Guidelines for Medical Necessity Determination for Gender-Affirming Surgery

This edition of the *Guidelines for Medical Necessity Determination* (Guidelines) identifies the clinical information that MassHealth needs to determine medical necessity for gender-affirming surgery (GAS). These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at 130 CMR 415.000: *Acute Inpatient Hospital Services*, 130 CMR 433.000: *Physician Services*, 130 CMR 410.000: *Outpatient Hospital Services*, 130 CMR 450.000: *Administrative and Billing Regulations*, Subchapter 6 of the *Acute Outpatient Hospital Manual*, and Subchapter 6 of the *Physician Manual* for information about coverage, limitations, service conditions, and other prior authorization (PA) requirements.

Providers serving members enrolled in a MassHealth-contracted accountable care partnership plan (ACPP), managed care organization (MCO), One Care organization, Senior Care Options (SCO) plan, or Program of All-inclusive Care for the Elderly (PACE) should refer to the ACPP's, MCO's, One Care organization's, SCO's, or PACE's medical policies, respectively, for covered services.

MassHealth requires PA for GAS. MassHealth reviews requests for PA based on medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

1 SECTION I. GENERAL INFORMATION

Sex and gender are two different constructs. Sex is a biological construct based on chromosomes and anatomy. Gender is a social construct and refers to attitudes, feelings, and behaviors often associated with a person's assigned gender. *Gender identity* refers to an individual's personal sense of self and gender. *Gender dysphoria* refers to clinically significant distress experienced due to discordance between gender identity and assigned gender. Gender dysphoria often intensifies around puberty, when there is a surge in biological sex hormones. Gender dysphoria has replaced *gender-identity disorder* in the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5). Gender dysphoria may manifest in a variety of ways, including desires to be treated consistently with one's gender identity, not assigned gender, and to have sex characteristics aligned with one's gender identity.

Gender-affirming surgery (GAS) refers to one or more reconstruction procedures that may be part of a multidisciplinary treatment plan involving medical, surgical, and behavioral health interventions available for the treatment of gender dysphoria. GAS may be part of therapeutic treatment to better align physical characteristics with gender identity. The evaluation of medical necessity will be individualized to each person and consider this principle and the totality of the person's gendered appearance.

MassHealth considers approval for coverage of GAS on an individual, case-by-case basis, in accordance with 130 CMR 415.000: *Acute Inpatient Hospital Services*, 130 CMR 433.000: *Physician Services*, 130 CMR 410.000: *Outpatient Hospital Services*, and 130 CMR 450.204: *Medical Necessity*.

2 SECTION II. CLINICAL GUIDELINES

A. CLINICAL COVERAGE

MassHealth bases its determination of medical necessity for GAS on clinical data including, but not limited to, indicators that would affect the relative risks and benefits of the procedure, including postoperative recovery.

MASCULINIZING GENDER-AFFIRMING SURGERIES

1. Bilateral mastectomy, reduction mammoplasty, and/or chest reconstruction/contouring may be medically necessary when all of the following criteria listed in subsections II.A.1.a. through b. are met and documented.

    a) The member has been assessed by a licensed qualified behavioral health professional[1], resulting in a diagnosis of gender dysphoria meeting DSM-5 criteria. This diagnosis must have been present for at least six months. Detailed information on the requirement for these assessments can be found later in Section III.A.1.

    b) Co-morbid medical or behavioral health conditions are appropriately managed, reasonably controlled, and not causing symptoms of gender dysphoria.

2. The masculinizing gender-affirming surgeries listed below may be medically necessary when all criteria listed in a. through d. are met and documented.

    - Hysterectomy
    - Salpingo-oophorectomy
    - Vulvectomy
    - Vaginectomy
    - Urethroplasty
    - Metoidioplasty (micropenis) OR phalloplasty (allows coital ability and standing micturition)
    - Scrotoplasty with insertion of testicular prosthesis
    - Electrolysis or laser hair removal performed by a licensed qualified professional for the removal of hair on a skin graft donor site before its use in genital gender-affirming surgery

    a) The member has been assessed by two licensed health professionals, one of whom must be a licensed qualified behavioral health professional and the other a clinician familiar with the member's health, with each assessment resulting in a diagnosis of gender dysphoria meeting DSM-5 criteria. The initial diagnosis (from one professional) must have been present for at least six months. Additional information on the requirement for these assessments can be found later in Section III.A.1.

    b) The member is 18 years of age or older.

1 Providers must either be licensed by the relevant licensing board to practice in the Commonwealth of Massachusetts or practicing under the supervision of such an independently licensed behavioral health professional.

c) Co-morbid medical or behavioral health conditions are appropriately managed, reasonably controlled, and not causing symptoms of gender dysphoria.

d) The member has had six continuous months of clinician-supervised hormone therapy appropriate to the member's gender goals, unless hormone therapy is medically contraindicated.

FEMINIZING GENDER-AFFIRMING SURGERIES

3. Augmentation mammoplasty with implantation of breast prostheses and mastopexy may be considered medically necessary when all criteria listed below are met and documented.

   a) The member has been assessed by a licensed qualified behavioral health professional, resulting in a diagnosis of gender dysphoria meeting DSM-5 criteria. This diagnosis must have been present for at least six months. Additional information on the requirement for these assessments can be found later in Section III.A.1.

   b) The member is 18 years of age or older.

   c) Co-morbid medical or behavioral health conditions are appropriately managed, reasonably controlled, and not causing symptoms of gender dysphoria.

   d) The member has had six months of clinician-supervised hormone therapy that has resulted in no or minimal breast development, unless hormone therapy is medically contraindicated.

4. The following feminizing gender-affirming surgeries may be medically necessary when all criteria listed in a. through d. are met and documented.

   - Penectomy
   - Clitoroplasty
   - Colovaginoplasty
   - Vulvoplasty
   - Labiaplasty
   - Orchiectomy
   - Electrolysis or laser hair removal performed by a licensed qualified professional for the removal of hair on a skin graft donor site before its use in genital gender-affirming surgery

   a) The member has been assessed by two independently licensed health professionals, one of whom must be a licensed qualified behavioral health professional and the other a clinician familiar with the member's health, with each assessment resulting in a diagnosis of gender dysphoria meeting DSM-5 criteria. The initial diagnosis (from one professional) must have been present for at least six months. Additional information on the requirement for these assessments can be found later in Section III.A.1.

   b) The member is 18 years of age or older.

   c) Co-morbid medical or behavioral health conditions are appropriately managed, reasonably controlled, and not causing symptoms of gender dysphoria.

   d) The member has had six continuous months of clinician-supervised hormone therapy appropriate to the member's gender goals, unless hormone therapy is medically contraindicated.

FACIAL FEMINIZATION OR MASCULINIZATION SURGERIES

5. The following procedures may be medically necessary when all criteria listed in a. through c. are met and documented.

    - Blepharoplasty
    - Brow lift
    - Cheek augmentation
    - Forehead contouring and reduction
    - Genioplasty
    - Hairline advancement
    - Lateral canthopexy
    - Lip lift
    - Lysis intranasal synechia
    - Osteoplasty
    - Rhinoplasty and septoplasty
    - Suction-assisted lipectomy
    - Tracheoplasty
    - Facial fat pad procedures

    a) The member has been assessed by a licensed qualified behavioral health professional, resulting in a diagnosis of gender dysphoria meeting DSM-5 criteria. This diagnosis must have been present for at least six months. Additional information on these assessments can be found later in Section III.A.1.

    b) The member is 18 years of age or older.

    c) Co-morbid medical or behavioral health conditions are appropriately managed, reasonably controlled, and not causing symptoms of gender dysphoria.

Hair removal may also be covered as part of gender dysphoria treatment. For further details, refer to the *Guidelines for Medical Necessity Determination for Hair Removal*.

B. NONCOVERAGE

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 *Guidelines for Medical Necessity Determination for Excision of Excessive Skin and Subcutaneous Tissue*)
- Reversal of previous GAS
- Revisions of previous GAS other than for complications (infections or impairment of function)
- Rhytidectomy
- Vocal cord surgery

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SECTION III. SUBMITTING CLINICAL DOCUMENTATION

A. PRIOR AUTHORIZATION

Requests for PA for GAS must be submitted by the surgeon performing the procedure and accompanied by clinical documentation that supports the medical necessity for the procedure, including, but not limited to, the assessment made by the qualified licensed health professional(s) resulting in a diagnosis of gender dysphoria and the referral(s) for surgery from the qualified licensed health professional(s). Documentation of medical necessity must include all the following.

1. A copy of the assessment performed by qualified licensed health professional(s), including date of onset and history resulting in a diagnosis of gender dysphoria meeting DSM-5 Criteria; referral(s) for the specific procedures, as outlined in clinical guidelines; and all other World Professional Association for Transgender Health (WPATH) recommended content for referral letters.

    a. A referral from an independently qualified licensed health professional who is a clinician familiar with the member's health, who has independently assessed the member, with the assessment resulting in a diagnosis of gender dysphoria meeting DSM-5 criteria, is required for the procedures described in subsection II.A.

    b. The referral should attest that the member has been independently evaluated by a licensed qualified behavioral health professional. The referral must be provided in the form of a letter and include description of the clinical rationale for the requested surgery.

2. Documentation that any coexisting behavioral health and/or medical conditions are appropriately managed and are reasonably controlled.

3. If hormone therapy is a required criterion, medical records must document patient compliance with the prescribed regimen and clinical response over the course of hormone therapy.

4. Documentation from the surgeon performing the GAS must include a full clinical assessment, a physical exam, description of the procedure(s) to be performed, and frontal and lateral photos (for facial surgery), and must also attest to all of the following:

    a. The member meets the clinical criteria for coverage described in Section II.A. of these Guidelines;

    b. The surgeon has collaborated with the qualified licensed health professional(s) and any other health care professionals involved in the member's care, including, but not limited to, the member's primary care clinician and the health care professional who is providing hormone therapy (if applicable);

    c. The surgeon has discussed risks and complications of the proposed surgery, including the surgeon's own complication rates, and has obtained informed consent from the member; and

    d. The surgeon has discussed preservation of fertility with the member before surgery and the member understands that fertility procedures are not covered by MassHealth. Any surgery resulting in sterilization must meet all applicable state and federal laws, regulations, and guidance. Sterilization consent form must be submitted, if applicable. Hysterectomy (HI-1) or Sterilization consent (CS-18) or (CS-21) forms are available at www.mass.gov/lists/masshealth-provider-forms-used-by-multiple-provider-types.

B. SUBMITTING DOCUMENTATION

As previously noted, all clinical information must be submitted by the surgeon performing the GAS.

Providers must electronically submit PA requests and all supporting documentation using the Provider Online Service Center (POSC), unless the provider has a currently approved electronic claims waiver (hereinafter, "waiver"). Please see *All Provider Bulletin 369* for further waiver information. Questions about POSC access should be directed to the MassHealth Customer Service Center at (800) 841-2900, TDD/TTY: 711.

For PA requests that are not submitted using the POSC, providers with currently approved waivers must include the MassHealth Prior Authorization Request (PA-1 Form) and all supporting documentation. The PA-1 Form can be found at mass.gov/prior-authorization-for-masshealth-providers.

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These Guidelines are based on review of the medical literature and current practice in the treatment of gender dysphoria. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment, products, or services. Some language used in this communication may be unfamiliar to other readers; such readers are encouraged to contact their health care provider for guidance or explanation.

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