



MEDICAL POLICY STATEMENT OHIO MEDICARE ADVANTAGE

Original Issue Date	Next Annual Review		Effective Date
05/18/2017	05/01/2018		05/18/2017
Policy Name			Policy Number
Gender Dysphoria			MM-0079
Policy Type			
MEDICAL	Administrative	Pharmacy	Reimbursement

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary under the Social Security Act is defined as "items and services, not otherwise meeting an exclusion, that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 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 Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

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A. SUBJECT

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 clinically-significant 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

- **Evidence of Coverage (EOC):** Means the contract between CareSource and its members that contains the information regarding coverage, limits and condition of health services. The Evidence of Coverage also describes payment information, and the rights and responsibilities of CareSource Members.
- **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 role.
- **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.
- **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.
- **Hormonal suppression** – initiated in early adolescence to suppress the development of secondary sex characteristics.
- **Hormonal (cross-sex) therapy** – maintenance therapy for adults to maintain FtM or MtF gender expression, whether or not sexual reassignment surgery is planned or performed.
- **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 serious limitations in study designs it permits only weak conclusions regarding sex reassignment surgery. No conclusions can be made about the comparative benefits of hormone therapy alone and 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. Topics included hormone suppression therapy, cross-sex hormone therapy, or 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. Pubertal Suppression by Hormones in children and early adolescents
 1. There were no puberty suppression studies that met inclusion criteria) in the ECRI review.
 2. Hayes created a report evaluating the evidence on "Hormone Therapy for the Treatment of Gender Dysphoria." It concluded "Statistically-significant improvements have not been consistently demonstrated by multiple studies for most outcomes." There were several serious limitations to the evidence, including gender dysphoria diagnosis was not confirmed and the study designs do not permit conclusion of causality. In addition, "The evidence for adolescent populations was too sparse to suggest any conclusions."
- B. Hormone (Cross-Sex) Therapy



1. ECRI found one systematic review and three primary studies evaluating 3,392 transgender individuals.
 2. The systematic review of psychological outcomes included MtF and FtM studies of any study design except case reports (n = 1,833; 1093 MtF, 801 FtM) was deemed very low quality evidence. It suggests hormonal interventions likely improved gender dysphoria, physiological functioning and comorbidities, sexual function and overall quality of life. The systematic review did not specify if studies had IRB oversight.
 3. Three primary studies of hormone therapy were identified (two approved by a United States IRB and one research policy approved by an unaccredited IRB at an Amsterdam Medical Center IRB).
 4. The Keo-Meier et al. study suggested positive effects of testosterone hormone in transgender men compared to healthy female and non-transgender males after three months of therapy using the Minnesota Multiphasic Personality Inventory, 2nd Edition in a nonrandomized controlled/comparison study. MMPI looks at personality traits, not gender dysphoria. It was approved by an IRB and found the proportion of men presenting with co-occurring psychopathology was significantly decreased vs healthy female controls and non-transgender males. (US IRB: University of Houston).
 5. The Gooren et al. study results report cross-sex hormone administration does not seem to be associated with increased risk of malignant breast development in either MtF or FtM transgender individuals (n= 3,102 transsexuals aged 18-80 exposed to cross-sex hormone >5 years).
 6. The Leinung et al. study of 192 MtF and 50 FtM individuals noted that the dysphoria present in many transgender persons is associated with significant mood disorders that interfere with successful careers. Among side effects reported were deep vein thrombosis, respiratory problems and pulmonary embolus events. The authors noted that mental health and psychiatric problems were inversely correlated with age at presentation for hormonal therapy, and suggested earlier start of hormonal therapy might be helpful. (US IRB: Albany Medical Center).
 7. Hayes performed a literature search and report on "Hormone Therapy for the Treatment of Gender Dysphoria." It concluded that "A substantial number of studies of cross-sex hormone therapy each show some positive findings suggesting improvement in well-being after cross-sex therapy. The benefits of hormone therapy appear to be of very small magnitude in the studies published to date. The literature does not provide guidance for assessing the clinical relevance of improvements in this population." Hayes cited serious limitations to the evidence it reviewed in the report. Its rating denotes that there is some positive evidence to suggest that hormonal therapy may help the symptoms of gender dysphoria in adults, but serious limitations in the evidence of both effectiveness and safety. More quality research is needed.
- C. 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.
 - 1.1 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.

- 1.2 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 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.
 - 2.1 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.
 - 2.2 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.
 - 2.3 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 may 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.
 - 2.4 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 19 peer-reviewed studies (primarily case studies) assessing the effectiveness of sexual reassignment surgery. In addition, 6 case series evaluating safety outcomes from 11/2004 to 4/2014 were summarized in a report titled, "Sex Reassignment Surgery for the Treatment of Gender Dysphoria. The findings included:



- 3.1 There is insufficient evidence to establish patient selection criteria for sexual reassignment surgery to treat gender dysphoria.
- 3.2 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.
- 3.3 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 comparative benefits of hormone therapy alone and SRS, or about different components of sexual reassignment surgery.

II. COMMENT BY GOVERNMENTAL AGENCIES AND PROFESSIONAL ORGANIZATIONS

A. Centers for Medicare and Medicaid Services

1. There was a longstanding National Coverage Determination (**NCD**) for transsexual Surgery which states transsexual surgery is not covered, however that determination has been overturned.
2. CMS reported a literature search of primary studies evaluating interventions for gender dysphoria. It 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 post-operative surveillance were included for 1965 to current date.
3. 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.”
 - 3.1 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.
 - 3.2 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.
 - 3.3 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 tools and considerable loss to follow up.
 - a. Of the 33 studies reviewed, some were positive, others were negative. CMS stated “Collectively the evidence is inconclusive.”
 - b. CMS stated there were six studies that could provide useful information.
 - c. Of these six studies, the four best-designed and conducted studies that assessed quality of life before and after surgery using validated (albeit non-specific) psychometric studies did not demonstrate clinically-significant changes or differences in psychometric test results after genital reassignment surgery.
 - d. 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)

1. At the time of this policy, the local MACs serving Ohio has not issued a local coverage determination (LCD).

World Professional Association for Transgender Health) 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 its 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.

- C. Food and Drug Administration
 - 1. Reassignment surgeries are procedures, and therefore not subject to FDA regulation
- D. 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.
- E. 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
- F. American Medical Association
 - 1. Made two resolutions under “Removing Financial Barriers to Care for Transgender Patients”
 - 2. Supports public and private insurance coverage for treatment of gender identity disorder
 - 3. Opposes categorical exclusions of coverage for treatment of gender identity disorder when prescribed by a physician
 - 4. Did not perform a systematic review of the literature for all categories of treatment for the position statement.
 - 5. Did not discuss the evidence for sexual reassignment surgery.
 - 6. Did not develop a guideline.
- G. American Academy of Child & Adolescent Psychiatry
 - 1. Provides information on psychosexual development
 - 2. Lists principles of care

III. COVERED SERVICES

- A. Behavioral Health services for children, adolescents and adults are covered for:
 - 1. 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 hormones or surgery 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. Hormones

For MtF members, it can take several years for the hormones to take full effect.

1. Must have a well-documented diagnosis of gender dysphoria
2. Must be medically necessary
3. Must be provided by a prescriber familiar with treatment gender dysphoria
4. Must be age 18 years or older
5. Must have the capacity to provide informed consent
6. Medications available are listed on the formulary

C. Surgery

1. Surgery will be reviewed for medical necessity on a case-by-case basis. Given the behavioral health diagnosis of Gender Dysphoria, it is recommended that the member receive behavioral health treatment with a QMHP for at least three months prior to surgery. In addition, the member must have lived a real-life experience for at least twelve continuous months that is congruent with their gender identity.
2. QMHP is responsible for providing and documenting informed consent to member from a behavioral-health perspective:
 - 2.1 Discussion of advantages and disadvantages of mental health outcomes related to gender transformation surgery
 - 2.2 Alternatives to surgery
3. WPATH discusses the relationship of surgeons with mental health professionals and hormone prescribing physicians:
 - 3.1 “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 involved in their clinical care.”
4. In addition, WPATH states that surgeons are responsible for discussing all of the following with patients seeking surgical treatments for gender dysphoria:
 - 4.1 The different surgical techniques available (with referral to colleagues who provide alternative options)
 - 4.2 The advantages and disadvantages of each technique
 - 4.3 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
 - 4.4 The inherent risks and possible complications of the various techniques; surgeons should inform patients of their own complication rates with each procedure

D. The following are requirements that apply for consideration of sexual reassignment surgery (List is not meant to represent all requirements):

1. Breast/chest surgery
 - 1.1 It is recommended that MtF patients undergo feminizing hormone therapy for a minimum of twelve continuous months prior to breast surgery to maximize breast growth in order to obtain better surgical results
 - 1.2 Hormone therapy is not a prerequisite for FtM chest surgery
 - 1.3 Hormone trial must be with a medication prescribed to the member
 - 1.4 One letter of recommendation from a QMHP to the surgeon is required
 - a. QMHP has evaluated the member within the past twelve months of the time of referral
 - b. 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)
 - c. If there is not a treating QMHP, a letter of recommendation may be made by a consulting QMHP



- d. 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
 - (1) Content of the QMHP referral letter must address at minimum:
 - i. Duration of evaluator's relationship with the member
 - ii. Member has well-documented diagnosis of gender dysphoria
 - iii. The gender dysphoria has been persistent for a minimum of six months or longer at the time of the referral for surgical evaluation
 - iv. If co-existing mental illness or a substance-related disorder is present, it is reasonably well controlled at the time of referral
 - v. Member has capacity to give informed consent for surgery
 - vi. Member is age 18 years or older
 - vii. Member has had a twelve-month or longer in real-life experience congruent with their gender identity
 - viii. The gender dysphoria diagnosis has been consistently persistent for a duration of 6 months or longer at the time of the authorization request.
 - ix. If co-existing mental illness is present, it is relatively well controlled, there has been no active intravenous drug use for the past 3 months and no suicidal attempts or behaviors in the past 6 months.
 - x. 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
- 2.1 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
 - 2.2 Hormone trial must be with a medication prescribed by a provider
 - 2.3 Two letters of recommendation from separate QMHPs to the surgeon are required
 - a. QMHP has evaluated the member within the past twelve months of the time of referral
 - b. If member has been in treatment, it is preferred that one of the recommendations is made by the treatment provider (if the provider is a QMHP)
 - c. If there is not a treating QMHP, the letters of recommendation may be made from two separate QMHPs
 - d. 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
 - (1) Content of referral must address at minimum:
 - i. Duration of evaluator's relationship with the member
 - ii. Member has well-documented diagnosis of gender dysphoria
 - iii. The gender dysphoria has been persistent for a minimum of six months or longer at the time of the referral for surgical evaluation
 - iv. If co-existing mental illness or a substance-related disorder is present, it is reasonably well-controlled at the time of referral
 - v. Member has capacity to give informed consent for surgery
 - vi. Member is age 18 years or older
 - vii. Member has had a twelve-month or longer in real life experience congruent with their gender identity
 - viii. The gender dysphoria diagnosis has been consistently persistent for a duration of 6 months or longer at the time of the authorization request
 - ix. If co-existing mental illness is present, it is relatively well controlled, there has been no active intravenous drug use for the past 3 months



- and no suicidal attempts or behaviors in the past 6 months
- x. QMHP communicates willingness to be available to treat the member during transition or make appropriate referral if member needs assistance with behavioral health treatment

IV. SERVICES REQUIRING MEDICAL NECESSITY REVIEW

- A. 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 in individuals under 18 to be not medically necessary. This is due to the virtual nonexistence of evidence-based 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.
- B. Sexual reassignment surgery
 - 1. All members requesting ANY of the sexual reassignment surgeries (see list below).
 - 1.1 MtF
 - a. Breast reconstruction
 - b. Penectomy
 - c. Orchiectomy
 - d. Vaginoplasty
 - e. Vulvoplasty
 - f. Clitoroplasty
 - g. Labiaplasty
 - 1.2 FtM
 - a. Mastectomy
 - b. Vaginectomy
 - c. Metoidioplasty
 - d. Hysterectomy
 - e. Salpingo-oophorectomy
 - f. Implantation of erectile prosthesis
 - g. Scrotal reconstruction
 - h. Testicular prosthesis or tissue expansion
- C. Minimum documentation requirements
 - 1. Surgeon
 - 1.1 Assessment including identifying characteristics
 - 1.2 Results of psychological assessment including diagnosis
 - 1.3 Surgery Plan
 - 1.4 Documentation of informed consent discussion
 - a. Notation of discussion of risks, benefits alternatives to treatment including no treatment
 - b. Medical stability for surgery and anesthesia
 - c. Expected outcome(s)
 - 2. Endocrinologist
 - 2.1 Assessment
 - 2.2 Exam and relevant laboratory
 - 2.3 Documentation of informed consent discussion
 - a. Notation of discussion of risks, benefits alternatives to treatment including no treatment
 - b. Medical monitoring plan
 - c. Statement of ongoing availability to member
 - d. Expected outcome(s)



3. Behavioral Health
(See Section III A 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. Electrolysis, hair removal
 14. Face lifts
 15. Facial bone reduction
 16. Facial feminization
 17. Hair removal
 18. Hair replacement
 19. Lip enhancement
 20. Lip reduction
 21. Liposuction of the waist
 22. Mastopexy
 23. Neck tightening
 24. Nose implants
 25. Pectoral implants
 26. Plastic surgery on eyes
 27. Reduction thyroid chondroplasty
 28. Rhinoplasty
 29. Skin resurfacing
 30. Voice modification surgery (laryngoplasty or shortening of the vocal cords)
 31. Voice therapy or voice lessons
 32. Any other surgeries or procedures deemed not medically necessary
 33. 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 their Gender Identity and does not deny or limit health services that ordinarily or exclusively 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

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.

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.

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

AUTHORIZATION PERIOD

F. RELATED POLICIES/RULES

G. REVIEW/REVISION HISTORY

DATES		ACTION
Date issued	05/18/2017	
Date Revised		
Date Effective	05/18/2017	

H. REFERENCES

1. Social Security Act, Sec. 1862(a)(1)(A-P). [42 U.S.C. 1395y]
2. Centers for Medicaid & Medicare Services (CMS). Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG 00446N). August 30, 2016.
3. CareSource Medical Necessity Determination policy
4. Sex Reassignment Surgery of the Treatment of Gender Dysphoria (Hayes, reviewed May 15, 2014).
5. Hormone Therapy for the Treatment of Gender Dysphoria (Hayes, reviewed May 19, 2014)
6. ECRI Institute Special Report, Gender Dysphoria January 2016. (ECRI, reviewed February 2, 2015).
7. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. Arlington, VA, American Psychiatric Association, 2013.
8. World Professional Association for Transgender Health (WPATH), 7th Edition 2001.
9. 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.
10. American Psychiatric Association Task Force Report on Treatment of Gender Identity (Byne et al., 2012).
11. Report of the American Psychological Association Task Force on Gender Identity and Gender Variance (2009).



12. 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).
13. 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).
14. American Psychological Association Fact sheet on “Gender Diversity and Transgender Identity in Adolescents, Meier, C et al.
15. 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].
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17. Gooren, LJ, van Trotsenburg, MA, Giltay, EJ, and van Diest, PJ. Breast cancer development in transsexual subjects receiving cross-sex hormone treatment. *J Sex Med*. 2013;10(12);3129-3134. PubMed 24010586 [PMID] (note: IRB VU University Medical Center, Amsterdam).
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19. 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]
20. Weigert, R, Frison, E, Sessiecq, Q, Al, MK, and Casoli, V.
21. 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.
22. 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.
23. 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].
24. American Psychological Association Guidelines for Psychological Practice with Transgender and Gender Nonconforming People, December, 2015.

For Medicare Plan members, reference the Applicable National Coverage Determinations (NCD) and Local Coverage Determinations (LCD). Compliance with NCDs and LCDs is required where applicable.

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