

# MEDICAL POLICY STATEMENT KENTUCKY MARKETPLACE

Policy Name	Po	olicy Number	Effective Date	
Gender Dyspho	ria	MM-0746	9/1/2019	
Policy Type				
MEDICAL	Administrative	Pharmacy	Reimbursement	

Health Insurance Exchange Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) apply to health insurance exchange health benefit plans administered by CSMG and its affiliates and are derived from literature based on and supported by applicable federal or state coverage mandates, clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Health care services or supplies needed to diagnose or treat an illness, condition, disease or its symptoms and that meet accepted standards of medicine. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any federal or state coverage mandate, Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

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**Gender Dysphoria** 

#### B. BACKGROUND

Individuals with gender dysphoria have persistent feelings of gender discomfort and inappropriateness for their natal anatomical sex, strong and ongoing cross-gender identification, and a desire to live and be accepted as a member of the opposite sex.

The Diagnostic and Statistical Manual of Mental Disorders—Fifth Edition (DSM-5, 2013) deleted the term "Gender Identity Disorder", and created a new category of "Gender Dysphoria" to reflect its position that gender dysphoria is no longer considered a sexual dysfunction. A clinicallysignificant distress or impairment in social, occupational, or other important area of functioning (in addition to the symptoms noted in DSM-5) is required to diagnose gender dysphoria. Gender nonconformity is not considered to be a psychiatric disorder.

There are typically three approaches that have been attempted to alleviate or to reduce the symptoms of gender dysphoria. These include psychotherapy, hormonal therapy, and sexual reassignment surgery (SRS). Not all individuals with gender dysphoria elect all of these approaches. Some individuals with gender dysphoria may wish to use hormones but not elect surgery. Sexual reassignment surgery involves surgery to alter the genitals and/or chest. Additional cosmetic surgeries have been performed to alter other secondary sex characteristics.

Older terminologies for gender dysphoria prior to 2013 included gender identity disorder, intersex, and transsexual. These terminologies are no longer consistent with current thinking and relate to different criteria no longer used.

#### C. DEFINITIONS

- Female-to-Male (FtM): An adjective to describe an individual born or assigned as female at birth ("natal female"), who is changing or who has changed to a more masculine body or gender role.
- Male-to-Female (MtF): An adjective to describe an individual born or assigned as male at birth ("natal male"), who is changing or who has changed to a more feminine body or gender
- Gender Dysphoria: Distress that accompanies the incongruence between one's experienced/expressed gender and one's assigned or natal gender. The incongruence must be experienced for at least 6 months, and cause distress.
- Gender-Nonconforming: Adjective used to describe individuals whose gender identity, role or expression differs from what is normative for the assigned sex in a given culture and historical period.
- Gender Identity: A category of social identity that refers to an individual's identification as male, female, neither, or a combination of male and female, and may be different from an individual's sex assigned at birth.
- Gender Expression: Refers to the way a person communicates gender identity to others through behavior, clothing, hairstyles, and voice or body characteristics.
- Gender Reassignment: A change of gender that can be medical (hormones, surgery), legal (government recognition) or both.
- Gender Role: Characteristics in personality, appearance, and behavior that in a given culture and historical period are designated as masculine or feminine. Some individuals express an alternative role that is not clearly masculine or feminine.
- Department of Health and Human Services (HHS), Office of Civil Rights (OCR): A federal agency that ensures equal access to certain health and human services and protects the privacy and security of health information.



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- Health services related to gender transition: means a range of health services related to gender transition, which includes treatment of gender dysphoria, is not limited to surgical treatments and may include services such as hormone therapy and psychotherapy, which may occur over the lifetime of the individual.
- Patient Protection and Affordable Care Act: means the major health reform bill passed by
  the Senate and signed into law in March 2010. Its purpose was to expand health coverage to
  those that were uninsured, through a combination of cost controls, subsidies and mandates.
- Qualified Mental Health Professional (QMHP): An individual with a master's or doctoral degree in a clinical behavioral health field; granted by an institution accredited by the appropriate national accrediting board, who demonstrates competence in use of the current Diagnostic and Statistical Manual of Mental Disorders and/or current version of the International Classification of Diseases, who is able to recognize co-existing mental health concerns and make referrals for co-existing medical concerns. QMHP should have documented training of supervision and/or continuing education in psychotherapy, including specialized training about gender nonconformities and the diagnosis and treatment of gender dysphoria.
- **Sex:** Usually based on the appearance of the external genitalia and defined as male or female as understood in the context of reproductive capacity, such as sex hormones, chromosomes, gonads and non-ambiguous external and internal genitalia. At times, sex is assigned when external genitalia are ambiguous.
- Sexual reassignment surgery (SRS): Surgery to change primary and/or secondary sex characteristics to affirm a person's gender identity. It has also been referred to as intersex surgery, transgender surgery, and gender confirmation surgery in the literature.
- **SRS Surgeon:** board-certified urologist, gynecologist, plastic surgeon or general surgeon competent in urological diagnosis and treatment of transgender individuals
- Transgender: An umbrella term for persons whose gender identity, gender expression or behavior does not conform to that typically associated with the sex to which they were assigned at birth. "Trans" is sometimes used as an acceptable shorthand when referring to "transgender."

#### D. POLICY

It is the policy of CareSource to comply with state and federal regulations.

CareSource treats all members consistent with their gender identity and does not deny or limit health services that ordinarily or exclusively are available to individuals of one sex to a transgender individual based on the fact that the individual's sex or gender is different from the one to which health services are normally or exclusively available.

CareSource covers those services that are medically necessary. In determining services that are medically necessary, or the coverage of health services related to gender transition, CareSource utilizes neutral standards supported by evidence-based criteria.

The prevalence of gender dysphoria is very small. In the US population the MtF prevalence is about 0.005-0.14%. FtM prevalence is thought to be 0.002 -0.003%. The determinants of gender dysphoria are poorly understood. Gender dysphoria is considered a psychological state. It is not discussed in terms of physical abnormalities. It is important to establish that dysphoria is present and the dysphoria must persist (i.e. it is not merely situational or temporary). A diagnostic assessment for gender dysphoria is an important part of an evaluation of gender-nonconforming individuals when mental health symptoms are present. It is recommended that the assessment be performed by a Qualified Mental Health Professional Gender Dysphoria is diagnosed using the Diagnostic and Statistical Manual of Mental Disorders criteria:

I. Evaluation of the Evidence The body of evidence for treating gender dysphoria is relatively large in size and low to very-low in quality. The evidence suggests positive benefits for treatment of GD, but because of



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serious limitations in study designs it permits only weak conclusions regarding sex reassignment surgery. No conclusions can be made about the benefits of SRS or about different components of SRS. Many of the studies were performed outside of the US. An additional concern is that Institutional Review Board (IRB) oversight of study design, ethics, and safety is not always clear. Studies researching treatments for gender dysphoria with a US IRB approval are rare. Some researchers do not present conflicts of interest they have related to the study.

Studies in children and adolescents under the age of 16 that have been under the purview of an IRB are virtually nonexistent. A few investigators added adolescent subjects into adult studies; however results were not reported separately in the study conclusions.

Minors are a vulnerable population according to US institutional review Board (IRB) standards. For persons less than age 18, to protect vulnerable minors according to US standards, studies must be approved by a US institutional review board (IRB) accredited by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP). This approach satisfies the US Code of Federal Regulations Title 25 Part 46 "Protection of Human Subjects", including research performed on minors (See http://www.aahrpp.org/learn/find-an-accredited-organization.

The ECRI Institute compiled a summary report for CareSource on Gender Dysphoria in January, 2016. ECRI searched studies from published PubMed, EMBASE, Cochrane Library, PsychINFO, and selected web-based resources between January 1, 2010 and January 8, 2016. The search was undertaken for clinical studies regarding gender dysphoria, study effectiveness, and the extent by which individuals were protected by an Institutional Review Board (IRB) for safety.

An additional inclusion requirement for the ECRI report was that results for adolescents and adults needed to be reported separately to be included. Studies not published in English were excluded. The topic included sexual reassignment surgery reporting at least one patient-oriented outcome. Outcomes included mortality, patient satisfaction, physical well-being, psychological- and sexual-related outcomes, quality-of-life, suicide, and adverse events.

#### A. Sexual Reassignment Surgery

- 1. There were two systematic reviews and four primary studies found in the ECRI search. Both were determined to be of low to intermediate quality. The majority of studies were of retrospective design. Standardized protocols and prospective study designs are needed for correct interpretation and comparability of data. Standardized outcome measures with protocols were not consistently used across studies. No IRB was noted for the systematic reviews. One of the primary studies had a US IRB.
  - a. Horbach et al. performed a systematic review including 26 studies published after 1994; looking at all techniques of vaginoplasty, where an outcome was reported. The authors concluded that penile skin inversion (n=1,461) technique is the most researched, however bowel vaginoplasty (n=102) did not seem to be inferior. Neovaginal stenosis was the most reported complication in both techniques. There was lack of standardization when comparing patient groups, surgical procedures, outcome measurement tools and follow-up. Study participants noted sexual function and satisfaction were "acceptable." The retrospective design made interpretation and generalization difficult due to lack of standardization. No IRB was noted for the study.
  - b. Bourman et al. studied 894 patients for clinical outcomes of intestinal vaginoplasty suggested low complication rates. Studies were all retrospective design and were of low quality. The study did not look at gender dysphoria, rather surgical complications. The author concluded vaginoplasty has a low complication rate based on evidence currently available. The study noted that more studies are



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needed to substantiate the findings using functional outcomes and quality of life studies, using prospective designs and standardized measures.

- 2. The four primary studies cited by ECRI included 630 transgender individuals.
  - a. Amend et al. looked at 24 consecutive patients undergoing MtF gender reassignment at a German university clinic. All data were entered prospectively into a database that was queried retrospectively. The author concluded that gender reassignment can be performed with minimal complications. Intraoperative complications rate was highest at 8.3% for bleeding. Postoperative complication rates showed highest rates at 8.3% for bleeding and transient urge incontinence. Secondary cosmetic correction surgery occurred in over half of the individuals (54.2%). An IRB approved the database content which included non IRB studies.
  - b. Weigert et al. did a prospective non-comparative cohort study in 35 consecutive MtF patients undergoing breast augmentation surgery satisfaction. The author concluded that the study results suggest gains in breast satisfaction were associated with psychosocial well-being and sexual well-being. No change was seen in physical well-being. The study was approved by IRB at University of Bordeaux, Bordeaux, France.
  - c. Dhejne et al. did a nonrandomized controlled/comparison study of 324 sex-reassigned individuals (191 MtF, 133 FtM), and compared them with matched controls by birth year and birth sex or reassigned sex. Overall mortality of sex-reassigned persons was higher during follow-up (adjusted HR 2.8; 95% CI 1.8-4.3) than controls of the same birth sex, particularly death from suicide (adjusted HR 19.1; 95% CI 5.8-62.9). Sex-reassigned persons also had an increased risk for suicide attempts (adjusted HR 4.9; 95% CI 2.9-8.5) and psychiatric inpatient care (adjusted HR 2.8; 95% CI 2.0-3.9) after adjustment for prior psychiatric morbidity. The author concluded that although sex reassignment my alleviate gender dysphoria, it may not suffice as treatment for transsexualism and should inspire improved psychiatric and somatic care for this group. FtM but not MtF had a higher risk of criminal convictions. The study was reviewed by an IRB, Karolinska Institute, Stockholm, Sweden.
  - d. Ainsworth and Spiegel did a survey of 247 MtF individuals on quality-of-life (intervention not specified) having 4 arms: facial feminization surgery (FFS), sexual reassignment surgery (SRS), FFS + SRS, and no surgery. The authors found mental health-related quality of life was statistically diminished (P < 0.05) in transgendered women without surgical intervention compared to female general population controls. There was no statistically-significant difference in the mental health related quality of life among transgendered women who had gender reassignment surgery, FFS, or both. They reported that surgical treatment was associated with improved mental health quality of life. The study was approved by an IRB at Boston University School of Medicine, Boston, MA.
- 3. Hayes performed a review of 36 studies assessing the effectiveness of sexual reassignment surgery. In addition, 13case series evaluating safety outcomes from 11/2004 to 4/2018 were summarized in a report titled, "Sex Reassignment Surgery for the Treatment of Gender Dysphoria. The findings included:
  - a. There is insufficient evidence to establish patient selection criteria for sexual reassignment surgery to treat gender dysphoria.
  - b. The quality of evidence in the published studies it reviewed was very low. The Hayes rating reflects the reporting of some positive evidence but serious limitations in the evidence of both effectiveness and safety.
  - c. The evidence suggests positive benefits but because of serious limitations permit only weak conclusions regarding sex reassignment surgery for gender dysphoria. No conclusions can be made about the benefits of SRS or about different components of sexual reassignment surgery.



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- II. COMMENT BY GOVERNMENTAL AGENCIES AND PROFESSIONAL ORGANIZATIONS
  - A. Centers for Medicare and Medicaid Services
    - CMS reported a literature search of primary studies evaluating interventions for gender dysphoria. Included a review of evidence of primary studies with emphasis on various surgical interventions, but other treatments including therapy, psychotherapy, psychiatric treatment, ancillary reproductive and gender modifying services and postoperative surveillance were included for 1965 to current date.
    - 2. The CMS literature search concluded "based on a thorough review of the clinical evidence available at this time, there is not enough evidence to determine whether gender reassignment surgery improves health outcomes."
      - a. The report noted that CMS is not issuing a NCD at this time because the available evidence for gender reassignment surgery provides limited data on specific health outcomes and the characteristics of specific patient populations that might benefit from surgery. The report also notes CMS is not in a position to endorse exclusive use of World Professional Association for Transgender Health (WPATH) guidelines given that WPATH acknowledges the guidelines should be flexible.
      - b. Of the 33 studies which met CMS inclusion criteria in the literature review, it states "All studies had potential methodological flaws." The quality and strength of evidence were low due to mostly observational study designs with no comparison groups, subjective endpoints, potential confounding, small sample sizes, lack of validated assessment tolls and considerable loss to follow up.
        - 01. Of the 33 studies reviewed, some were positive, others were negative. CMS stated "Collectively the evidence is inconclusive."
        - 02. CMS stated there were six studies that could provide useful information.
        - 03. Of these six studies, the four best-designed and conducted studies that assessed quality of life before and after surgery using validated (albeit nonspecific) psychometric studies did not demonstrate clinically-significant changes or differences in psychometric test results after genital reassignment surgery.
        - 04. The two remaining studies assessed functional endpoints showing increased mortality and psychiatric hospitalization compared to matched controls. Mortality was primarily due to suicide, but death due to neoplasm and cardiovascular disease was increased 2-2.5 times as well.
  - B. Local Medicare Administrative Contractors (MACs)
    At the time of this policy, the local MAC serving Kentucky has not issued a local coverage determination.
  - C. World Professional Association for Transgender Health (WPATH) is an international professional non-profit organization with a mission to promote evidence- based care, education, research, advocacy, public policy and respect in transgender health. WPATH published Ethical Guidelines for Professionals and Standards of Care (SOC) for Gender Identity Disorders. Although the standards are comprehensive and have a reference list, neither a systematic approach nor an appraisal of evidence was used. WPATH criteria for surgery are based on "available evidence and expert clinical consensus." WPATH states that it's SOC are flexible clinical guidelines. Providers are permitted to depart from these SOC for the following reasons: unique anatomic, social or psychological situations, lack of resources, research protocols, and the need for harm reduction.
  - D. Food and Drug Administration (FDA)
    - 1. Reassignment surgeries are procedures, and therefore not subject to FDA regulation
    - 2. FDA does review and approve the type of implants
  - E. American Psychiatric Association
    - 1. Created a position statement that appropriately-evaluated transgender and gender variant individuals can benefit greatly from medical and surgical treatments
    - 2. Has not issued evidence-based guidelines in either children or adults.
    - 3. Did not perform a systematic review of the literature for all categories of treatment for the position statement.



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- F. American Psychological Association
  - 1. Developed guidelines for the psychological practice with transgender and gender nonconforming people
  - 2. Did not perform a systematic review of the literature for all categories of treatment for the position statement. Review was mostly psycho-social approach.
  - 3. Notes evidence may be lacking for empirically-based recommendations
- G. American Medical Association
  - Made three resolutions under "Clarification of Medical Necessity for Treatment of Gender Dysphoria"
    - a. Supports public and private insurance coverage for treatment of gender dysphoria
    - b. Recognize that medical and surgical treatments for gender dysphoria are medically necessary when following standards of care
    - Will advocate for federal, state, and local policies to provide medically necessary care
  - 2. Did not discuss the evidence for sexual reassignment surgery.
  - 3. Did not perform a systematic review of the literature for all categories of treatment for the position statement.
- H. American Academy of Child & Adolescent Psychiatry
  - 1. Provides information on psychosexual development
  - 2. Lists principles of care
- I. Endocrine Society
  - 1. Developed clinical practice guideline based on consensus from experts for endocrine treatment of gender dysphoria/gender incongruent persons.
  - 2. Found the quality evidence to be low related to surgical intervention.

#### III. COVERED SERVICES

- A. Behavioral Health services for children, adolescents and adults are covered for:
  - An assessment by a qualified mental health professional to evaluate and document if member meets DSM criteria for gender dysphoria.
  - 2. Treatment of medically-necessary services by a qualified mental health professional (QMHP). The focus of gender dysphoria treatment should provide ample opportunity for the member to experience and socially adjust to living in the desired gender identity including issues related to living a real-life experience as the member explores their new gender identity and contemplates transition. Qualified mental health professionals can help members considering potential interventions to have clear and realistic expectations of the outcomes intended.
  - 3. Members presenting with gender dysphoria may have a number of co-existing behavioral health disorders including depression, suicidal ideation, substance abuse, sexual concerns, eating disorders, personality disorders, psychotic disorders and autism spectrum disorders. Suicide behaviors and attempts create an elevated risk for future attempts and should be addressed appropriately by the QMHP. Provider collaboration is essential.
- B. Surgery requires a medical necessary review (see IIIC and IV)
  - 1. QMHP is responsible for providing and documenting informed consent to member from a behavioral-health perspective:
    - a. Discussion of advantages and disadvantages of mental health outcomes related to gender transformation surgery
    - b. Discussion of alternatives to surgery
  - 2. WPATH discusses the relationship of surgeons with mental health professionals and physicians:
    - a. "The role of the surgeon in the treatment of gender dysphoria is not that of a mere technician. Rather, conscientious surgeons will have insight into each patient's history and the rationale that led to the referral to surgery. To that end, surgeons must talk at length with their patients and have close working relationships with other professionals who have been actively



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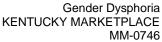
involved in their clinical care."

- 3. In addition, WPATH states that surgeons are responsible for discussing all of the following with patients seeking surgical treatments for gender dysphoria:
  - a. The different surgical techniques available (with referral to colleagues who provide alternative options)
  - b. The advantages and disadvantages of each technique
  - c. The limitations of a procedure to achieve "ideal" results; surgeons should provide a full range of before-and-after photographs of their own patients, including both successful and unsuccessful outcomes
  - d, The inherent risks and possible complications of the various techniques; surgeons should inform patients of their own complication rates with each procedure
- C. The following are requirements that apply for consideration of sexual reassignment surgery: (List is not meant to represent all requirements)
  - 1. Breast/chest surgery
    - a. Unless contraindicated or is unable to take, individual has participated in 12 consecutive months of cross-sex hormone therapy for the desired gender.
    - b. Hormone trial must be with a medication prescribed to the member
    - d. One letter of recommendation from a QMHP to the surgeon is required
      - 01. QMHP has evaluated the member within the past twelve months of the time of referral
      - 02. If member has been in behavioral health treatment, it is preferred that the recommendation is made by the behavioral health treatment provider (if the provider is a QMHP)
      - 03. If there is not a treating QMHP, a letter of recommendation may be made by a consulting QMHP
      - 04. If the QMHP is a member of a treatment team with the surgeon, documentation in the integrated clinical record is an option in lieu of a letter
      - 05. Content of the QMHP referral letter must address at minimum:
        - (1) Duration of evaluator's relationship with the member
        - (2) Member has well-documented diagnosis of gender dysphoria
        - (3) A member specific treatment plan
        - (4) Member has capacity to give informed consent for surgery
        - (5) Member is age 18 years or older
        - (6) Member has had a twelve-month or longer real-life experience congruent with their gender identity
        - (7) The gender dysphoria diagnosis has been consistently persistent for a duration of 6 months or longer at the time of the authorization request.
        - (8) If co-existing mental illness substance related disorder are present, it is relatively well controlled, there has been no active intravenous drug use for the past 3 months and no suicide attempts or behaviors in the past 6 months.
        - (9) QMHP communicates willingness to be available to treat the member during transition or make appropriate referral if member needs assistance with behavioral health treatment

#### 2. Genital surgery

- At least twelve months of continuous hormone treatment is required to be considered for surgery, unless there is a well-documented contraindication or refusal to take hormones
- b. Hormone trial must be with a medication prescribed by a provider
- c. Hair removal may be simultaneously approved with genital surgery based on medical necessity when skin flap area contains hair needing to be removed
- Two letters of recommendation from separate QMHPs to the surgeon are required
   QMHP has evaluated the member within the past twelve months of the time of referral
  - 02. If member has been in treatment, it is preferred that one of the





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- recommendations is made by the treatment provider (if the provider is a QMHP)
- 03. If there is not a treating QMHP, the letters of recommendation may be made from two separate QMHPs
- 04. If the QMHP is a member of a treatment team with the surgeon, documentation in the integrated clinical record is an option in lieu of a letter
- 05. Content of referral must address at minimum:
  - (1) Duration of evaluator's relationship with the member
  - (2) Member has well-documented diagnosis of gender dysphoria
  - (3) Member has capacity to give informed consent for surgery
  - (4) A member specific treatment plan
  - (5) Member is age 18 years or older
  - (6) Member has had a twelve-month or longer in real life experience congruent with their gender identity
  - (7) QMHP communicates willingness to be available to treat the member during transition or make appropriate referral if member needs assistance with behavioral health treatment
  - (8) The gender dysphoria diagnosis has been consistently persistent for a duration of 6 months or longer at the time of the authorization request.
  - (9) If co-existing mental illness or substance use disorder are present, it is relatively well controlled, there has been no active intravenous drug use for the past 3 months and no suicide attempts or behaviors in the past 6 months.

#### IV. SERVICES REQUIRING MEDICAL NECESSITY REVIEW

- A. Prior Authorization (PA) must be submitted for genital or breast surgery involved with the gradual progression from male to female or female to male. The PA is only valid if the member is eligible for the applicable item or service on the date of service.
- B. Members under the age of 21 will be reviewed for medical necessity as required by the Early Periodic Screening, Diagnosis and Treatment (EPSDT) program. In general, CareSource considers hormonal and surgical services for gender transition not medically necessary. This is due to the virtual nonexistence of research in these populations, particularly in regard to long-term outcomes and safety data and United States IRB oversight. CareSource periodically reviews the literature and reviews policies annually and as needed when new literature comes available. Notwithstanding the foregoing, CareSource does review each request on a case-by-case basis in accordance with medical necessity policies as well as federal and state regulations for sterilization.
- C. Hair removal
  - 1. All members requesting ANY of the hair removal procedures for anticipated skin flap areas to create the new structures (does not include the perineum)
    - a. Creation of a neovagina in MtF (does not include vulvoplasty alone)
    - b. Creation of a neophallus in FtM
- D. Sexual reassignment surgery
  - 1. All members requesting ANY of the sexual reassignment surgeries (see list below).
    - a. MtF
      - 01. Breast reconstruction
      - 02. Penectomy
      - 03. Orchiectomy
      - 04. Vaginoplasty
      - 05. Vulvoplasty
      - 06. Clitoroplasty
      - 07. Labiaplasty
      - 08. Urethroplasty
      - 09. Prostatectomy
    - b. FtM



- 01. Mastectomy
- 02. Phalloplasty
- 03. Urethroplasty
- 04. Vulvectomy
- 05. Vaginectomy
- 06. Metoidioplasty
- 07. Hysterectomy08. Salpingo-oophorectomy
- 09. Implantation of erectile prosthesis
- 10. Scrotal reconstruction
- 11. Testicular prosthesis or tissue expansion
- E. Minimum documentation requirements
  - 1. Surgeon
    - a. Assessment including identifying characteristics
    - b. Results of psychological assessment including diagnosis
    - c. Surgery Plan
    - d. Documentation of informed consent discussion
      - 01. Notation of discussion of risks, benefits alternatives to treatment including no treatment
      - 02. Hair removal
      - 03. Medical stability for surgery and anesthesia
      - 04. Expected outcome(s)
  - 2. Endocrinologist
    - a. Assessment
    - b. Exam and relevant laboratory
    - c. Documentation of informed consent discussion
      - 01. Notation of discussion of risks, benefits alternatives to treatment including no treatment
      - 02. Medical monitoring plan
      - 03. Statement of ongoing availability to member
      - 04. Expected outcome(s)
  - 3. Behavioral Health

(See Section III above).

#### V. THE FOLLOWING ITEMS ARE NOT COVERED

- A. Procedures or surgeries to enhance secondary sex characteristics are considered cosmetic and are not medically necessary.
- B. A list of services, procedures or surgeries not covered is included below, this list may not be all inclusive:
  - 1. Reversal of genital surgery or reversal of surgery to revise secondary sex characteristics
  - 2. Abdominoplasty
  - 3. Blepharoplasty
  - 4. Breast augmentation
  - 5. Brow lift
  - 6. Body contouring
  - 7. Botox treatments
  - 8. Calf implants
  - 9. Cheek or malar implants
  - 10. Chin implants
  - 11. Collagen injections
  - 12. Drugs for hair loss or hair growth
  - 13. Face lifts
  - 14. Facial bone reduction
  - 15. Facial feminization



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- 16. Perineal skin hair removal
- 17. Hair removal for vaginoplasty without creation of neovagina
- 18. Hair removal when genital surgery is not yet requested
- 19. Hair removal when re-assignment surgery is not approved
- 20. Hair replacement
- 21. Lip enhancement
- 22. Lip reduction
- 23. Liposuction
- 24. Mastopexy
- 25. Neck tightening
- 26. Nose implants
- 27. Pectoral implants
- 28. Plastic surgery on eyes
- 29. Reduction thyroid chondroplasty
- 30. Rhinoplasty
- 31. Skin resurfacing
- 32. Voice modification surgery (laryngoplasty or shortening of the vocal cords)
- 33. Voice therapy or voice lessons
- 34. Any other surgeries or procedures deemed not medically necessary
- 35. Reproduction services including but not limited to sperm preservation, oocyte preservation, cryopreservation of embryos, surrogate parenting, donor eggs and donor sperm and host uterus.

## VI. SERVICES COVERED FOR MEMBERS THAT HAVE COMPLETED SEXUAL REASSIGNMENT SURGERY.

- A. CareSource treats all members consistent with the Gender Identity and does not deny or limit health services that ordinarily or exclusively are available to individuals of one sex to a transgender individual based on the fact that the individual's sex or gender is different from the one to which health services are normally or exclusively available. (See examples below):
  - 1. Breast cancer screening for FtM-identified persons
  - 2. Prostate cancer screening for MtF- identified persons

#### E. CONDITIONS OF COVERAGE

The codes listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the services described by this code is a covered or non-covered health service. Coverage is determined by the benefit documents, medical necessity criteria and/or CMS national/local coverage determinations.

CPT CODE	DESCRIPTION	
55970	Intersex surgery, male to female	
55980	Intersex surgery, female to male	
ICD-10 CODE	DESCRIPTION	
F64-F64.9	Gender Identity disorder	
F64.1	Gender identity disorder in adolescence or adulthood	
Z87.890	Person history of sex reassignment	



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#### G. REVIEW/REVISION HISTORY

DATES		ACTION
Date issued	5/18/2017	
Date Revised	5/29/2019	
Date Effective	9/1/2019	Updated evidence, changed policy number (was MM-0080), removed pharmacy portions, added additional requirements for consideration of surgery, added specifics on hair removal, items not covered and added types of surgery for medical necessary review

#### H. REFERENCES

- 1. Centers for Medicare & Medicaid (CMS). Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG 00446N). August 30, 2016
- 2. ECRI Institute Special Report, Gender Dysphoria January 2016. (ECRI, reviewed February 2, 2015).
- 3. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. Arlington, VA, American Psychiatric Association, 2013.
- 4. World Professional Association for Transgender Health (WPATH), 7th Edition 2001.
- 5. CMS Department of Health and Human Services Departmental Appeals Board (DAB) has invalidated National Coverage Determination (NCD) 140.3 "Transsexual Surgery" pursuant to section 1869(F)(1)(A)(iii) of the Social Security Act (SSA). (Docket #A-13-47, Decision #2576) dated May 30, 2014. As a consequence of this decision, NCD 140.3 is no longer valid. Implementation of this decision occurred on June 29, 2014
- 6. Centers for Medicare & Medicaid Services (CMS). Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N). August 30, 2016.
- Am. Acad. Child Adolesc. Psychiatry, 2012;51(9):9570974American Academy of Child & Adolescent Psychiatry
- 8. American Psychiatric Association Task Force Report on Treatment of Gender Identity (Byne et al., 2012).
- 9. Report of the American Psychological Association Task Force on Gender Identity and Gender Variance (2009).
- 10. Recommendations for Promoting the Health and Well-Being of Lesbian, Gay, Bisexual and Transgender Adolescents: A Position paper of the Society of Adolescent Health and Medicine (SAHM, 2013).
- 11. Dhejne D, Lichtenstein P, Borman M, Johansson AL, Langstrom N, Landen M. Long-term follow up of transsexual persons undoing sex reassignment surgery: Cohort study in Sweden, 2011;6(2).
- 12. American Psychological Association Fact sheet on "Gender Diversity and Transgender Identity in Adolescents, Meier, C et al.
- Murad, MH, Elamin, MB, Garcia, MZ, Mullan, RJ, Murad, A, Erwin, PJ and Montori, VM. Hormonal therapy and sex reassignment: a systematic review and meta-analysis if quality of life and psychosocial outcomes. *Clin Endocrinol* (Oxf). 2010;72(2):214-231. PubMed 19473181 [PMID].
- 14. Keo-Meier, CL, Herman, LI, Reisner, SL, Pardo, ST, Sharp, C and Babcock, JC. Testosterone and MMPI-2 improvement in transgender men: a prospective study. *J Consult Clin Psychol.* (note: IRB University of Houston, TX).
- 15. Leinung, MC. Urizar, MF, Patel, N, and Sood, SC. Endocrine treatment of transsexual persons; extensive personal experience. *Endocr Pract*. 2013;19(4):644-650. PubMed 23512380 [PMID] (note: IRB Albany Medical Center, NY).



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- Amend, B, Seibold, J, Toomey, P, Stenzl, A, and Sievert, DK, Surgical reconstruction for male-to-female sex reassignment. Eur Urol. 2013;64(1):141-149 PubMed 23375962 [PMID]
- 17. Weigert, R, Frison, E, Sessiecq, Q, Al, MK, and Casoli, V.
- 18. Ainsworth, TA, Spiegel, JH, Quality of life of individuals with and without facial feminization surgery or gender reassignment surgery. Quality of life research: an international journal of quality of life aspect of treatment, care and rehabilitation. 2010;19(7):1019-1024. PubMed 20461468.
- 19. Horbach, SE, Bouman, MB, Smit, JM, Ozer, M Buncamper, ME and Mullender, MG. Outcome of Vaginoplasty in Male-to-Female Transgenders: A Systematic Review of Surgical Techniques. *J Sex Med.* 2015;12(6):1499-1512. PubMed 25817066.
- Bouman, MD, van Zeijl, MC, Buncamper, MD, Meijerink, WJ, van Bodegraven, AA, and Mullender, MD. Intestinal Vaginoplasty Revisited: a Review of Surgical Techniques, complication and sexual function. J Sex Med. 2014;11(7);1835-1847. PubMed 24697986 [PMID].
- 21. American Psychological Association Guidelines for Psychological Practice with Transgender and Gender Nonconforming People, December, 2015.
- 22. Sex Reassignment Surgery for the Treatment of Gender Dysphoria. Hayes. (2018). Retrieved on 1/14/2019 from https://www.hayesinc.com/subscribers/subscriberHome.do
- American Medical Association. Memorial Resolutions Adopted Unanimously (2016)
   Retrieved on 1/14/2019 from https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/hod/a16-resolutions.pdf
- 24. Practice Parameter on Gay, Lesbian, or Bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance in Children and Adolescents Adelson, Stewart L. Journal of the American Academy of Child & Adolescent Psychiatry, Volume 51, Issue 9, 957 974
- 25. The Journal of Clinical Endocrinology & Metabolism, Volume 102, Issue 11, 1 November 2017, Pages 3869–3903, https://doi.org/10.1210/jc.2017-01658
- 26. Tran, B. N., Epstein, S., Singhal, D., Lee, B. T., Tobias, A. M., & Ganor, O. (2018). Gender Affirmation Surgery. Annals of Plastic Surgery, 1. doi:10.1097/sap.000000000001350
- 27. Weissler, J. M., Chang, B. L., Carney, M. J., Rengifo, D., Messa, C. A., Sarwer, D. B., & Percec, I. (2018). Gender-Affirming Surgery in Persons with Gender Dysphoria. Plastic and Reconstructive Surgery, 141(3), 388e-396e. doi:10.1097/prs.0000000000004123
- 28. DEPARTMENT OF DEFENSE REPORT AND RECOMMENDATIONS ON ... (2018, February). Retrieved May 22, 2019, from https://partner-mco-archive.s3.amazonaws.com/client\_files/1521898539.pdf
- 29. Zhang, W. R., Garrett, G. L., Arron, S. T., & Garcia, M. M. (2016). Laser hair removal for genital gender affirming surgery. *Translational Andrology and Urology*, *5*(3), 381-387. doi:10.21037/tau.2016.03.27

This document contains excerpts from the Hayes Medical Technology Directory as follows: Hayes, Inc., Hayes Medical Technology Directory Report, Sex Reassignment Surgery for the Treatment of Gender Dysphoria. Lansdale, PA: Hayes, Inc.; August 2018

This document contains excerpts from Emergency Care Research Institute (ECRI) Health Technology Assessment Information Service special report, Gender Dysphoria; January 2016.

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Independent medical review – 10/2015

