful continuous full time living in the social role congruent with their desired gender which encompasses all life experiences expected to occur as part of family, work and social relationships. (see Policy Guidelines)

**Medically necessary** male to female sex reassignment surgical procedures include the following:

- Orchiectomy
- Penectomy
- Vaginoplasty
- Clitoroplasty
- Labiaplasty

**Medically necessary** female to male sex reassignment surgical procedures include the following:

- Hysterectomy
- Salpingo-oophorectomy
- Vaginectomy/colpectomy
- Initial mastectomy/breast reduction
- Urethroplasty
- Metoidioplasty
- Phalloplasty
- Scrotoplasty
- Placement of testicular prosthesis

Gender reassignment surgery is considered **not medically necessary** when one or more of the criteria above have not been met.

When intended to improve the gender specific appearance of an individual, the following surgical procedures are considered **not medically necessary** (this is not an all-inclusive list):

- Liposuction/body contouring/lipofilling
- Rhinoplasty
- Facial bone reconstruction for feminization or masculinization;
- Jaw/mandibular reduction/augmentation/sculpturing
- Chin augmentation/reshaping

- Cheek, chin and nose implants
- Tracheal shaving/reduction thyroid chondroplasty
- Face lift (e.g., face, brow, etc.)
- Blepharoplasty/brow reduction/brow lift
- Voice modification surgery
- Hair removal or electrolysis/hairplasty
- Breast augmentation/implants
- Skin resurfacing
- Lip reduction/enhancement
- Procedures (prior to gender reassignment surgery) aimed at preserving fertility (e.g., procurement, cryopreservation, storage)
- Abdominoplasty
- Implants for body contouring (e.g., calf, pectoral)
- Collagen injections

### Policy Guidelines

The medical necessity criteria in this protocol are based upon the Standards of Care (SOC) for the Health of Transsexual, Transgender, and Gender Nonconforming People, Seventh Version, published by the World Professional Association for Transgender Health (WPATH) (2011) and the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. DSM-5. American Psychiatric Association. Washington, DC. May 2013. The World Professional Association for Transgender Health (WPATH) is a nonprofit, interdisciplinary professional and educational organization devoted to transgender health.

The choice of genital surgical procedures performed for gender dysphoria are formed by the gender goal, for example vaginoplasty, clitorolabioplasty, penectomy and orchidectomy are indicated for male-to-female transsexuals, and penile and scrotal reconstruction is indicated for female-to-male transsexuals.

Gender reassignment surgery is often the final step of treatment for severe gender dysphoria, the results are irreversible and the process carries inherent medical and psychological risks. A multidisciplinary approach to treatment including behavioral, medical and surgical specialists provides optimal outcomes.<sup>8, 10</sup> A diagnosis of gender dysphoria facilitates access to healthcare, and appropriate treatment. Diagnosis and counseling through a qualified mental health professional facilitates individualized treatment which may consist of hormone therapy, gender reassignment surgery, a change in gender role or a combination of these therapies to achieve the goals of comfortable gender role expression and improved quality of life while providing appropriate medical services. Hormone therapy may also be recommended to precede gender reassignment surgery and must be undertaken only with medical supervision. Hormone therapy begins the physical gender transition process by altering skin, body hair, muscle mass and strength, voice quality, body fat distribution as well as the size and function of sex organs. Hormone therapy is utilized to modify secondary sex characteristics while gender reassignment surgery permanently alters primary sex characteristics. Gender reassignment surgery is the most deliberated step, and may be considered only after 12 months of real-life experience living in the desired gender role to provide a realistic awareness of the personal, vocational, legal, economic, educational and familial adjustments which accompany a gender role transition. Living in an identity congruent gender role

enables individuals to socially adjust and relate to family, friends and their community in their desired gender role. (**Note:** Verification via communication with individuals who have related to the individual in an identity-congruent gender role, or requesting documentation of a legal name change, may be reasonable in some cases.)

With regard to real-life experience, the 2011 WPATH document specifically states:

The criterion noted above 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. As noted in section VII, 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).

Health professionals should clearly document a patient's experience in the gender role in the medical chart, including the start date of living full time for those who are preparing for genital surgery. In some situations, if needed, health professionals may request verification that this criterion has been fulfilled: They may communicate with individuals who have related to the patient in an identity-congruent gender role, or request documentation of a legal name and/or gender marker change, if applicable.

Once these treatment decisions have been made, established and have been stable for at least 12 months, an individual may be considered for gender reassignment surgery.

For both transmen (female-to-male individuals) and transwomen (male-to-female individuals), additional surgeries have been proposed to enhance the gender appropriate appearance of the individual. Procedures such as breast augmentation, liposuction, Adam's apple reduction, rhinoplasty, facial reconstruction, and others have no medically necessary role in gender identification and are considered not medically necessary.

At least one of the professionals submitting a letter must have a master's degree and be capable of adequately evaluating co-morbid psychiatric conditions. It is also required that mental health professionals treating gender dysphoria have had continuing education in the assessment and treatment of gender dysphoria. Two separate letters, or one letter signed by both (for example, if practicing within the same clinic) are required. For providers working with a multidisciplinary specialty team, a letter may not be necessary, rather, a clearly documented assessment and recommendation can be documented in the patient's chart.

According to the Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, version 7 published by WPATH each recommendation letter for surgery from a qualified mental health provider should include all of the following content:

- The client's general identifying characteristics
- Results of the individual's psychosocial assessment, including any diagnosis
- The duration of the mental health professional's relationship with the client, including the type of evaluation and therapy or counseling to date

- An explanation of the WPATH criteria for surgery that have been met, and a brief description of the clinical rationale for supporting the patient's request for surgery
- A statement that informed consent has been obtained from the patient
- A statement that the mental health professional is available for coordination of care and welcomes a phone call to establish this.

### Background

In May 2013, the American Psychiatric Association published an update to their Diagnostic and Statistical Manual of Mental Disorders, Fifth edition (DSM-5). This update included a significant change to the nomenclature replacing the term "Gender Identity Disorder (GID)" with "Gender Dysphoria". The new criteria for adolescents and adults are as follows:

#### Gender dysphoria in Adolescents and Adults\*

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

\*From: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. DSM-5. American Psychiatric Association. Washington, DC. May 2013. Page 451-459.

Sex reassignment therapy encompasses all the psychological, medical and surgical procedures involved in the transition from one gender presentation to another and may include hormone replacement therapy and various surgical procedures as well as psychological counseling and an extended period of time living completely in the desired gender role.

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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16. World Professional Association for Transgender Health (WPATH) (formerly The Harry Benjamin International Gender Dysphoria Association). Standards of Care for Gender Identity Disorders. 6th version. 2001 Feb.