

Subject: Gender Dysphoria Treatment		Original Effective Date: 11/24/14
Molina Clinical Policy: MCP-216	Revision Date(s):	

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Transsexualism also known as gender dysphoria is the condition in which a person with apparently normal somatic sexual differentiation of one gender is convinced that he or she is actually a member of the opposite gender. It is associated with an irresistible urge to be in the opposite gender hormonally, anatomically, and psychosocially. According to the American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders (DSM-V) gender dysphoria is described as a condition in which an individual is intensely uncomfortable with their biological gender and strongly identifies with, and wants to be, the opposite gender. For a person to be diagnosed with gender dysphoria there must be a marked difference between the individual’s expressed/experienced gender and the gender others would assign him or her, and it must continue for at least six months. In children, the desire to be of the other gender must be present and verbalized. This condition causes clinically significant distress or impairment in social, occupational, or other important areas of functioning. Gender dysphoria is manifested in a variety of ways, including strong desires to be treated as the other gender or to be rid of one’s sex characteristics, or a strong conviction that one has feelings and reactions typical of the other gender.

The current ICD-10 criteria for transsexualism include: ¹²

- The desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatments.
- The transsexual identity has been present persistently for at least two years.
- The disorder is not a symptom of another mental disorder or a genetic, intersex, or chromosomal abnormality.

The treatment of gender dysphoria requires a multidisciplinary team and step-wise approach in order to promote optimal health for individuals of this diverse population. The initial assessment of a patient with transsexualism is based on psycho-diagnostic instruments and ideally should be performed by a mental health professional. Counseling is essential before initiating hormonal or surgical treatment. It is recommended that when or before hormone treatment starts, the individual should begin living in the role of the opposite gender. The World Professional Association for Transgender Health Standards of Care provides the following criteria for starting hormone therapy and for undergoing surgical procedures: diagnosis of persistent, well-documented gender dysphoria, the capacity to make a well-informed decision, the person must be of legal age; and any medical or mental issues are well-controlled. The goal of treatment in female-to-male transsexual individuals is to stop menses and induce virilization, including a male pattern of sexual hair, male physical contours, and clitoral enlargement. The principal hormonal treatment is a testosterone preparation. For male-to-female transsexual individuals the goal is elimination of sexual hair growth, induction of breast formation, and a more female fat

distribution are essential. To accomplish this, a near-complete reduction of the biological effects of androgens is required.

Genital sex reassignment surgery is the final step for many transsexual individuals to live successfully in their preferred gender role. In male-to-female transsexual persons, a bilateral orchiectomy is performed to remove the main source of endogenous testosterone. In addition to gonadectomy, other procedures include penectomy, cosmetic surgery to create a clitoris, and surgical construction of a vagina. For female-to-male transsexual individuals, an oophorectomy, hysterectomy, and vaginectomy are generally performed after one to two years of androgen therapy according to practice guidelines.

RECOMMENDATION

1. Hormone Replacement may be considered medically necessary and may be authorized when there is a **benefit** for treatment of gender dysphoria and ALL of the following criteria are met ^{2 6}:
 - Age 18 years or older; and
 - The individual has the capacity to make a fully informed decision and to consent for treatment; and
 - A definitive diagnosis of persistent gender dysphoria has been made and documented by a qualified mental health professional such as a licensed psychiatrist, psychologist or psychotherapist and all of the following are present: [ALL]
 - The desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatment; and
 - The transsexual identity has been present persistently for at least two years; and
 - The disorder is not a symptom of another mental disorder; and
 - The disorder causes clinically significant distress or impairment in social, occupational, or other important areas of functioning; and
 - Recommendation for hormone replacement treatment has been made by an endocrinologist who has confirmed the diagnosis of persistent gender dysphoria by the qualified mental health professional; and
 - Initial hormone therapy must be prescribed by an endocrinologist preceded by all of the following: [ALL]
 - Documentation that the individual has lived as their new gender full-time for 3 months or more prior to the administration of hormones; and
 - Documentation of continuous psychotherapy after the initial evaluation for a minimum of three months to identify any comorbid psychiatric diagnosis that may require treatment; and
 - Documentation that the individual has demonstrable knowledge of the risks and benefits of hormone replacement

2. Surgical Treatment* may be considered medically necessary and may be authorized when there is a **benefit** for surgical treatment of gender dysphoria and ALL of the following criteria are met ^{3 6}:

- Age 18 years of age or older; and
 - The individual has the capacity to make a fully informed decision and to consent for treatment; and
 - A definitive diagnosis of persistent gender dysphoria has been made and documented by a qualified mental health professional such as a licensed psychiatrist, psychologist or psychotherapist and all of the following are present: [ALL]
 - The desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatment; and
 - The transsexual identity has been present persistently for at least two years; and
 - The disorder is not a symptom of another mental disorder; and
 - The disorder causes clinically significant distress or impairment in social, occupational, or other important areas of functioning; and
 - Documentation of two separate written referrals for surgery or one letter signed by both qualified mental health professionals if practicing within the same office; and
 - Continuous hormone therapy has been provided for 12 months under the supervision of an endocrinologist with documentation of compliance and the type, frequency, and route of the medication administered for 12 months or more unless hormones are not clinically indicated; and
 - There is documentation that the individual has lived as their new gender full-time for 12 months or more; and
 - There is documentation from medical and mental health providers that there are no contraindications to the planned surgery and any medical or mental issues are well-controlled; and
 - The surgery must be performed by a qualified provider at a facility with a history of treating individuals with persistent gender dysphoria disorder
3. *Surgical Procedures for Gender Reassignment for the Treatment of Persistent Gender Dysphoria may include any of the following:

Male-to-Female Procedures

- Clitoroplasty
- Orchiectomy
- Penectomy
- Vaginoplasty
- Vulvoplasty

Female-to-Male Procedures

- Hysterectomy

- Mastectomy
- Metoidioplasty
- Oophorectomy
- Phalloplasty
- Salpingectomy
- Vaginectomy

4. **Exclusions:** The following ancillary procedures and services for the treatment of gender dysphoria are excluded and are considered cosmetic⁴, including but not limited to:

- blepharoplasty,
- collagen injections,
- face-lifting, hair removal or transplantation,
- facial bone reduction,
- facial implants,
- laryngoplasty,
- liposuction, lip reduction or enhancement,
- reduction thyroid chondroplasty,
- rhinoplasty,
- skin resurfacing,
- voice modification surgery, and voice therapy or lessons

SUMMARY OF MEDICAL EVIDENCE¹⁵⁻²⁸

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 and cross sectional studies that compared outcomes in either transgendered patients who had undergone SRS versus those who had not undergone SRS. The majority 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 1 month to 7 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 mental health professional, and that while 1 referral is sufficient for breast or chest surgery, 2 independent referrals should be required for genital SRS. Individuals who have medical contraindications to surgery should not undergo SRS.¹⁵⁻²⁰

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 cross-sex 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

each assessed and results were generally positive.²¹⁻²⁷ 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.²⁸

Medically necessary criteria were developed according to the World Professional Association for Transgender Health Standards of Care, 7th version.⁶

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
55970	Intersex surgery; male to female
55980	Intersex surgery; female to male

HCPCS	Description

ICD-9	Description
302.50 -302.53	Trans-sexualism
302.6	Gender identity disorder in children or NOS
302.85	Gender identity disorder in adolescents or adults

ICD-10	Description
F64-F64.9	Gender identity disorders

REFERENCES

- Centers for Medicare and Medicaid Services. Transmittal #: R169NCD; Issue Date: June 27, 2014 Subject: Invalidation of National Coverage Determination 140.3 - Transsexual Surgery. Accessed at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R169NCD.html>
- Hayes Medical Technology Directory. Hormone Therapy for the Treatment of Gender Dysphoria. Winifred Hayes Inc. Lansdale, PA. May 19, 2014.
- Hayes Medical Technology Directory. Sex Reassignment Surgery for the Treatment of Gender Dysphoria. Winifred Hayes Inc. Lansdale, PA. May 19, 2014.
- Hayes Medical Technology Directory. Ancillary Procedures and Services for the Treatment of Gender Dysphoria. Winifred Hayes Inc. Lansdale, PA. May 19, 2014.
- Day P. Trans-gender reassignment surgery. New Zealand health technology assessment (NZHTA). The clearing house for health outcomes and Health technology assessment. February 2002; Volume 1 Number 1 Available at: http://nzhta.chmeds.ac.nz/publications/trans_gender.pdf.

6. World Professional Association for Transgender Health (WPATH). Standards of care for the health of transsexual, transgender, and gender nonconforming people. 7th version. 2011. Available at: <http://www.wpath.org/documents/Standards%20of%20Care%20V7%20-%202011%20WPATH.pdf>.
7. World Professional Association for Transgender Health (WPATH) (formerly The Harry Benjamin International Gender Dysphoria Association). Standards of Care for Gender Identity Disorders. 6th version. 2001 Feb. Available at: <http://wpath.org/Documents2/socv6.pdf>.
8. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. 2013. Washington, DC. Pages 451-459.
9. American Psychiatric Association. Gender Dysphoria. 2013. Accessed at: <http://www.dsm5.org/documents/gender%20dysphoria%20fact%20sheet.pdf>
10. Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab* 2009; 94:3132.
11. Center of Excellence for Transgender Health. Surgical options. Accessed at <http://transhealth.ucsf.edu/trans?page=protocol-surgery>
12. World Health Organization (WHO). The ICD-10 Classification of Mental and Behavioural Disorders. Geneva 1993. Accessed at: <http://www.who.int/classifications/icd/en/GRNBOOK.pdf>
13. UpToDate: Transsexualism: Gooren L, Tangpricha V. Epidemiology, pathophysiology, and diagnosis. August 2014.
14. UpToDate: Transsexualism: Gooren L, Tangpricha V. Treatment of transsexualism. August 2014.
15. Berry MG, Curtis R, Davies D. Female-to-male transgender chest reconstruction: a large consecutive, single-surgeon experience. *J Plast Reconstr Aesthet Surg*. 2012;65(6):711-719.
16. Motmans J, Meier P, Ponnet K, T'Sjoen G. Female and male transgender quality of life: socioeconomic and medical differences. *J Sex Med*. 2012;9(3):743-50.
17. Weigert R, Frison E, Sessiecq Q, Al Mutairi K, Casoli V. Patient satisfaction with breasts and psychosocial, sexual, and physical well-being after breast augmentation in male-to-female transsexuals. *Plast Reconstr Surg*. 2013;132(6):1421-1429.
18. Heylens G., Verroken C., De Cock S., T'Sjoen G., De Cuypere G. Effects of different steps in gender reassignment therapy on psychopathology: a prospective study of persons with a gender identity disorder. *J Sex Med*. 2014;11(1):119-126.
19. Dhejne C, Lichtenstein P, Boman M, Johansson AL, Långström N, Landén M. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. *PLoS One*. 2011;6(2):e16885.
20. Ainsworth TA, Spiegel JH. Quality of life of individuals with and without facial feminization surgery or gender reassignment surgery. *Qual Life Res*. 2010;19(7):1019-1024.
21. Gorin-Lazard A, Baumstarck K, Boyer L, et al. Hormonal therapy is associated with better self-esteem, mood, and quality of life in transsexuals. *J Nerv Ment Dis*. 2013;201(11):996-1000.
22. Gorin-Lazard A, Baumstarck K, Boyer L, et al. Is hormonal therapy associated with better quality of life in transsexuals? A cross-sectional study. *J Sex Med*. 2012;9(2):531-541.
23. Colizzi M, Costa R, Todarello O. Transsexual patients' psychiatric comorbidity and positive effect of cross-sex hormonal treatment on mental health: Results from a longitudinal study. *Psychoneuroendocrinology*. 2014;39:65-73.

24. Fisher AD, Castellini G, Bandini E, et al. Cross-sex hormonal treatment and body uneasiness in individuals with gender dysphoria. *J Sex Med.* 2014;11(3):709-719
25. Costantino A, Cerpolini S, Alvisi S, Morselli PG, Venturoli S, Meriggiola MC. A prospective study on sexual function and mood in female-to-male transsexuals during testosterone administration and after sex reassignment surgery. *J Sex Marital Ther.* 2013;39(4):321-335.
26. Heylens G, Verroken C, De Cock S, T'Sjoen G, De Cuypere G. Effects of different steps in gender reassignment therapy on psychopathology: a prospective study of persons with a gender identity disorder. *J Sex Med.* 2014;11(1):119-126.
27. Wierckx K, Elaut E, Declercq E, et al. Prevalence of cardiovascular disease and cancer during cross-sex hormone therapy in a large cohort of trans persons: a case-control study. *Eur J Endocrinol.* 2013;169(4):471-478.
28. Murad MH, Elamin MB, Garcia MZ, et al. Hormonal therapy and sex reassignment: a systematic review and meta-analysis of quality of life and psychosocial outcomes. *Clin Endocrinol (Oxf).* 2010;72(2):214-231.

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Policy (MCP) document and provide the directive for all Medicare members. | Molina Clinical Policy

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members.