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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Transgender refers to an individual whose sex assigned at birth (e.g., typically based on external genitalia) does not match their gender identity (one's psychological sense of their gender). **Gender dysphoria** (previously gender identity disorder) may occur in some individuals; this includes the psychological distress resulting from an incongruence between one's sex assigned at birth and one's gender identity. Gender dysphoria frequently starts in childhood however some may not experience it until adolescence or later. To have multiple domains of gender affirmation, someone who is transgender may seek affirmation in all, or some, in the following ways (APA, 2020):

- Socially (changing their name and pronouns);
- Legally (changing gender markers on government-issued documents);
- Medically (pubertal suppression or gender-affirming hormones [GAHs]); and/or
- Surgically (vaginoplasty, facial feminization surgery, breast augmentation, masculine chest reconstruction, etc.)

Gender identity is unlike **gender expression**. Gender <u>identity</u> refers to an individual's psychological sense of their gender – gender <u>expression</u> refers to the way in which one presents to the world in a gendered way. For example, in the United States, wearing a dress is a feminine form of gender expression while wearing a suite is a masculine form. Culturally defined expectations vary across time and culture. An individual's gender expression does not always align with their gender identity. Gender identity is also unlike **sexual orientation** which refers to the type of individual someone is sexually attracted to.; those who are transgender have the same diversity of sexual orientations as those who are cisgender. (APA, 2020).

NOTE: For common terms used when discussing gender dysphoria and gender care, please refer to the Supplemental Information section below.

Levin et al. (2021) note that awareness of an individual's gender identity begins very early in life. Consciousness of physical differences occurs between the 1 and 2 years of age; by age 3, children are able to identify themselves as a boy or a girl and by age 4 a child's gender identity is stable. A child's gender identity becomes more established during middle childhood and can be reflected in their interest in playing more exclusively with those of their own gender as well as taking interest in acting like, looking like, and having things similar to same-sex peers. Some children may display gender-role confusion – for example, a boy may lack interest in traditionally masculine activities and identify with females and/or feminine traits. The same can occur for girls who may identify more with males and/or masculine traits. Due to this conflict about one's gender, the child may dislike the parts of themselves that is a boy or a girl; resolution occurs by the time a child completes adolescence however some may continue to experience dysphoria and seek treatment to transition to the opposite gender.

According to federal and state population studies from 2016, approximately 1.3 million adults (0.5% of the total population) and 300,000 youths in the United States identify as transgender (UCLA, 2022; ACOG, 2021). The majority of those who identify as transgender are concentrated in the Western and Southern regions of the United States. In terms of race or ethnicity, adults who are American Indian and Alaska Native Resources (AIAN) account for 0.9% of the population followed by Latinx (0.7%), Black (0.6%), White (0.5%), and Asian (0.5%); all other races account for an



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additional 1%. Among youth identifying as transgender, the highest percentages were found among AIAN (1.8%) and Latinx (1.8%) populations followed by those who are Black (1.4%), White (1.3%), and Asian (1.0%); all other races account for an additional 1.5%. Based on data from the Centers for Disease Control and Prevention's Behavioral Risk Factor Surveillance System, differences were not statistically significant among racial and ethnic groups. However, previous research indicates that more people who identify as transgender are Latinx, AIAN, and Asian than White. (UCLA, 2022).

Cedars Sinai (2020) conducted a study that included 210 adults (155 transgender women, 55 transgender men) who sought gender-affirming surgery. Results showed that gender dysphoria was first experience by age 7 in 73% of transgender women and 78% of transgender men. Before starting social transition and/or hormonal therapy, transgender women waited 27 years on average while transgender men waited 23 years. These findings indicate that individuals who received counseling and support services earlier likely would have lessened the distress and negative health effects that many transgender individuals encounter as well as improved overall quality of life.

Etiology of Gender Dysphoria

Research is ongoing however gender dysphoria may originate from a complex biopsychosocial link. Growing research also shows a correlation between gender dysphoria and childhood abuse, neglect, maltreatment, and physical or sexual abuse. Those with gender dysphoria and higher rates of body dissatisfaction typically have a poor prognosis with respect to mental health. These individuals also report higher rates of depression, suicidal ideations, and substance use. (Garg et al., 2021).

History and Physical

Patients typically present to a primary care physician, endocrinologist, or mental health provider. It is essential that the healthcare team document a good history of the patient and should include a developmental history including their childhood, education status, academic performance, social support, history of trauma (mental, physical, sexual), legal history, and if they are currently married, have a partner, or have children. A patient's psychiatric history should include any previous suicide attempts, self-injury behavior, and previous inpatient psychiatric condition(s), including if the patient has a psychiatrist or a psychotherapist and any past psychiatric treatment / medication use. Substance use should also be noted (Garg et al., 2021).

Treatment and Management

Due to more social acceptance and improved access to care, this population is presenting earlier before puberty whereas in the past individual's may have presented at adulthood or late adolescence. Providers should make necessary referrals according to the unique needs of the patient in an effort to build support. For children, individual, family, and group therapy is recommended to explore and counsel on issues stemming from gender preference. For adolescents, the anticipation of puberty is a concern; hormonal treatment and psychotherapy should be considered simultaneously. For adults, options include psychotherapy as well as hormonal and surgical treatments. Counseling is recommended to begin prior to starting treatment and should include, at minimum: (Garg et al., 2021)

- Care Team. A comprehensive approach with an endocrinologist and mental health providers.
- **Expectations.** While transgender hormonal and surgical treatment options will be helpful in addressing the patient's external appearance to align with their gender identity, providers should discuss unrealistic expectations sufficiently. A supportive system of peers, friends, and family is also helpful.
- Treatment Risks. Providers should discuss potential risks including venous thromboembolism, bone mineral
 density changes, and pubertal suppression.
- **Fertility Preservation.** Prior to initiation of hormonal and surgical treatment, the patient may lose the ability to reproduce. Providers should discuss fertility preservation with the patient.
- Sexual Health. Higher rates of sexually transmitted infections, including HIV, which are higher in this population.



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It is important that providers understand that treatment options can be influenced by expectations of one's family or culture as well as the opinion of health professionals, insurance coverage, and the availability of services. Phenotypic interventions may be appropriate and include social transition and affirmation (e.g., living partially or completely in the preferred gender role by adapting hairstyle, clothing, pronouns, and possibly a new name) and hormonal interventions to suppress endogenous puberty and/or alter secondary sexual characteristics. Primary care providers should make available education, support, and referral to mental health providers as applicable especially when there is evidence of gender dysphoria; coexisting anxiety, depression, or suicidality; or serious interpersonal conflicts with peers or family (e.g., bullying). Medical interventions typically progress from reversible (e.g., social transition, pubertal suppression) to partially reversible interventions (e.g., GAHs) to irreversible interventions (e.g., surgical interventions). Proper attention and early intervention, as well as support of the individual's family and peers, will increase the safety and health of transgender youth. (Olson-Kennedy & Forcier, 2022).

Additional information can be found below in the *Summary of Medical Evidence* section, including a summary of the World Professional Association for Transgender Health (WPATH) *Standards of Care*.

Surgical Procedures for Transgender Individuals

(Coleman et al., 2022; ACOG, 2021)

Masculinizing surgical procedures (female-to-male [FtM]) may include the following:

- Breast or Chest Surgery. Subcutaneous mastectomy, creation of a male chest.
- **Genital Surgery.** Hysterectomy (with or without salpingo-oophorectomy), reconstruction of the fixed part of the urethra, which can be combined with a metoidioplasty or with a phalloplasty (employing a pedicled or free vascularized flap), vaginectomy, scrotoplasty, and implantation of erection or testicular prostheses.
- Nongenital, Nonbreast Surgical Interventions. Voice surgery (rare), liposuction, lipofilling, pectoral implants, and various aesthetic procedures.

Feminizing surgical procedures male-to-female (MtF) may include the following:

- Breast or Chest Surgery. Augmentation mammoplasty (implants/lipofilling).
- Genital Surgery. Penectomy, orchiectomy, vaginoplasty, clitoroplasty, vulvoplasty.
- Non-Genital, Non-Breast Surgical Interventions. Facial feminization surgery, liposuction, lipofilling, voice surgery, thyroid cartilage reduction, gluteal augmentation (implants/lipofilling), hair reconstruction, and various aesthetic procedures.

Health Disparities for Transgender Youth

Levine et al. (2013) note a lack of research on transgender youth in the areas of medical, mental health, and substance abuse issues. The population also experiences family and/or peer rejection, harassment, trauma, abuse, legal problems, educational problems, poverty and homelessness. Transgender people face extremely high rates of verbal harassment and physical violence both at home and school. Mental health issues faced by transgender youth including depression and suicidality, anxiety, body image distortion, substance abuse, and post-traumatic stress disorder.

Healthy People 2030 is focused on collecting data on LGBT health issues and specifically improving the health of LGBT adolescents. Research shows that LGBT adolescents are especially at risk for being bullied, having suicidal thoughts, and using illegal drugs. (DHHS, n.d.). Objectives of Healthy People 2030 include:

- Adolescents with the goal of reducing bullying of LGBT students.
- Drug and Alcohol Abuse with the aim of reducing the proportion of LGBT students who have used illicit drugs.
- Mental Health and Mental Disorders with a focus on the reduction of suicidal thoughts in LGBT students.
- Public Health Infrastructure which includes increasing the number of national surveys to obtain data on LGNT
 populations and increasing the number of states, territories, and DC that include sexual orientation and gender
 identity questions in the Behavioral Risk Factor Surveillance System.
- Sexually Transmitted Infections with a focus on reduction in new HIV diagnoses and infections as well as increasing the linkage to HIV medical care and knowledge of HIV status and increase the proportion of those age 13 years and over living with diagnosed HIV infection who are virally suppressed. The objective also aims to reduce the rates of syphilis in men who have sex with men.

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COVERAGE POLICY

Medicaid

Please note that there may be State Medicaid mandates and Health Plan regulations regarding coverage of gender dysphoria treatment. Refer to the State's current information prior to applying this policy; State mandates and/or regulations supersede this policy.

<u>This policy addresses the surgical treatment of gender dysphoria</u>. For specific hormone therapy criteria, please see *Pharmacy PA Criteria: Gender Dysphoria Hormone Therapy (Policy Number C17908-A)*. The following Molina Clinical Policies are also available: *Breast Implant Removal (MCP-315)* and *Blepharoplasty (MCP-204)*.

Please see the Appendix section at the end of this policy for additional State coverage information.

Initial Criteria

- 1. Surgical treatment may be considered medically necessary when ALL of the following criteria are met:
 - a. Member is age 18 years or older; AND
 - b. A gender reassignment treatment plan is created specific to the Member; AND
 - c. Member has the capacity to make a fully informed decision and to consent for treatment; AND
 - d. Member has a documented diagnosis of gender dysphoria as defined by the *Diagnostic and Statistical Manual of Mental Disorders*, *5th Edition*, *Text Revision (DSM-V-TR)* including 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:
 - i. 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); **OR**
 - ii. 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); **OR**
 - iii. A strong desire for the primary and/or secondary sex characteristics of the other gender; OR
 - iv. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender); **OR**
 - v. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender); **OR**
 - vi. 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).

AND

- e. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning as evidenced by documentation from a behavioral health professional as defined by the World Professional Association for Transgender Health (WPATH)**. Documentation should indicate that the Member meets **ALL** of the following clinical criteria:
 - i. Diagnosis of gender dysphoria; AND
 - ii. Co-morbid psychiatric or other medical conditions are stable, and the Member is clinically cleared to undergo surgery; **AND**
 - iii. Completion of twelve (12) months of continuous, full-time, real-life experience (e.g., the act of fully adopting a new or evolving gender role or gender presentation in everyday life) in the experienced gender; **AND**
 - iv. While the duration of needed treatment and number of sessions is up to the discretion of the behavioral health professional, documentation in the medical record should reflect the Member's understanding of all applicable medical, pharmaceutical, and behavioral health therapies (including risks and complications).

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AND

f. When medically indicated, there is documentation that the Member has participated in six (6) consecutive months of gender affirming hormone therapy of the experienced gender continuously and responsibly (e.g., screenings and follow-ups with the professional provider). Any Member contraindications should be documented.

NOTE: The purpose of mental health evaluations and referral letters for surgery is to ensure that the Provider(s) responsible for the care of the Member understand the Member's medical history.

- ** To avoid delays in medical necessity determinations, Providers may request sample referral letters from the surgeon and/or hospital. The following suggestions align with WPATH guidance: (Coleman et al., 2022).
- Letter must be written at least twelve (12) months prior to the date of the Member's surgery consult. To ensure best surgery outcomes, the timeframe may be shortened dependent upon the nature of the Member's treatment plan; AND
- For Members undergoing mastectomy (male chest contouring), breast augmentation, hysterectomy, laryngeal shave, and most facial surgeries, <u>one</u> letter is needed to document satisfaction of any applicable criteria. For Members undergoing metoidioplasty, phalloplasty, and vaginoplasty, <u>two</u> letters are required; **AND**
- Letters should include the following:
 - Member identifying information (e.g., general identification [age, sex/gender, relationship status, race/ethnicity] and reason surgery is being sought); AND
 - b. Duration and nature of the therapeutic relationship with the Member, including evaluation, treatment type, and duration; AND
 - c. Explanation of how the Member meets criteria <u>and</u> a brief clinical reason to support the Member's surgery. This includes the Member's capacity to make an informed decision and consent about treatment. For Member's undergoing genital surgery, six (6) of continuous cross gender hormone therapy should be documented unless there are contraindications and/or the Member is unable/unwilling to use hormones; **AND**
 - d. Summary of the Member's psychosocial assessment that includes, but is not limited to: diagnoses; chronological history of the Member's cross-gender feelings; initial and current gender and any sexual, psychiatric (personality, developmental), and/or substance abuse diagnoses; AND
 - e. Background related to family, development, education and occupation, relational and social history; AND
 - f. Documentation of Member's current psychiatric stability and if the diagnosis is controlled; AND
 - g. Medication listing (medical and psychiatric) including dosage, starting date, and prescribing Provider; AND
 - h. Expected support level from the Member's family, friends, colleagues, etc.; AND
 - Legal status of gender change (including name and gender) on identification (e.g., birth certificate, driver's license passport);
 AND
 - j. Qualifications of the evaluator and/or letter author including appropriate level of education, supervision, training and State credentials to treat individuals with gender dysphoria and who seek treatment (including continuing education opportunities); experience utilizing the DSM-V-TR; the ability to recognize and diagnose co-morbid behavioral health concerns and differentiate from gender dysphoria; and a strong understanding of gender non-conforming identities and expressions (including how to assess and treat individuals with gender dysphoria).
- 2. Surgical procedures **may be considered medically necessary** when applicable criteria are met for **ANY/ALL** of the following:
 - a. For Male-to-Female (MtF) procedures:
 - Breast Augmentation Mastoplasty when indicated by ALL of the following:
 - Referral letter from a qualified behavioral health Provider confirming **ALL** of the following:
 - Member has a documented diagnosis of persistent gender dysphoria; AND
 - Member has an understanding of potential risks, harms, and irreversibility of procedure; AND
 - Member has full decision-making capacity to give fully informed consent; AND
 - There is documented appropriateness for the proposed surgery (e.g., clinical rationale supporting the request for surgery); **AND**
 - Appropriate psychosocial assessment confirms that comorbid mental health issues are absent or under control. This includes, but is not limited to, substance abuse, major depression, and bipolar disorder.
 - ii. Member has undergone at least six (6) months of continuous hormone therapy consistent with gender dysphoria treatment goals (e.g., estrogen) or reason for contraindication, as documented by a Provider (e.g., endocrinologist, primary care).

OR

Orchiectomy when indicated by ALL of the following:

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- i. Two referral letters from mental health professionals who have independently assessed patient, one of whom is acting in a purely evaluative capacity (not involved in long-term care), with each letter attesting to ALL of the following:
 - o Member has a documented diagnosis of persistent gender dysphoria; AND
 - Member has an understanding of potential risks, harms, and irreversibility of procedure; AND
 - Member has full decision-making capacity to give fully informed consent; AND
 - There is documented appropriateness for the proposed surgery (e.g., clinical rationale supporting the request for surgery); **AND**
 - Appropriate psychosocial assessment confirms that comorbid mental health issues are absent or under control. This includes, but is not limited to, substance abuse, major depression, and bipolar disorder.
- ii. Member has undergone at least six (6) of continuous hormone therapy consistent with gender dysphoria treatment goals (e.g., estrogen) or reason for contraindication, as documented by a Provider (e.g., endocrinologist, primary care).

OR

- Genital Reconstructive Surgery (e.g., vaginoplasty, penectomy, labioplasty, clitoroplasty)
 - i. Two referral letters from mental health professionals who have independently assessed patient, one of whom is acting in a purely evaluative capacity (not involved in long-term care), with each letter attesting to ALL of the following:
 - o Member has a documented diagnosis of persistent gender dysphoria; AND
 - Member has an understanding of potential risks, harms, and irreversibility of procedure; AND
 - Member has full decision-making capacity to give fully informed consent; AND
 - There is documented appropriateness for the proposed surgery (e.g., clinical rationale supporting the request for surgery); AND
 - Appropriate psychosocial assessment confirms that comorbid mental health issues are absent or under control. This includes, but is not limited to, substance abuse, major depression, and bipolar disorder.
 - ii. Member has undergone at least six (6) of continuous hormone therapy consistent with gender dysphoria treatment goals (e.g., estrogen) <u>or</u> reason for contraindication, as documented by a Provider (e.g., endocrinologist, primary care).
 - iii. Documentation that the Member has lived in the gender role consistent with their gender identity for at least 12 months.

OR

- Voice Disorders when the Member meets ALL of the following:
 - i. Diagnosis of voice disorder; AND
 - ii. Evidence of voice-gender incongruence (if the Member is undergoing voice rehabilitation).

Additional procedures that may be considered medically necessary include:

- Electrolysis (when required for vaginoplasty); OR
- Mammaplasty; OR
- Prostatectomy; OR
- Urethroplasty; OR
- Vulvoplasty.

OR

- b. For Female-to-Male (FtM) procedures:
 - <u>Mastectomy</u> when medically necessary as indicated by referral letter from a qualified behavioral health Provider confirming **ALL** of the following:
 - i. Member has a documented diagnosis of persistent gender dysphoria; AND
 - ii. Member has an understanding of potential risks, harms, and irreversibility of procedure; AND

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- iii. Member has full decision-making capacity to give fully informed consent; AND
- iv. There is documented appropriateness for the proposed surgery (e.g., clinical rationale supporting the request for surgery); **AND**
- v. Appropriate psychosocial assessment confirms that comorbid mental health issues are absent or under control. This includes, but is not limited to, substance abuse, major depression, and bipolar disorder.

OR

- <u>Oophorectomy</u> when medically necessary (usually with hysterectomy and salpingectomy) and when ALL of the following are met:
 - iv. Two referral letters from mental health professionals who have independently assessed patient, one of whom is acting in a purely evaluative capacity (not involved in long-term care), with each letter attesting to **ALL** of the following:
 - Member has a documented diagnosis of persistent gender dysphoria; AND
 - o Member has an understanding of potential risks, harms, and irreversibility of procedure; AND
 - o Member has full decision-making capacity to give fully informed consent; AND
 - There is documented appropriateness for the proposed surgery (e.g., clinical rationale supporting the request for surgery); AND
 - Appropriate psychosocial assessment confirms that comorbid mental health issues are absent or under control. This includes, but is not limited to, substance abuse, major depression, and bipolar disorder.
 - v. Member has undergone at least six (6) of continuous hormone therapy consistent with gender dysphoria treatment goals (e.g., testosterone) or reason for contraindication, as documented by a Provider (e.g., endocrinologist, primary care).

OR

- <u>Genital Reconstructive Surgery</u> (e.g., vaginectomy, metoidioplasty, scrotoplasty, phalloplasty, urethroplasty, placement of testicular prosthesis)
 - i. Two referral letters from mental health professionals who have independently assessed patient, one of whom is acting in a purely evaluative capacity (not involved in long-term care), with each letter attesting to ALL of the following:
 - Member has a documented diagnosis of persistent gender dysphoria; AND
 - Member has an understanding of potential risks, harms, and irreversibility of procedure; AND
 - Member has full decision-making capacity to give fully informed consent; AND
 - There is documented appropriateness for the proposed surgery (e.g., clinical rationale supporting the request for surgery); **AND**
 - Appropriate psychosocial assessment confirms that comorbid mental health issues are absent or under control. This includes, but is not limited to, substance abuse, major depression, and bipolar disorder.
 - ii. Member has undergone at least six (6) of continuous hormone therapy consistent with gender dysphoria treatment goals (e.g., testosterone) or reason for contraindication, as documented by a Provider (e.g., endocrinologist, primary care).
 - iii. Documentation that the Member has lived in the gender role consistent with their gender identity for at least 12 months.

OR

- Voice Disorders when the Member meets ALL of the following:
 - Diagnosis of voice disorder: AND
 - ii. Evidence of voice-gender incongruence (if the Member is undergoing voice rehabilitation).
- Breast Reconstruction; OR
- Electrolysis (when required for phalloplasty); OR
- Hysterectomy; OR

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- Salpingo-oophorectomy; OR
- Vulvectomy.
- c. Members undergoing **reconstructive chest surgery** (e.g., initial mastectomy, breast augmentation) must have **ONE** letter of recommendation from a qualified behavioral health Provider.

NOTE: Certain post-mastectomy services related to breast reconstruction and treatment of physical complications from mastectomy including nipple-areola reconstruction may be covered by the Women's Health and Cancer Rights Act (WHCRA), 29 U.S. Code § 1185b.

- d. Members undergoing hysterectomy, salpingo-oophorectomy, orchiectomy must have documentation of:
 - At least six (6) of continuous hormonal sex reassignment therapy; AND
 - Two (2) recommendations for gender reassignment surgery by qualified mental health providers must be submitted to the surgeon performing the genital surgery.
- e. Members undergoing reconstructive genital surgery must have the following:
 - Documentation of at least six (6) of continuous hormonal sex reassignment therapy; AND
 - Recommendation for surgery by two qualified mental health professionals; documentation must be submitted to the surgeon performing surgery. (If the first referral is from the Member's psychotherapist, the second referral should be from an individual who has had only an evaluative role with the Member);
 AND
 - Documentation that the Member has lived for at least 12 continuous months in a gender role that corresponds with their gender identity.

Additional Services

The following may be considered medically necessary for Members undergoing gender affirming procedures:

- 1. *Behavioral Health.* Services including, but not limited to, counseling for gender dysphoria and related psychiatric conditions (e.g., anxiety, depression).
- 2. Hormonal Therapy. This includes, but is not limited to androgens, anti-androgens, GnRH analogues*, estrogens, and progestins. Prior authorization requirements may apply. Please reference *Pharmacy PA Criteria: Gender Dysphoria Hormone Therapy (Policy Number C17908-A)*.
- 3. Laboratory Testing. For the monitoring of prescribed hormonal therapy.
- Age-Related, Gender-Specific Services. This includes but is not limited to preventive health (as applicable to the Member's biological anatomy such as cancer screenings [e.g., cervical, breast, prostate]) and treatment of the prostate.

Limitations

Medicaid defines cosmetic surgery as services that are intended primarily to change or improve a Member's physical appearance that would be considered within a normal anatomic variation and **are not covered.** Please check State mandates and health plan regulations regarding coverage and exclusions for cosmetic services. Mandates and/or regulations supersede this policy. The following procedures and services for the treatment of gender dysphoria **may be considered cosmetic and/or not medically necessary**, including but not limited to:

- Blepharoplasty removal of redundant skin of upper and/or lower eyelids and protruding periorbital fat
- Chin Augmentation
- Collagen Injections
- Cricothyroid Approximation voice modification that raises the vocal pitch by simulating contractions of the cricothyroid muscle with sutures
- Facial Feminizing Procedures



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- Hair Removal / Hair Transplantation (e.g., electrolysis, laser hair removal)**
- Laryngoplasty reshaping of laryngeal framework (voice modification surgery)
- Liposuction removal of fat
- Lip Enhancement, Reduction, Lift and Lip Filling
- Mastopexy breast lift
- Rhinoplasty reshaping of nose
- Trachea Shave / Reduction Thyroid Chondroplasty reduction of the thyroid cartilage
 - ** Electrolysis or laser hair removal sessions may be considered medically necessary for skin graft preparation for genital surgery.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

¹Oles et al. (2022) performed the first systematic review of available gender-affirming surgery publications (including all procedures) to analyze outcomes reported in the literature as well as methods used for outcome assessment. While some procedures have been long performed, data is limited for each and requires a review of the literature to understand current knowledge and to steer needed future research. The systematic review was conducted following Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines to identify all outcomes measures gender-affirming surgery cohorts. In total, 15,186 references were identified, 4162 papers advanced to abstract review, and 1826 underwent full-text review; upon review, there were 406 cohort publications. Of non-genitoplasty titles, 35 were mastectomy, 6 mammoplasty, 21 facial feminization, and 31 voice/cartilage. Although 59% of non-genitoplasty papers addressed PCOs in some form, only 4.3% used instruments partially validated in transgender patients. Overall, data were reported heterogeneously and were biased towards high-volume centers. The authors present a comprehensive list of outcome instruments which offers an ideal starting basis for discussions between patients and providers regarding deficiencies that require attention. In addition, consistent use of the same outcome measures and validated gender-affirming surgery-specific instruments are needed as they represent two primary barriers to high-quality research where improvement efforts should be focused.

²Oles et al. (2022) also performed a systematic review focusing on genital reconstruction. Gender affirming surgery results were analyzed in a multidimensional way, involving complication rates and anatomic (e.g., vaginal depth), functional (e.g., urinary), and psychosocial outcomes. Of the total references identified (as noted above), there were 406 GAS cohort publications (171 vaginoplasty, 82 phalloplasty, 16 metoidioplasty, 23 oophorectomy/vaginectomy, and 21 with multiple procedures). Although 69% of genitoplasty papers addressed patient-centered outcomes, only 1% used metrics validated in the transgender population. Forty-three different outcome instruments were used. No instrument was used in more than 15% of published series and 38 were used in only one or two publications. Overall, the review identified high patient satisfaction for genital procedures however there was little concordance between study methods – nearly 90% of patient-focused outcome metrics appeared once or twice. The authors suggest standardization of outcome instruments and measurement methods by taking a patient-inclusive, multidisciplinary approach to improve quality of care.

Akhavan et al. (2021) analyzed data from the literature that were specific to gender-affirming mastectomies, vaginoplasty, vulvaplasty, mastectomy, metoidioplasty, and phalloplasty. The review found that gender affirmation surgery is generally safe and complication rates are low for gender-affirming mastectomy and breast augmentation; complication rates for genital surgeries are also considerable low. Surgery can decrease rates of gender dysphoria, depression, and suicidality as well as greatly improve quality-of-life measures. Gaps exist in the research with respect to female-to-male surgery as well as surgical complication rates for genital surgery, facial masculinization and feminization, and patient-reported outcomes.



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Almazan et al. (2021) evaluated associations between gender affirming surgeries and mental health outcomes (e.g., psychological distress, substance use, and suicide risk). A secondary analysis of data was conducted from the 2015 U.S. Transgender Survey, which includes the largest existing data set across the 50 states and Washington, D.C. The focus of the survey is on the surgical and mental health experiences of transgender individuals. Data of the 27,715 adults that participated in 2015 were analyzed between November 1, 2020, and January 3, 2021. Over 12% (3559 participants) endorsed undergoing one or more types of gender affirming surgery at least two years prior to submitting survey responses; almost 60% (16,401 participants) endorsed a desire to undergo one or more types of gender affirming surgery but denied undergoing any of these. Upon adjusting the data for sociodemographic factors and exposure to other types of gender-affirming care, undergoing one or more types of gender affirming surgery was associated with lower past-month psychological distress, past-year smoking, and past-year suicidal ideation.

Eftekhar et al. (2020) conducted a systematic review and meta-analysis on the quality of life (QoL) of the transgender population post transsexual surgery. Of the nearly 500 articles initially identified (published through December 2019), eight articles were selected for meta-analysis – this included 1099 patients. The mean of QoL in transgender individuals was 70.45 based on World Health Organization Quality of Life (WHOQoL-BREF) and The 36-item short form of the Medical Outcomes Study questionnaire (SF36). Further analysis indicated that the weighted mean QoL in male to female and female to male indicate that the mean QoL in female to male was 57.54 and 62.47 in male to female (based on SF36 questionnaire). The weighted mean QoL in female to male was 69.99 and 70.65 in male to female (based on WHOQoL-BREF questionnaire). Analysis results support approaches to gender reassignment.

Weinforth et al. (2019) performed a systematic literature to assess the available date on QoL following male-to-female reassignment surgery. A total of 13 articles (1101 study participants) were reviewed; the number of trans women in each study ranged from 3 to 247 and had a mean age of 39.9 years (range of 18-76). Seven questionnaires were utilized used to analyze participants QoL following surgery. Results show that gender reassignment surgery benefits emotional well- being, sexuality, and general QoL. In addition, participants reported "freedom from pain", "fitness", and "energy". Some studies identified worsening in some patients following surgery however, overall improved QoL was reported.

Chest Surgery

Cohen et al. (2019) performed a literature review using PubMed for articles related to patients who were transgender female to male. Often, chest contouring is the first surgery that patients undergo and helps individuals assimilate into their new gender role. While there are different techniques to create an aesthetic male chest, it requires adjustment of breast tissue volume, proper nipple-areolar complex placement, and abolishment of the inframammary fold. Consensus on the preferred technique is varied. The authors identified 67 unique articles – 22 met inclusion criteria; 2447 unique patients were analyzed. The authors found that further research is needed with respect to patient selection, surgical decision making, and patient-reported outcomes for various chest contouring techniques. Specific research is needed regarding the ideal nipple-areolar complex shape, size, and location.

Tolstrup et al. (2020) performed a systemic comprehensive literature review using PubMed, EMBASE, CINAHL, PsycINFO, Scopus and the Cochrane Library to identify studies that evaluated gender-confirming chest surgery in a non-cis gender population. Outcome measures were reviewed. A total of 849 records were found; 47 were included in the review. Feminizing gender-confirming chest surgery was analyzed in 11 studies while masculinizing gender-confirming chest surgery was evaluated in 39 studies. Categories of patient-reported outcomes were used in 29 studies and included aesthetic outcome, functional outcome and mental health parameters. In conclusion, the summary of outcome domains and classifications found large variations in outcome evaluation between studies. While several studies reported on similar outcome categories, there was a high level of heterogeneity of domains and classifications of outcomes. Future research should focus on the evaluation of outcomes with an effort to streamline reporting and compare surgical outcomes between studies.

Genital Surgery

Nassiri et al. (2020) performed a systematic review to evaluate the effect of gender reassignment surgery on the development of urethral complication. A total of 879 articles published up until June 2019 were included and identified the Pubmed, Scopus, Embase, and Web of Science databases. Following examination and removal of articles that



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were not pertinent to the review, 32 studies were examined which included a total of 3463 patients. Female-to-male (FtM) surgery and male-to-female (MtF) surgery was discussed in 23 and 10 studies, respectively (one study discussed both). Differing patterns of complications were observed in FtM and MtF surgeries; increased complications were noted FtM surgeries due to the larger size of the neourethra. Complications related to meatal stenosis (a concern in MtF surgery) ranged from 4 to 40%; meatotomy for repair was often required. Stricture and fistulization are often reported complications following FtM surgery; studies reporting on fistulae involving the urethra found that 19 to 54% of fistulae resolved spontaneously without further surgical intervention. The authors concluded that high rates of complications are reported in the medical literature which emphasizes the need for proper patient education regarding risks and benefits of surgery.

Rooker et al. (2019) conducted a comprehensive literature review to analyze and aggregate reported characteristics and outcomes of penile prosthesis implantation in the trans masculine patient. Penile prostheses are often used to achieve erectile rigidity after phalloplasty in trans masculine patients. Due to the delicate nature of the neophallus and lack of native erectile tissue, complications and challenges are of concern. While novel phalloplasty and prosthesis insertion techniques have been developed, none have proven superior. The authors used the Medline, EMBASE, and Cochrane Registry databases; articles through February 2019 were included. Studies included and analyzed those prosthesis outcomes in patients who received a neophallus as part of a gender-affirming procedure. A total of 23 journal articles (retrospective or case series/reports) were reviewed – this included 1,056 patients who underwent phalloplasty and 792 who received a penile prosthesis. Over 83% of the prostheses were inflatable versus 16% were non-inflatable. The number of cylinders used for each prosthesis was 61% (single-cylinder) and 39% (double-cylinder). Follow-up duration had a mean of 3.0 years. Complications were reported by 36% of patients who received a prosthesis; at follow-up 60% of patients had their original implant present and 84% reported achieving penetration. While prosthesis implantation in gender-affirming operations may pose a significant risk of complication, this is a reasonable and useful method to achieve rigidity necessary for sexual intercourse.

Massie et al. (2018) performed a retrospective chart review of a single surgeon's experience with penile inversion vaginoplasty (performed from July 2014 to June 2016). Information analyzed included patient demographic data, postoperative complications, and patient-reported outcome data. The data were correlated by binary logistic regression to identify predictors of postoperative complications and patient satisfaction. Penile inversion vaginoplasty is the current gold standard procedure for MtF transgender patients undergoing gender-confirming genital surgery. While data concerning complications have been extensively reported in the medical literature, studies regarding patient-reported outcomes are limited. The aim of the study was to report postoperative complications and patient-reported outcomes based on the largest cohort in the United States undergoing penile inversion vaginoplasty. A total of 117 patients underwent penile inversion vaginoplasty. Common complications included granulation tissue (26%), intravaginal scarring (20%), and prolonged pain (20%). A majority of patients (94%) reported that they felt positive about their genitals and would have the surgery again. Over 70% of patients reported resolution of their gender dysphoria. Predictors of patient dissatisfaction included intravaginal scarring, prolonged pain, excessive external scarring, loss of sensation, and hematoma/excessive bleeding. Regardless of the moderate complication risks, patient satisfaction is very high following penile inversion vaginoplasty.

Studies and Trials

Surgical Treatment

There are no randomized controlled trials evaluating the effectiveness of surgical treatment of gender dysphoria (GD). Available evidence consists of cohort studies comparing outcomes in patients that underwent sex reassignment surgery (SRS) versus transgendered patients that had not undergone SRS. In addition, cross-sectional studies were also reviewed that compared outcomes in transgendered patients who had undergone SRS versus those who had not undergone SRS. Most of the studies did not explicitly state inclusion and exclusion criteria. Sample sizes ranged from 35 to 376 patients. Follow-up time since SRS varied widely across studies and ranged from one month to seven years. There is insufficient evidence to establish definitive patient selection criteria for SRS to treat GD. Professional groups recommend that SRS be restricted to individuals who are referred for sex reassignment services by a qualified behavioral health professional, and that while one referral is sufficient for breast or chest surgery, two independent referrals should be required for genital SRS. Individuals who have medical contraindications to surgery should not undergo SRS. (Heylens et al., 2014; Weigert et al., 2013; Berry et al., 2012; Motmans et al., 2012; Dhejne et al., 2011; Ainsworth & Spiegel, 2010).

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Hormone Treatment

There are no randomized controlled trials evaluating the effectiveness of hormone treatment for gender dysphoria. Available evidence consists of cross-sectional studies where a group of transgender individuals, some of whom had undergone gender affirming hormone therapy and some of whom had not, responded to questionnaires. Sample sizes in these studies of adults ranged from 50 to 376. The studies most commonly evaluated quality of life (QOL) or functional status with instruments such as the SF-36 Health Survey (QualityMetric Inc.), mood-related conditions such as depression or anxiety, and/or psychosocial conditions such as perceived social support or partnership status. A variety of other behavioral and social outcomes were assessed; results were generally positive. (Colizzi et al., 2014; Fisher et al., 2014; Costantino et al., 2013; Gorin-Lazard et al., 2013; Wierckx et al., 2013; Gorin-Lazard et al., 2012). A systematic review based on 28 studies (1833 participants; 1091 MtF and 801 FtM) published from 1996 to February 2008 included a meta-analysis of the QOL and psychosocial outcomes of hormone therapy. 80% of the study participants reported significant improvement in quality of life and reported significant improvement in psychiatric symptoms. (Murad et al., 2010).

Cardiovascular Risks

Schutte et al. (2022) conducted an exploratory study to evaluate the cardiovascular risks and gender-affirming hormone therapy (specifically markers of inflammation and hemostasis). A total of 48 trans women and 47 trans men were included (ages 18 to 50); participants had no history of cardiovascular events. Trans women were using estradiol patches plus cyproterone acetate (CPA) and trans men were using testosterone gel. Measurements were performed for all participants before and after 3 and 12 months of hormone therapy. The study found an increase in platelet activation and coagulation marker concentrations in trans women using transdermal estradiol plus CPA. No increase was noted in the trans men. Concentrations of inflammatory markers were less in trans women and increased in trans men. Hormone therapy is shown to affect hemostasis in transgender persons and therefore may be a catalyst to the presence of increased cardiovascular risk.

Swe et al. (2022) reviewed limited, non-randomized studies suggesting that transgender women on gender affirming hormone therapy (GAHT) have increased risks of myocardial infarction, ischemic stroke and venous thromboembolism (or VTE). Conversely, evidence does not demonstrate an increased cardiovascular risk in transgender men receiving GAHT. Evidence also demonstrates an improvement in gender dysphoria and quality of life. Monitoring for standard cardiovascular risk factors is recommended for transgender individuals who are receiving GAHT – this includes. Providers should adhere to current guidelines regarding lifestyle programs and preventive screenings.

Children and Adolescents

The American Academy of Child and Adolescent Psychiatry (AACAP) posted a literature review conducted on gender dysphoria in childhood and adolescence.

- Aitken et al. (2016) examines self-harm, suicidal ideation, and suicidal behavior (by parent report). Children with gender dysphoria show an increase in self-harm and suicidality as age progressed.
- Dheine et al. (2016) provides an overview of existing studies on psychiatric disorders in transgender patients.
 This population has an increased risk of psychiatric morbidity however, symptoms improve with gender affirming care and mental health care.
- Durwood et al. (2017) researchers of the TransYouth Project analyzed depression, anxiety, and self-worth in children age 9-14 who had socially transitioned. Results showed that transgender children had similar rates of depression and marginally higher rates of anxiety.
- Olson et al. (2016) examined depression and anxiety in transgender children who have socially transitioned.
 Research showed that when support was received for their gender identities, normative rates of depression were found as well as decreased anxiety.

Tordoff et al. (2022) conducted a study of 104 youths aged 13 to 20 years (mean age 15.8) – 61% were transmasculine individuals, 26% were transfeminine individuals, and 10% were nonbinary or gender fluid individuals, and 3% responded "I don't know" or did not respond to the gender identity question. Baseline data show that 57% of all participants had moderate to severe depression, 50% had moderate to severe anxiety, and 43% reported self-harm or suicidal thoughts. By the conclusion of the study, 66% received puberty blockers, GAHs, or both – 34% did not receive either intervention. The authors found that gender affirming interventions decrease levels of depression and suicidality over a 12-month time. This supports existing data to suggest that gender affirming care increases well-being among transgender youth.

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National and Specialty Organizations

World Professional Association for Transgender Health (WPATH)

Since 1979, WPATH has published the internationally accepted *Standards of Care* guidelines. The Standards aim to provide clinical guidance for health professionals assisting transgender and gender diverse (TGD) individuals with access to safe and effective pathways for achieving lasting comfort with their gendered selves. The objective is to maximize an individual's overall physical health, psychological well-being, and self-fulfillment. Assistance may include primary care, gynecologic and urologic care, reproductive options, voice and communication therapy, mental health services (e.g., assessment, counseling, psychotherapy), and hormonal and surgical treatments. After initial publication in 1980, the Standards were updated in 1981, 1990, 1998, 2001, 2011, 2012, and 2022 – current chapters include:

- Terminology*
- 2. Global Applicability
- 3. Population Estimates
- 4. Education*
- 5. Assessment of Adults*
- 6. Adolescents*
- 7. Children*
- 8. Nonbinary*
- 9. Eunuchs*
- 10. Intersex
- 11. Hormone Therapy
- 12. Surgery and Postoperative Care and Follow-Up
- 13. Voice and Communication
- 14. Primary Care
- 15. Reproductive Health
- 16. Sexual Health*
- 17. Mental Health

Appendices include Methodology; Glossary; Gender-Affirming Hormonal Treatments; Summary Criteria for Hormonal and Surgical Treatments for Adults and Adolescents; and Gender-Affirming Surgical Procedures (Coleman et al., 2022).

A summary of the new chapters and recommendations are included below (Coleman et al., 2022).

- **Education.** An overview is provided of education surrounding gender affirming care as well as recommendations for those at the governmental, nongovernmental, institutional and provider levels. The aim of education is to increase access to competent, compassionate health care as well as encourage a broader discussion between educators and health care professionals.
- Assessment of Adults. This chapter includes assessments for gender-affirming medical and surgical
 treatments (GAMSTs). Recommendations are centered around the proper licensure of Providers as well as
 continuing education and skill to identify co-existing mental health or other psychosocial concerns and how
 they differ from gender dysphoria, incongruence, and diversity physical health conditions should also be
 evaluated for any impact to the outcome of a GAMST. Recommendations also focus when to recommend
 GAMSTs and how to ensure fulfillment of diagnostic criteria prior to treatments (in regions requiring a diagnosis
 to access care).
- Adolescents. A new chapter was included on the population due to the significant increase in referrals as well
 as an increase of studies focused on adolescent gender diversity-related care, and specific developmental
 and gender affirming care issues. Recommendations are centered around the assessment process of
 adolescents requiring GAMSTs as well as how to work with youth and their families.

^{*} New chapter for 2022

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- Children. Developmentally appropriate psychosocial practices and therapeutic approaches for prepubescent gender diverse children are included.
- **Non-Binary.** A chapter is included discussing the broad description of the term "nonbinary" and its usage from a biopsychosocial, cultural, and intersectional perspective. The importance of access to gender-affirming care, specific gender-affirming medical interventions, and appropriate level of support is discussed.
- **Eunuchs.** A new chapter was included on individuals who identify as eunuch (individuals assigned male at birth and wish to eliminate masculine physical features, masculine genitals, or genital functioning). The unique needs of the population are explored.
- Sexual Health. The impact of sexual health on physical and psychological well-being for transgender people
 is explored with respect to sexual functioning, pleasure, and satisfaction.

The American Academy of Child and Adolescent Psychiatry (AACAP) published practice principles that address issues faced by children and adolescents who identify as gay, lesbian, bisexual, gender nonconforming, or gender discordant. The following principles focus on cultural competence, research needs, and ethics (Adelson & AACAP, 2012):

- 1. **Principle 1.** All children and adolescents should complete a comprehensive diagnostic evaluation that is age-appropriate and assesses their psychosexual development.
- 2. **Principle 2.** Confidentiality must be upheld when assessing sexual and gender minority youth.
- 3. **Principle 3.** With respect to the individual's sexual orientation, gender nonconformity, and gender identity, family dynamics should be assessed as they relate to cultural values of the individual, their family, and community.
- 4. **Principle 4.** Providers should assess the individual for commonly encountered situations by this population that can increase the risk of psychiatric diagnoses.
- 5. **Principle 5.** Providers should focus on establishing healthy psychosexual development in sexual and gender minority youth. This includes protecting their full capacity for identity formation and adaptive functioning.
- 6. **Principle 6.** Providers should understand that evidence does not exist that one's sexual orientation can be altered via therapy (and that such attempts may be harmful).
- 7. **Principle 7.** Providers should be aware of current literature supporting the natural course of gender discordance and associated psychopathology and how it impacts the selection of treatment goals and modalities.
- 8. **Principle 8.** Providers should be available as a liaison with schools, community agencies, and other health care providers to advocate for the unique needs of this population and their families.
- Principle 9. Mental health providers should be knowledgeable of community and professional resources for sexual and gender minority youth.

The American Academy of Pediatrics (AAP) (2021) published a policy statement on Office-Based Care for Lesbian, Gay, Bisexual, Transgender, and Questioning Youth. The AAP notes that pediatricians should provide factual, current, nonjudgmental information in a confidential manner to lesbian, gay, bisexual, transgender, and questioning (LGBTQ) youth. Particular attention should also be paid to the effects of homophobia and heterosexism that can contribute to increased mental health issues for sexual minority youth. Providers should acknowledge and affirm their patient's feelings of gender dysphoria; referral to a qualified mental health professional is vital to assist the patient as well as educate them and assess their readiness for transition. Those who receive the right assistance and care are more likely to live a healthy, productive life as they go through adolescence and enter young adulthood. The AAP (2018) also published a policy statement on Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents. Highlights include the need for more formal training, standardized treatment and research that focuses on safety and medical outcomes.

The AAP also published a policy statement titled *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents* (Rafferty et al., 2018). The statement aims to bring attention to the need for more formal training, standardized treatment, and research on safety and medical outcomes surrounding the care of transgender individuals. Concepts and challenges faced by providers, as well as families and loved ones, are discussed and potential solutions are provided to promote the health and positive development of youth that identify as transgender to eliminate discrimination and stigma.



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The American College of Obstetricians and Gynecologists (ACOG) published *Committee Opinion Committee No. 823: Health Care for Transgender and Gender Diverse Individuals* in 2021 to provide clinical guidance to obstetrician—gynecologists caring for transmasculine and transfeminine patients to offer inclusive patient care. In addition, ACOG notes that most medications used for gender transition are common and can be safely prescribed by a variety of health care professionals when given proper appropriate training and education. This includes, but is not limited to, obstetrician—gynecologists, family or internal medicine physicians, endocrinologists, psychiatrists, and advanced practice clinicians. Additional recommendations include discussion of fertility and parenting desires, prior to starting hormone therapy or gender affirmation surgery. Patients should also know that gender-affirming hormone therapy is not effective contraception; sexually active individuals should be educated about contraceptive options if they do not wish to become pregnant or cause pregnancy in others. Finally, to lead preventive medical care, any anatomical structure present that warrants screening should be screened, regardless of the patient's gender identity.

The **American Psychiatric Association (APA)** (2017) published *A Guide for Working with Transgender and Gender Nonconforming Patients*. Sections include:

- History and Epidemiology
- Definitions of Gender, Sex, and Sexual Orientation and Pronoun Usage
- Gender Dysphoria Diagnosis
- Medical Treatment and Surgical Interventions
- Best Practices
- Writing Letters of Support to Insurers and Surgeons
- Gender-Affirming Therapy
- Terminology
- Resources and References

In addition, the APA (2015) published *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People*. A total of 16 guidelines were developed to aid providers with affirmative psychological practice across the lifespan of the population. The guidelines are categorized in five clusters: (1) foundational knowledge and awareness; (2) stigma, discrimination, and barriers to care; (3) lifespan development; (4) assessment, therapy, and intervention; and (5) research, education, and training.

The **Endocrine Society** published the *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline* (Hembree et al., 2017). Recommendations are summarized below:

- Adolescents who meet diagnostic criteria for gender dysphoria/gender incongruence should initially undergo treatment to suppress pubertal development.
- Pubertal hormone suppression should start after girls and boys first exhibit physical changes of puberty.
- GnRH analogues should be used to suppress pubertal hormones (where indicated).
- Adolescents requesting sex hormone treatment should begin with a gradual increasing dose schedule. This
 should be initiated following confirmation by a multidisciplinary team as well as informed consent by the patient
 (which is often established by age 16). The Society notes that while some studies show administration of
 hormones before age 13.5 to 14, a multidisciplinary team should evaluate for final determination.
- Approval for gender affirming surgery should be given only after completion of at least 1 year of consistent and compliant hormone treatment unless hormone therapy is not desired or medically contraindicated.
- Genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old.
- Puberty blocking and gender-affirming hormone treatment in pre-pubertal children with gender dysphoria/gender incongruence is not recommended.

The Endocrine Society (2009) also published a clinical practice guideline titled *Endocrine Treatment of Transsexual Persons* which focuses on gender dysphoria and provides a standard of care for supporting transgender individuals. Recommendations include evidence that treatment of gender dysphoria is medically necessary. Sections include:

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- 1. Diagnostic Procedure
- 2. Treatment of Adolescents
- 3. Hormonal Therapy for Transsexual Adults
- 4. Adverse Outcome Prevention and Long-Term Care
- 5. Surgery for Sex Reassignment

The **Endocrine Society** and the **Pediatric Endocrine Society** (2020) published a position statement on *Transgender Health* in support of medical interventions for transgender youth and adults. This includes puberty suppression, hormone therapy, and medically indicated surgery which are considered safe and effective when properly monitored and established as the standard of care. Patients should also undergo necessary screenings related to medically necessary surgeries.

The **Society for Adolescent Health and Medicine (SAHM)** published a *Position Paper on Promoting Health Equity and Nondiscrimination for Transgender and Gender-Diverse Youth* (2020) that encourages Providers treating adolescent and young adults to receive training in providing culturally effective, evidence-based care for transgender youth. The SAHM states that additional research on gender-affirming health care is needed and advocates for policies that protect the rights of transgender youth to limit barriers to healthcare. The SAHM aligns with other professional organizations and promotes the call for gender affirmation as a mainstay of treatment and is opposed to the notion that diversity in gender is pathological.

SUPPLEMENTAL INFORMATION

The following are terms related to gender care (Coleman et al., 2022; Perzanowski et al., 2020; Rafferty et al., 2018).

Term	Definition
Affirmed Gender	When one's true gender identity, or concern about their gender identity, is communicated
	to and validated from others as authentic
Agender	A term that is used to describe one who does not identify as having a particular gender.
Cisgender	Used to describe an individual who identifies and expresses a gender that is consistent with the culturally defined norms of the sex they were assigned at birth.
Eunuch	Individuals assigned male at birth and wish to eliminate masculine physical features, masculine genitals, or genital functioning
FTM	Used to describe individuals who were assigned female sex at birth but who have a gender
(affirmed male; trans male)	identity and/or expression that is asserted to be more masculine.
Gender Dysphoria	A concept designated in the <i>DSM-V-TR</i> as clinically significant distress or impairment related to a strong desire to be of another gender, which may include desire to change primary and/or secondary sex characteristics. Not all transgender or gender diverse people experience dysphoria.
Gender Expression	The external way an individual expresses their gender (e.g., clothing, hair, mannerisms, voice/speech patterns, activities, or social roles).
Gender Identity	An individual's deep internal sense of being female, male, a combination of both, somewhere in between, or neither, resulting from a multifaceted interaction of biological traits, environmental factors, self-understanding, and cultural expectations.
Gender Identity Disorder	A psychiatric diagnosis (previously defined in the <i>DSM-V-TR</i> that was changed to "gender dysphoria" in the <i>DSM-V-TR</i>). Primary criteria include a strong, persistent gender affirming identification and significant distress and social impairment. This diagnosis is no longer appropriate for use and may lead to stigma – the term may be found in older research.
Gender Perception	How others interpret a person's gender expression.
Gender Diverse	An umbrella term to describe individuals with gender identities and/or expressions that vary from expected developmental norms; includes individuals who identify as multiple genders or with no gender at all.



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Term	Definition
MTF (affirmed female;	Used to described individuals who were assigned male sex at birth but who have a gender
trans female)	identity and/or expression that is asserted to be more feminine.
Nonbinary	Individuals whose gender identity is neither girl/woman nor boy/man.
Sex	Assignment made at birth, usually male or female, based on external genital anatomy; may
	be based on internal gonads, chromosomes, or hormone levels.
Sexual Orientation	Describes the types of individuals toward whom a person has emotional, physical, and/or
	romantic attachments.
Transgender	An umbrella term describing individuals whose gender identity does not align in a traditional
	sense with the gender they were assigned at birth. It may also be used to refer to a person
	whose gender identity is binary and not traditionally associated with that assigned at birth.

The following are terms related to diagnoses (Garg et al., 2021):

Other Specified Gender Dysphoria applies to presentations in which symptoms characteristic of gender dysphoria that cause clinically significant distress or impairment in social, occupational, or other important areas of functioning predominate but do not meet the full criteria for gender dysphoria. The "other specified gender dysphoria" category is used in situations in which the clinician chooses to communicate the specific reason that the presentation does not meet the criteria for gender dysphoria. This is done by recording "other specified gender dysphoria" followed by the specific reason (e.g., "brief" gender dysphoria).

Unspecified Gender Dysphoria applies to presentations in which symptoms characteristic of gender dysphoria that cause clinically significant distress or impairment in social, occupational or other important areas of functioning predominate but do not meet the full criteria for gender dysphoria. The "unspecified gender dysphoria" category is used in situations in which the clinician chooses not to specify the reason that the criteria are not met for gender dysphoria and includes presentations in which there is insufficient information to make a more specific diagnosis.

Differential Diagnoses for gender dysphoria include: autogynephilia; body dysmorphic disorder; gynandromorphophilia; intersex states; psychosis; paraphilic disorders; self-amputation; schizophrenia; and transvestitism.

CODING & BILLING INFORMATION

CPT Codes

CP1 Codes	
CPT	Description
55970	Intersex surgery; male to female
19325	Breast augmentation with implant
54125	Amputation of penis; complete
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
54690	Laparoscopy, surgical; orchiectomy
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
57291	Construction of artificial vagina; without graft
57292	Construction of artificial vagina; with graft
57296	Revision (including removal) of prosthetic vaginal graft; open abdominal approach
57335	Vaginoplasty for intersex state
57426	Revision (including removal) of prosthetic vaginal graft, laparoscopic approach
55980	Intersex surgery; female to male
19303	Mastectomy, simple, complete
53410	Urethroplasty, 1-stage reconstruction of male anterior urethra
53420	Urethroplasty, 2-stage reconstruction or repair of prostatic or membranous urethra; first stage
53425	Urethroplasty, 2-stage reconstruction or repair of prostatic or membranous urethra; second stage

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53430	Urethroplasty, reconstruction of female urethra
54410	Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at
5 4410	the same operative session
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis
0	through an infected field at the same operative session, including irrigation and debridement of
	infected tissue
54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile
	prosthesis at the same operative session
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile
	prosthesis through an infected field at the same operative session, including irrigation and
	debridement of infected tissue
54660	Insertion of testicular prosthesis (separate procedure)
55175	Scrotoplasty; simple
55180	Scrotoplasty; complicated
56625	Vulvectomy simple; complete
57106	Vaginectomy, partial removal of vaginal wall
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 g or less
58262	Vaginal hysterectomy, for uterus 250 g 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 g
58291	Vaginal hysterectomy, 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	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 g or less
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g 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 g; with removal of
	tube(s) and/or ovary(s)
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or
	ovary(s)
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s)
	and/or ovary(s)
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral (separate procedure)

The following CPT codes may be considered Cosmetic Procedures and non-covered:

Blepharoplasty	
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

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Body Con	touring
15769	Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or
	legs; 50 cc or less injectate
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or
	legs; each additional 50 cc injectate, or part thereof (list separately in addition to code for primary
	procedure
15773	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears,
	orbits, genitalia, hands, and/or feet; 25 cc or less injectate
15774	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears
	orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (list separately in
	addition to code for primary procedure)
	and Reconstruction
19316	Mastopexy
19350	Nipple/areola reconstruction
Brow Lift	
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
Calf Impla	nt
27656	Repair, fascial defect of leg
Cheek, Ma	lar, Pectoral Implant
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
Chin/Nose	Implants, Chin Recontouring
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
21270	Malar augmentation, prosthetic material
Collagen I	njections
11950	Subcutaneous injection of filling material (eg, collagen); 1 cc or less
11951	Subcutaneous injection of filling material (eg, collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (eg, collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (eg, collagen); over 10.0 cc
	sion and Peels
15780	Dermabrasion; total face (eg, for acne scarring, fine wrinkling, rhytids, general keratosis
15781	Dermabrasion; segmental, face
15782	Dermabrasion; regional, other than face
15783	Dermabrasion; superficial, any site (eg, tattoo removal)
15788	Chemical peel, facial; epidermal
15789	Chemical peel, facial; dermal
15792	Chemical peel, nonfacial; epidermal
15793	Chemical peel, nonfacial; dermal
	Neck Tightening
15824	Rhytidectomy; forehead
15825	Rhytidectomy; neck with platysmal tightening (platysmal flap, P-flap)
15826	Rhytidectomy; glabellar frown lines
15828	Rhytidectomy; cheek, chin, and neck
15829	Rhytidectomy; superficial musculoaponeurotic system (SMAS) flap
	e Reduction
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21209	Osteoplasty, facial bones; reduction
	Reduction and Contouring
21137	Reduction forehead; contouring only
21137	Reduction forehead, contouring only Reduction forehead; contouring and application of prosthetic material or bone graft (includes
Z1130	obtaining autograft)
Hair Remo	
	IVAL



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Hair Transr	Hair Transplant		
15775			
15776	Punch graft for hair transplant; 1 to 15 punch grafts		
	Punch graft for hair transplant; more than 15 punch grafts tion, Contouring, Augmentation		
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)		
21121	Genioplasty; sliding osteotomy, single piece		
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (eg, wedge excision or bone wedge reversal for asymmetrical chin)		
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)		
Laryngopla			
31599	Unlisted procedure, larynx		
Lip Lift and			
40799	Unlisted procedure, lips		
Liposuction	n-Lipectomy		
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical		
	panniculectomy		
15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh		
15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg		
15834	Excision, excessive skin and subcutaneous tissue (includes lipectomy); hip		
15835	Excision, excessive skin and subcutaneous tissue (includes lipectomy); buttock		
15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm		
15837	Excision, excessive skin and subcutaneous tissue (includes lipectomy); forearm or hand		
15838	Excision, excessive skin and subcutaneous tissue (includes lipectomy); submental fat pad		
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area		
15876	Suction assisted lipectomy; head and neck		
15877	Suction assisted lipectomy; trunk		
15878	Suction assisted lipectomy; upper extremity		
15879	Suction assisted lipectomy; lower extremity		
Rhinoplast			
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		
30420	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)		
30435	Rhinoplasty, secondary, intermediate revision (bony work with osteotomies)		
30450	Rhinoplasty, secondary, intermediate revision (bory work with osteotomies)		
	duction Chondroplasty		
31750	Tracheoplasty; cervical		
	Voice Modification		
31899	Unlisted procedure, trachea, bronchi		
3.000	Complete processing, tradition, province		

HCPCS Codes - None.

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

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APPROVAL HISTORY

2/8/2023 Policy reviewed, changed the duration of hormone therapy for adults from 12 months to 6 months per WPATH 8 update; included

updates to national and specialty organizations, including WPATH 8.

4/13/2022 New policy.

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APPENDIX

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.

Additional State Information

ILLINOIS

As of January 1, 2020, the Illinois Department of Healthcare and Family Services ("the Department") reimburses for gender-affirming surgeries and services subject to the establishment of medical necessity and prior authorization.

The Department has provided the criteria that must be met for approval of gender affirming surgery in <u>89 III. Adm.</u> Code 140.413.