Policy Number	**SUR717.001**
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Gender Assignment Surgery and Gender Reassignment Surgery with Related Services

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

I.GENDER ASSIGNMENT SURGERY

Gender assignment surgery for patients with ambiguous genitalia diagnosed at birth or in infancy is considered reconstructive surgery and **may be considered medically necessary.**

II. GENDER REASSIGNMENT SURGERY

NOTE: State Legislation may apply. Carefully check for legislative mandates that may apply for each plan.

ILLINOIS Legislative Mandate: 50 Illinois. Administrative. Code 2603.35 provides that a group health insurance plan that is neither a grandfathered plan nor a plan offering excepted benefits shall not discriminate on the basis of an insured's or prospective insured's actual or

perceived gender identity, or on the basis that the insured or prospective insured is a transgender person.

Pursuant to the above, Gender Reassignment Surgery would be a covered benefit for Illinois insured policies subject to the coverage criteria set forth below.

CAREFULLY REVIEW the member's benefit contract for gender reassignment surgery and related services provisions. If there is a discrepancy between this medical policy and the member's benefit contract, the contract will govern.

Refer to Coding section for information on CPT codes to report female-to-male breast/chest surgery.

Gender reassignment surgery -- also known as transsexual surgery or sex reassignment surgery -- and related services **may be considered medically necessary** when meeting the criteria for gender dysphoria listed below.

Otherwise, gender reassignment surgery and related services **are considered not medically necessary**.

A. Gender Reassignment Surgery and Related Services for Children and Adolescents:
The following services **may be considered medically necessary** for the treatment of gender dysphoria for children and adolescents:

- Hormone therapy (such as, puberty-suppressing hormones or masculinizing/feminizing hormones);
- Psychological services, including but not limited to psychotherapy, social therapy, and family counseling; and/or
- Chest surgery for female-to-male (FtM) individuals.

The individual being considered for surgery and related services must meet ALL the following criteria. The individual must have:

- Been diagnosed with persistent, well-documented gender dysphoria; **and**
- The required referrals prior to any surgery or related service(s):
  - Prior to feminizing or masculinizing hormonal therapy, one required referral from the individual's qualified mental health professional (**see NOTE 2**) competent in the assessment and treatment of gender dysphoria; **and/or**
  - Prior to breast/chest surgery, e.g., mastectomy, chest reconstruction, or breast augmentation, one required referral from the individual's qualified mental health professional (**see NOTE 2**) competent in the assessment and treatment of gender dysphoria.

NOTE 1: The 2012 World Professional Association for Transgender Health (WPATH) Version 7, Standards of Care (SOC) (6) state that adolescent individuals seeking irreversible interventions, such as genital surgery:
"Genital surgery should not be carried out until (i) patients reach the legal age of majority to give consent for medical procedures in a given country, and (ii) patients have lived continuously for at least 12 months in the gender role that is congruent with the gender identity. The age threshold should be seen as a minimum criterion and not an indication in and of itself for active intervention."

B. Criteria for Coverage of Gender Reassignment Surgery and Related Services for Adults:
The individual being considered for surgery and related services must meet ALL the following criteria. The individual must have:

- Reached the age of majority; **and**
- The capacity to make a fully informed decision and to consent for treatment; **and**
- Been diagnosed with persistent, well-documented gender dysphoria; **and**
- The required referrals prior to any surgery or related service(s):
    - Prior to feminizing or masculinizing hormonal therapy, one required referral from the individual's qualified mental health professional (**see NOTE 2**) competent in the assessment and treatment of gender dysphoria; **and/or**
    - Prior to breast/chest surgery, e.g., mastectomy, chest reconstruction, or breast augmentation, one required referral from the individual's qualified mental health professional (**see NOTE 2**) competent in the assessment and treatment of gender dysphoria; **and/or**
    - Prior to any genital surgery, e.g., hysterectomy, salpingo-oophorectomy, orchiectomy, and/or other genital reconstructive procedures, two separate required independent referrals (or one signed by both referring providers) from the individual's qualified mental health professionals (**see NOTE 2**) competent in the assessment, treatment of gender dysphoria, and addressing the identical/same surgery to be performed.

NOTE 2: Psychotherapy and Mental Health Services:
Psychotherapy is not required for gender reassignment services except when a mental health professional recommends psychotherapy based on initial assessment prior to gender reassignment surgery. The recommendation for psychotherapy must specify the goals of treatment along with estimates of the frequency and duration of therapy throughout the individual's experience living in one's affirmed gender.

C. Gender Reassignment Pharmaceutical Services:
Continuous hormone replacement therapy **may be considered medically necessary** prior to gender reassignment of either male-to-female (MtF) or FtM surgical services or following gender reassignment MtF or FtM surgical services.

Continuous hormone replacement therapy may include the following services:

- Hormone injections by the medical provider, such as during an office visit; and/or

- Self-administered oral and injectables obtained from a pharmacy.

NOTE 3: It is not uncommon for an individual to receive continuous hormone replacement therapy for 12-months or more.

Pharmaceutical agents to treat hair loss or growth, sexual performance post-gender reassignment genital surgery (e.g., Viagra or Cialis), and/or cosmetic enhancements, including collagen and/or botulinum toxin injections, **are considered not medically necessary.**

D. Gender Reassignment Laboratory Services:
Laboratory testing to monitor continuous hormonal replacement therapy for treatment of gender dysphoria **may be considered medically necessary**.

E. Primary Sexual Characteristic Gender Reassignment Chest and/or Genital Surgeries:
MtF surgical procedures performed as part of gender reassignment services for an individual who has met the above criteria for gender dysphoria **may be considered medically necessary** and include the following:

- Breast modification, including but not limited to breast enlargement, breast augmentation, mastopexy, implant insertion, and silicone injections, and nipple or areola reconstruction;
- Clitoroplasty;
- Coloproctostomy;
- Colovaginoplasty;
- Labioplasty;
- Orchiectomy;
- Penectomy;
- Penile skin inversion;
- Repair of introitus;
- Vaginoplasty with construction of vagina with graft; and/or
- Vulvoplasty.

Female-to-Male (FtM) surgical procedures performed as part of gender reassignment services for an individual who has met the above criteria for gender dysphoria **may be considered medically necessary** and include the following:

- Hysterectomy;
- Metoidioplasty;
- Phalloplasty;
- Placement of an implantable erectile prostheses;
- Placement of testicular prostheses;
- Salpingo-oophorectomy;
- Scrotoplasty;
- Subcutaneous mastectomy, including nipple or areola reconstruction;
- Vaginectomy (colpectomy);
- Urethroplasty; and/or

- Urethromeatoplasty.

F. <u>Secondary</u> Sexual Characteristic (Masculinizing or Feminizing) Gender Reassignment Surgeries and Related Services:

Procedures or services to create and maintain gender specific characteristics (masculinization or feminization) as part of the overall desired gender reassignment services treatment plan **may be considered medically necessary for the treatment of gender dysphoria ONLY.** These procedures may include the following:

- Abdominoplasty;
- Blepharoplasty;
- Brow lift;
- Calf implants;
- Cheek implants;
- Chin or nose implants;
- External penile prosthesis (vacuum erection devices);
- Face lift (rhytidectomy);
- Facial bone reconstruction/sculpturing/reduction, includes jaw shortening;
- Forehead lift or contouring;
- Hair removal (laser hair removal or electrolysis) which may include donor skin sites; or hair transplantation (hairplasty);
- Laryngoplasty;
- Lip reduction or lip enhancement;
- Liposuction/lipofilling or body contouring or modeling of waist, buttocks, hips, and thighs reduction;
- Neck tightening;
- Pectoral implants;
- Reduction thyroid chondroplasty or trachea shaving (reduction of Adam's apple);
- Redundant/excessive skin removal;
- Rhinoplasty (nose correction);
- Skin resurfacing;
- Testicular expanders;
- Voice modification surgery; and/or
- Voice (speech) therapy or voice lessons.

NOTE 4: Preparatory or ancillary procedures (such as anesthesia, tissue harvesting for skin, fat, nerve or muscle grafting, etc.) and supplies or equipment (such as stents, prosthesis, implants, etc.) that are required for the procedures listed above are considered an integral part of the MtF or FtM transition process.

NOTE 5: Surgical repairs or revisions related to MtF or FtM procedures may be required, such as removal and replacement of prostheses.

G. Gender Primary or Secondary Sexual Characteristic Revision Surgeries

When there is documented evidence of physical functional impairment, gender primary or secondary sexual characteristic revision procedures or services **are considered medically necessary**.

When there is **no** documented evidence of physical functional impairment, gender primary or secondary sexual characteristics revision services **are considered not medically necessary** (refer to appropriate procedure-specific policy).

H. Gender Reassignment Reproductive Services:
Procurement, cryopreservation/freezing, storage/banking, and thawing of reproductive tissues, such as oocytes, ovaries, embryos, spermatozoa, and testicular tissue **may be considered medically necessary** for individuals with gender dysphoria because gender reassignment services, such as long-term cross-sex hormone therapy or surgical procedures, may render an individual infertile whether or not the individual has reproduced in the past.

I. Reversal of Gender Reassignment Surgical Procedures
For reversal of any of the prior gender reassignment surgical procedure(s) or service(s) for gender primary or secondary sexual characteristics, the patient must meet the same criteria for gender dysphoria to have those reversal procedures **considered medically necessary**.

If the criteria for gender dysphoria is not met, then reversal of any prior gender reassignment surgical procedure(s) or service(s) for gender primary or secondary sexual characteristics **is considered not medically necessary.**

J. Preventive Medicine Gender Reassignment Services:
Preventive medicine services **considered medically necessary** in conjunction with gender reassignment services include:

- Breast cancer screening for FtM individuals; or
- Cervical cancer screening for FtM individuals; or
- Prostate cancer screening for MtF individuals; or
- Contraception pharmaceuticals for FtM individuals at risk of pregnancy.

Policy Guidelines

The CPT codes for mastectomy (19303 and 19304) are for breast cancer and should not be used to bill for reduction mammaplasty for female to male (transmasculine) gender affirmation surgery. A more appropriate code to report this service is 19318, as it includes the work that is necessary to create a more aesthetically pleasing result.

Description

Gender Assignment Surgery

Gender assignment surgery (GAS), also known as genitoplasty, is genital reconstruction of ambiguous genitalia in newborns or infants difficult to classify as a male or female. The extent of the ambiguity varies. In very rare instances, the physical appearance may be fully developed as the opposite of the genetic sex (e.g., a genetic male may have developed the appearance of a typical female). (1) To the lay person the determination of an infant's sex can easily be identified as male or female, by virtue of outward genital anatomy, secondary sexual characteristics and behavior within their relevant cultural context. Arriving at a satisfactory scientific definition is more difficult as gender reflects the outcome of complex interactions occurring from the time of conception and extending throughout pre- and postnatal life. (2)

Intersex anomalies associated with ambiguous genitalia may result from major chromosomal abnormalities or from specific gene mutations as in congenital adrenal hyperplasia. (2) Typically, the ambiguous genitalia in genetic females (babies with two X chromosomes) include an enlarged clitoris that has the appearance of a small penis. The urethral opening can be anywhere along, above, or below the surface of the clitoris. The labia may be fused, resembling a scrotum. The infant may be thought to be a male with undescended testicles. Sometimes a lump of tissue is felt within the fused labia, further making it look like a scrotum with testicles. (3, 4)

In a genetic male (babies with one X and one Y chromosome), the ambiguous genitalia typically include a small penis (less than 2-3 centimeters or 0.8-1.2 inches) that may appear to be an enlarged clitoris (the clitoris of a newborn female is normally somewhat enlarged at birth). The urethral opening may be anywhere along, above, or below the penis; it can be placed as low as the peritoneum, further making the infant appear to be female. There may be a small scrotum with any degree of separation, resembling labia. Undescended testicles commonly accompany ambiguous genitalia. (3, 4)

Disorders which include ambiguous genitalia, which are usually not life threatening, have serious and potentially lifelong consequences for the affected child and, depending on the underlying cause, are likely to entail surgery in childhood and in later life, for example endocrine replacement therapy in conjunction with steroid replacement for those with congenital adrenal hyperplasia. (1) Making a correct determination of gender is both important for treatment purposes, as well as the emotional well-being of the child. Some children born with ambiguous genitalia may have normal internal reproductive organs.

The incidence of a child with a disorder of sexual development (DSD) is approximately 1 in 1000 to 4500 live births. (21-22) The most frequently occurring etiology was congenital adrenal hyperplasia (CAH) followed by androgen insensitivity and mixed gonadal dysgenesis. A list of the most common causes is listed below:

- Pseudohermaphroditism, the genitalia are of one sex, but some physical characteristics of the other sex are present.
- True hermaphrodism, a very rare condition in which both ovarian and testicular tissue is present. The child may have parts of both male and female genitalia.

- Mixed gonadal dysgenesis, an intersex condition in which there appears to be some male structures (gonads, testis), as well as a uterus, vagina, and fallopian tubes.
- Congenital adrenal hyperplasia, a potentially life-threatening condition, has several forms, but the most common form causes the genetic female to appear male.
- Chromosomal abnormalities, including Klinefelter's syndrome (XXY) and Turner's syndrome (XO).
- Maternal ingestion of certain medications (including androgenic steroids) may cause a genetic female to look more male.
- Lack of production of specific hormones can cause the embryo to develop with a female body type regardless of genetic sex, such as the lack of testosterone cellular receptors. (1)

Regulatory Status

Gender assignment surgical procedures are surgical interventions and, as such, are not subject to regulation by the U.S. Food and Drug Administration (FDA).

Gender Reassignment Surgery

Gender dysphoria (formerly known as 'gender identity disorder') is a condition recognized by the Diagnostic and Statistical Manual (DSM) of Mental Disorders and commonly known as transsexualism. (5) The diagnostic criteria describe many individuals who experience dissonance between their sex at birth and personal gender identity, which is not the same as having ambiguous genitalia. According to the American Academy of Pediatrics, based on population surveys completed in 2014 of 19 states, it suggested that the number of adults who identify as "gender non-conforming" or transgender is 0.6% (1.4 million). (7) On the basis of that data, it is estimated that 0.7% of youth, ages 13 to 17 years (~150,000) identify as transgender.

Gender reassignment surgery (GRS) is also known as sex reassignment surgery; genital reconstruction surgery; sex affirmation surgery; sex realignment surgery; intersex surgery, or sex-change operation. It is a term used for the culmination of a series of surgical procedures and treatments by which a person's physical appearance and the function(s) of existing sexual characteristics are altered or even irreversibly changed to that of the opposite sex. Gender reassignment generally consists of several treatment plans, which include the diagnostic phase (mostly supported through mental health professional interaction) followed by continuous hormonal therapy (through an endocrinologist). It includes living openly in a manner consistent with the affirmed gender or completed with the GRS itself. (5)

Other terms are used to describe these procedures. These include sex reconstruction surgery; gender confirmation surgery; feminizing genitoplasty or penectomy, orchidectomy and vaginoplasty for trans women, with masculinizing genitoplasty or phalloplasty for trans men. (Definitions of these procedures can be found later in this Description section.) These procedures and services are used to treat individuals diagnosed with gender dysphoria in transsexual or transgender people. (1, 2, 6)

Guidelines for GRS and related services have been developed by the World Professional Association for Transgender Health (WPATH) (1), formerly known as the Harry Benjamin International Gender Dysphoria Association. WPATH is an international, multispecialty, professional association whose mission is to promote evidence-based care, education, research, advocacy, public policy, and respect for transgender health. In May 2010, WPATH urged de-psychopathologization of gender nonconformity worldwide by stating, "The expression of gender characteristics, including identities, that are not stereotypically associated with one's assigned sex at birth is a common culturally-diverse human phenomenon [that] should not be judged as inherently pathological or negative." WPATH clarified the related procedures and services when an individual is considering surgical transformation from male-to-female (MtF) or female-to-male (FtM), as well as how the treatment differs for gender dysphoria and transsexualism. (1)

WPATH Standards of Care (SOC)

The WPATH SOC document provides an overview of surgical procedures to treat patients with gender dysphoria, otherwise known as gender affirming surgeries. (6, 7)

"For the MtF (male-to-female) patient, surgical procedures may include the following:

1. Breast/chest surgery: augmentation mammoplasty (implants/lipofilling);
2. Genital surgery: penectomy, orchiectomy, vaginoplasty, clitoroplasty, vulvoplasty;
3. Non-genital, non-breast surgical interventions: facial feminization surgery, liposuction, lipofilling, voice surgery, thyroid cartilage reduction, gluteal augmentation (implants/lipofilling), hair reconstruction, and various aesthetic procedures."

"For the FtM (female-to-male) patient, surgical procedures may include to following:

1. Breast/chest surgery: subcutaneous mastectomy, creation of male chest;
2. Genital surgery: hysterectomy/salpingo-oophorectomy, reconstruction of the fixed part of the urethra, which can be combined with a metoidioplasty or with a phalloplasty (employing a pedicle or free vascularized flap), vaginectomy, scrotoplasty, and implantation of erection and/or testicular prostheses;
3. Non-genital, non-breast surgical interventions: voice surgery (rare), liposuction, lipofilling, pectoral implants, and various aesthetic procedures."

SOC criteria for surgical services were introduced as a guide to decision making for breast/chest and genital surgery. (6) However, the SOC does not include criteria for other surgical procedures, such as masculinizing or feminizing facial surgery. The SOC does not stipulate the number, sequence, and/or timing of surgical procedures because they will vary from patient to patient, according to an individual patient's clinical needs and expectations, in collaboration with mental health and surgical professionals. (6)

Terminology in Relationship to Gender Reassignment Surgery and Related Services

Health care terminology for transsexual, transgender, and gender nonconforming individuals is rapidly evolving; new terms are being introduced and definitions of existing terms are changing.

This tends to create misunderstanding, debate, or disagreement about the language used in this field.

For the purposes of this policy document, we have defined terms that may be unfamiliar or that have specific meanings in the "SOC." Although others may adopt these definitions, WPATH has acknowledged that the terms they use may be defined differently in different cultures, communities, and contexts. (1)

- Affirmed gender is when an individual's true gender identity, or concern about their gender identity, is communicated to and validated from others as authentic. (7)
- Agender is an individual who does not identify as having a particular gender. (7)
- Bioidentical hormones are structurally identical to those found in the human body and generally derived from plant sources. The hormones used in bioidentical hormone therapy (BHT) need to be commercially processed to become bioidentical. (6)
- Bioidentical compounded hormone therapy (BCHT) are prepared, mixed, assembled, packaged, or labeled as a drug by a pharmacist and custom-made for an individual according to a physician's specifications. (6)
- Cisgender or cissexual describes related types of gender identity perceptions, where the individuals' experiences of their own gender agree with the sex they were assigned at birth. Cisgender may be a complement to transgender. (6)
- Cross-sex hormone therapy, transgender hormone therapy or medical affirmation refers to a form of hormone replacement therapy in which sex hormones and other hormonal medications are administered for the purpose of more closely aligning with the individual's secondary sexual characteristics. (7)
- Disorders of sex development are the congenital conditions in which the development of chromosomal, gonadal, or anatomic sex is atypical. Some people strongly object to the "disorder" label and instead view these conditions as a matter of diversity (1), preferring the terms intersex and intersexuality.
- Female-to-Male (FtM) describes individuals assigned female at birth who are changing or who have changed their body and/or gender role from birth-assigned female to a more masculine body or role. (6)
- Feminizing hormone therapy for transgender women or transfeminine individuals consists of estrogens and antiandrogens/androgen inhibitor. (7)
- Gender diverse is an umbrella term to describe an ever-evolving array of labels that individuals may apply when their gender identity, expression, or even perception does not conform to the norms and stereotypes others expects of their assigned sex. (7)
- Gender dysphoria, formerly known as gender identity disorder, is characterized by strong persistent cross-gender identification or a discrepancy between with the continuous discomfort or distress about one's anatomic sex (person's sex assigned at birth) or, by a sense of inappropriateness in the gender role of that sex. (1, 2) This includes inappropriateness, clinically caused impairment in social, occupational, or other important areas of functioning. (2)
- Gender identity is the intrinsic sense of knowing to which sex one belongs—that is the awareness that 'I am female" (a girl or woman), or "I am male" (a boy or a man). Gender

identity is the private experience of gender role, and gender role is the public expression of gender identity. Gender role can be defined as everything one says and does, including sexual arousal, to indicate to others or to oneself the degree to which one is male or female. Some individuals describe themselves not as gender-nonconforming, but as unambiguously cross-sexed or unique/transitional. Such individuals no longer consider themselves to be either male or female. An individual may never fully embrace the gender role they were assigned at birth or an individual may actualize their gender identity, role, and expression in a way that does not involve a change from one gender to another gender. (1, 6) Gender identity and sexual orientation (see below) are distinct but interrelated constructs. Therefore, being transgender does not imply a sexual orientation, and individuals who identify still identify as straight, gay, bisexual, etc., on the basis of their attractions. (7)

- Gender identity disorder is a psychiatric diagnosis defined previously in the DSM-IV (changed to "gender dysphoria" in the DSM-5). This diagnosis is no longer appropriate for use and may lead to stigma, but the term may be found in older research. (7)
- Gender non-conforming is an adjective to describe individuals whose gender identity, role, or expression differs from what is normative for their assigned sex in a given culture and historical period or the individual differs from the cultural norms prescribed for people of a particular sex. (1)
- Gender role or expression are characteristics in personality, appearance, and behavior that in a given culture and historical period are designated as masculine or feminine (that is, more typical of the male or female social role). While most individuals present socially in clearly masculine or feminine gender roles, some people present in an alternative gender role such as "genderqueer" or specifically transgender. All people tend to incorporate both masculine and feminine characteristics in their gender expression in varying ways and to varying degrees. (1)
- Gender perception is the way others interpret an individual's gender expression. (7)
- "Genderqueer" is the identity label that may be used by individuals whose gender identity and/or role does not conform to a binary understanding of gender as limited to the categories of man or woman, male or female. (6)
- Genital phenotype is largely determined by androgenic stimulation of the external genitalia in embryonic and fetal life and depends on the presence of the appropriate receptors in the target tissues. (2)
- Gonadal phenotype is defined by the internal genitalia and the external morphology and microanatomy of the gonads (testis or ovary). (2)
- Hormones that express the sexual differentiation in humans include estrogens, progesterone, and androgens, such as testosterone. (6)
- Internalized transphobia describes the discomfort with one's own transgender feelings or identity as a result of internalizing society's normative gender expectations.
- Legal affirmation refers to the changing of gender and name recorded on birth certificate, school records, passports, and other documents. (7)
- Masculinizing hormone therapy for transgender men or transmasculine individuals consists of androgens, such as testosterone. (7)

- Male-to-Female (MtF) describes individuals assigned male at birth who are changing or who have changed their body and/or gender role from birth-assigned male to a more feminine body or role. (6)
- Natural hormones are derived from natural sources such as plants and animals. Natural hormones may or may not be bioidentical. (6)
- Puberty blockers are gonadotropin-releasing hormone (GnRH) analogues, such as leuprolide and histrelin. (7)
- Sex is assigned at birth as male or female, usually based on the appearance of the external genitalia, also known as "natal gender". When the external genitalia are ambiguous, other components of sex (internal genitalia, chromosomal and hormonal sex) are considered in order to assign sex. For most people, gender identity and expression are consistent with their sex assigned at birth; for transsexual, transgender, and gender nonconforming individuals, gender identity or expression differ from their sex assigned at birth. (1)
- Sexual characteristics are the physical and behavioral traits of an organism. In humans, sex organs or primary sexual characteristics are those an individual is born with. These traits are distinguished from secondary sex characteristics that develop later in life usually during puberty. The development of primary and secondary sexual characteristics is controlled by sex hormones produced in the body after the initial fetal stage, dependent on the presence or absence of the Y-chromosome and/or the testis-determining factor/gene to determine development. (6)
- Sexual orientation refers to an individual's identity relation to the gender(s) to which they are sexually and romantically attracted. (7)
- Social affirmation refers to adopting gender-affirming hairstyles, clothing, name, gender pronouns, and restrooms, including other facilities. (7)
- Surgical affirmation are the surgical/procedural approaches to feminize or masculinize physical features of an individual. (7)
- Transgender describes a diverse group of individuals who cross or transcend culturally-defined categories of gender. The gender identity of transgender people differs to varying degrees from the sex they were assigned at birth. (6)
- Transition is the period of time when individuals change from the gender role associated with their sex assigned at birth to a different gender role. For many people, this involves learning how to live socially in another gender role; for others this means finding a gender role and expression that is most comfortable for them. Transition may or may not include feminization or masculinization of the body through hormones or other medical procedures. The nature and duration of transition is variable and individualized. (1, 6)
- Trans men assume male gender identities. Trans men have an internal sense of being male and generally seek to make their maleness known socially and legally along with conforming their primary and secondary sex characteristics to a more typical male appearance. (1)
- Transsexualism is a gender dysphoria disorder in which the person manifests, with constant and persistent conviction, the desire to live as a member of the opposite sex and progressively takes steps to live in the opposite sex role full-time. These individuals who seek to change or who have changed their primary and/or secondary sex characteristics

through feminizing or masculinizing medical interventions (hormones and/or surgery), typically accompanied by a permanent change in gender role**.** (2)

- Transvestism or cross-dressing describes the individual clothing and adopting a gender role presentation that, in a given culture, is more typical of the other sex. (5)
- Trans women assume female gender identities. Trans women have an internal sense of being female and generally seek to make their femaleness known socially and legally along with conforming their primary and secondary sex characteristics to a more typical female appearance. (11)

Definitions of Irreversible Chest and Genital Surgical Procedures for Gender Reassignment

- Augmentation mammaplasty – insertion of breast implants or lipofilling (suctioning of body fat from one body area and filling into another body area) to create the female chest.
- Clitoroplasty – creation of a clitoris, utilizing the penile glans.
- Genitoplasty – genital reconstruction or modification of genitalia.
- Hysterectomy/salpingo-oophorectomy – removal of the uterus with or without ovaries and fallopian tubes.
- Metoidioplasty – following testosterone replacement therapy, the clitoris enlarges to be separated from the labia minora to create a penis.
- Orchiectomy – both testicles are removed.
- Penectomy – removal of the penis.
- Phalloplasty – construction or reconstruction of the penis.
- Reconstruction of the fixed part of the urethra – associated surgical reconstruction with the scrotoplasty to create a scrotal complex.
- Scrotoplasty – creation of a penis from external genitalia, such as the labia majora, with or without testicular prosthesis insertion or implant.
- Subcutaneous mastectomy – removal of breast tissue, sparing the nipple-areola complex to create the male chest.
- Vaginectomy – removal of part or the entire vagina.
- Vaginoplasty – construction or reconstruction of the vaginal canal and may include neovaginoplasty, the partial or total construction of the vulvo-vaginal complex.
- Vulvoplasty – a reduction of the labia and may be known as a labiaplasty.

Regulatory Status

Gender reassignment surgical procedures are surgical interventions and, as such, are not subject to regulation by the FDA. The devices and medications/combinations of medications used in the treatment of gender dysphoria are subject to FDA approval or clearance. Refer to the FDA web site at <https://www.fda.gov> for additional information on devices and medications that may be utilized for treatment.

Rationale

This policy was originally created in 2006 and has updated regularly with searches of the MedLine database and the current World Professional Association for Transgender Health

(WPATH) Standards of Care (SOC). The most recent literature search was performed through July 2021. The following is a summary of the key literature to date.

Gender Assignment Surgery

The ability to diagnose infants born with intersex conditions has advanced rapidly in recent years. In most cases today, clinicians can promptly make an accurate diagnosis and counsel parents on therapeutic options. However, the paradigm of early gender assignment has been challenged by the results of clinical and basic science research, which show that gender identity development likely begins in utero. While the techniques of surgical genital reconstruction have been mastered, the understanding of the psychological and social implications of gender assignment is poor. (1-3)

Treatment of ambiguous genitalia is controversial. No one debates the need to treat underlying physiologic problems such as those associated with congenital adrenal hyperplasia or tumors in the gonads. However, treatment for ambiguous genitalia depends on the type of disorder but will usually include corrective surgery to remove or create reproductive organs appropriate for the gender of the child. Treatment may also include hormone replacement therapy. Controversy revolves around issues of gender assignment by the physician and family which may not correlate with gender preference by the patient in adulthood. (1-4)

For example, Reilly and Woodhouse interviewed and examined 20 patients with the primary diagnosis of micropenis in infancy and concluded, "[A] small penis does not preclude a normal male role and a micropenis or microphallus alone should not dictate a female gender reassignment in infancy." More particularly, these doctors found that when parents "were well counseled about the diagnosis they reflected an attitude of concern but not anxiety about the problem, and they did not convey anxiety to their children. They were honest and explained problems to the child and encouraged normality in behavior. They believed that this is the attitude that allows these children to approach their peers with confidence. (2-4, 8)

From a medico-legal standpoint, the best approach to managing these cases is to provide parents with as much information as possible so that they can make informed decisions. Adequate counseling and support for parents is vital. The ideal management method is a team approach including neonatologists, geneticists, endocrinologists, surgeons, counselors, and ethicists. (2, 3, 9)

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in July 2021 did not identify any ongoing or unpublished trials that would likely influence this policy.

Professional Guidelines and Position Statements

There are no professional guidelines and position statements that would likely influence this policy.

Section Summary: Gender Assignment Surgery

The available evidence supports the conclusion that psychological, medical, and/or surgical services are required for the treatment of ambiguous genitalia; therefore, considered medically necessary.

Gender Reassignment Surgery

Within the past decade, addressing transgender health care concerns has come to the forefront for inclusion and diversity worldwide. (10) These concerns have transcended to all facets of the lesbian, gay, bisexual, or transgender (LGBT) community, including initiating changes in the health care services offered to transgender individuals.

In January 2016, ECRI published a report on gender dysphoria. (12) Their review included 10 publications of systematic reviews and primary studies targeting puberty suppression therapy, cross-sex hormonal therapy, and sexual reassignment surgery. The following is a summary of their review:

- *Puberty Suppression Therapy*: ECRI did not identify any studies that met their review inclusion criteria addressing this topic in the adolescent population.
- *Cross-Sex Hormonal Therapy*: ECRI reviewed 1 systematic review and 3 primary studies. The systematic review reported on 28 studies of 1833 patients (1093 MtF [male-to-female]; 801 FtM [female-to-male]) who received endocrine therapy as part of their sex reassignment treatment -- 80% of the patients demonstrated significant improvements in gender dysphoria; 78% of the patients demonstrated significant improvements in psychological symptoms; 80% of the patients reported significant improvement in quality of life; and 72% of the patients reported significant improvement in sexual function. The primary studies focused on specific issues and resolutions following hormonal therapy: 1) psychological functioning following testosterone treatment for FtM patients; 2) incidence of breast cancer following androgen deprivation and estrogen treatment for MtF; and 3) mood disorders following hormonal treatment starting by age 32.
- *Sexual Reassignment Surgery*: ECRI evaluated 2 systematic reviews and 4 primary studies. One review included 25 studies of patients having undergone MtF penile skin inversion and the bowel vaginoplasty technique, in which the sexual function and patient satisfaction were considered “overall acceptable.” The second review indicated that sexual satisfaction was “high”; however, quality of life was not reported. The primary studies focused on patient satisfaction, postoperative complications, psychosocial and sexual well-being, mortality, morbidity, and criminal rates. One study reported higher overall mortality, increased risk of suicide attempts, psychiatric inpatient care, and higher risk of criminal conviction rates. Other studies reported overall satisfaction with surgical procedures, improved mental health, and better quality of life. Postoperative complications were noted in 2 of the studies.

Later in 2016, ECRI released a summary of hormonal treatment with gonadotropin-releasing hormone (GnRH) analogues that can suppress the secretion of luteinizing hormone and follicle-stimulating hormone, being used as a puberty blocker in transgender children and adolescents. (13) The ECRI review indicated the evidence is consistent in showing that GnRH analogues

benefit this transgender population by improving symptoms of depression, anxiety, body image, emotional and behavioral problems, and quality of life.

Revisions Following Initial GRS Treatment

Revisions to primary or secondary sexual characteristics should always be interpreted in the context of specific benefit language. The requirement of the presence of a functional impairment for a specific etiology may vary as applied to any physiological condition. It should be noted that the presence of a functional impairment would render treatment medically necessary and thus not subject to contractual definitions of reconstructive or cosmetic.

Reversal Following Regret of GRS Treatment

Misdiagnosed gender dysphoric patients may regret any gender reassignment treatments. Regret following hormonal and surgical treatment was reported at 1.83% in an 8-year case series reported by Judge et al., in 2014, of 218 patients of both transgender sexes. (14) In 2014, Dhejne et al. reported 2.2% (n=15) of the 767 patients over 50 years experienced regrets, but over time, the number of regrets has significantly declined. (15) This study was inclusive of both transgender sexes. Two other studies were reviewed from Krege et al. (16), and Nelson et al. (17), all of which found that 0% reported no regrets following gender reassignment surgery (GRS) treatments.

Seven patients who regretted their decision to undergo MtF sexual reassignment surgery were studied by Djordjevic et al. (18) Following 3 independent psychiatric evaluations for each patient, reversal surgeries were planned: 4 patients completed all steps of reversal, 2 are partially completed and awaiting completion, and 1 patient has declined a portion of the reversal. The reviewers concluded understanding the characteristics of patients regretting GRS will assist future patients opting for these services.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in November 2020 did not identify any ongoing or unpublished trials that would likely influence this policy.

Professional Guidelines and Position Statements

World Professional Association for Transgender Health (WPATH)

WPATH, formerly the Harry Benjamin International Gender Dysphoria Association, is the most widely recognized SOC and have been recognized by national medical and mental health organizations. (1, 5, 6, 10) WPATH states their overall goal to provide clinical guidance for health professionals to assist transsexuals, transgenders, and gender-nonconforming individuals with safe and effective pathways to achieve lasting personal comfort with their gendered selves, in order to maximize their overall health, psychological well-being, and self-fulfillment. (5)

In the 2012 WPATH SOC Seventh Version, clarifies the recommended medically necessary GRS and related services as the following: (6)

"In a June 2008 Clarification Statement, WPATH reiterated the procedures which are considered components of sex reassignment by the Standards of Care and specifically stated that these services are considered medically necessary when clinically indicated. WPATH underscores the clinical significance of the full range of reconstructive interventions including non-genital procedures (e.g., breast augmentation, mastectomy and chest reconstruction, facial feminization surgeries, and facial hair removal).

To ensure treatment effectiveness, WPATH emphasizes that individuals must have access to the procedures which match their clinical needs. Individuals may have a clinical need for specific procedures, although not every individual will require surgery or every possible intervention. Coverage must extend to include the variations which may exist for a given surgery type, and permit a multiple stage surgical process, to ensure clinical appropriateness for the individual." (6, 10)

In November 2015, the International Journal of Transgenderism published recommendations for speech-language therapy for individuals seeking the development of voice and communication that reflects their unique sense of gender. (19) The authors acknowledge the WPATH SOC recognition of speech-language congruency of inner and outer self. Davies et al. expand the speech-language recommendations to include the clinical care by professionals that require trans-specific voice-and-communication assessments, voice feminization protocols-and-voice feminizing surgeries, and voice masculinization protocols. (19)

American Psychiatric Association (APA)
In 2012, the APA Task Force published a report on the treatment of gender identity disorder. (20) The APA stated the following:
"There are some level B studies examining satisfaction/regret following sex reassignment (longitudinal follow-up after an intervention, without a control group); however, many of these studies obtained data retrospectively and without a control group (APA level G). Overall, the evidence suggests that sex reassignment is associated with an improved sense of well-being in the majority of cases, and also indicates correlates of satisfaction and regret. No studies have directly compared various levels of mental health screening prior to hormonal and surgical treatments on outcome variables; however, existing studies suggest that comprehensive mental health screening may be successful in identifying those individuals most likely to experience regrets."

American Academy of Pediatrics (AAP)
In 2018, the AAP released a policy statement, with recommendations focused on children and youth that identify as transgender rather than the larger LGBTQ (lesbian, gay, bisexual, transgender, queer) population. (7) The AAP stated that any discrimination based on gender identity or expression, real or perceived, is damaging to the socio-emotional health of children, families, and society. In particular, the AAP recommends the following, which includes the psychosocial, healthcare insurer, medical/mental health provider, community, family, auxiliary service, educational, workforce, legal, and federal government aspects of a child or youth seeking gender reassignment services: (7)

1. "That youth who identify as TGD [transgender and gender diverse] have access to comprehensive, gender-affirming, and developmentally appropriate health care that is provided in a safe and inclusive clinical space";
2. "That family-based therapy and support be available to recognize and respond to the emotional and mental health needs of parents, caregivers, and siblings of youth who identify as TGD";
3. "That electronic health records, billing systems, patient-centered notification systems, and clinical research be designed to respect the asserted gender identity of each patient while maintaining confidentiality and avoiding duplicate charts";
4. "That insurance plans offer coverage for health care that is specific to the needs of youth who identify as TGD, including coverage for medical, psychological, and, when indicated, surgical gender-affirming interventions";
5. "That provider education, including medical school, residency, and continuing education, integrate core competencies on the emotional and physical health needs and best practices for the care of youth who identify as TGD and their families";
6. "That pediatricians have a role in advocating for, educating, and developing liaison relationships with school districts and other community organizations to promote acceptance and inclusion of all children without fear of harassment, exclusion, or bullying because of gender expression";
7. "That pediatricians have a role in advocating for policies and laws that protect youth who identify as TGD from discrimination and violence";
8. "That the health care workforce protects diversity by offering equal employment opportunities and workplace protections, regardless of gender identity or expression"; and
9. "That the medical field and federal government prioritize research that is dedicated to improving the quality of evidence-based care for youth who identify as TGD".

Centers for Medicare and Medicaid Services (CMS)

In the CMS Proposed Decision Memo for Gender Dysphoria and GRS released in June 2016, CMS stated the following: (23)

"While we are not issuing a NCD [National Coverage Determination], CMS encourages robust clinical studies that will fill the evidence gaps and help inform the answer to the question posed in this proposed decision memorandum. Based on the gaps identified in the clinical evidence, these studies should focus on which patients are most likely to achieve improved health outcomes with gender reassignment surgery, which types of surgery are most appropriate, and what types of physician criteria and care setting(s) are needed to ensure that patients achieve improved health outcomes."

<u>Section Summary: Gender Reassignment Surgery</u>

The criteria in the 2012 World Professional Association for Transgender Health (WPATH) Seventh Version Standards of Care (SOC) are supported by evidence-based peer-reviewed scientific literature. Long-term trials of continuous hormonal therapy and living in one's affirmed gender, as well as social support, acceptance by family and peers, contribute to the improvements to the individual's well-being and health, following GRS procedures. Multi-disciplinary mental, medical, surgical, and speech-therapy professionals are crucial towards the

best results to match the gender body identity to the intended gender identity role. Therefore, applicable GRS procedures and related services may be considered medically necessary when meeting the coverage criteria and the member's Benefit Contract allowance for these services.

Summary of Evidence

Gender Assignment Surgery

For individuals requiring gender assignment services following birth as a newborn or infant when ambiguity varies to identify their specific sexual gender, the evidence includes a variety of studies over the years, including a statement from the U.S. National Institute of Health. Relevant outcomes following corrective surgery, which may or may not correlate with the patient in adulthood. The evidence is sufficient to provide the psychosocial, medical, and/or surgical services for treatment of ambiguous genitalia.

Gender Reassignment Surgery

For individuals seeking gender reassignment surgery (GRS) with related services, the evidence primarily includes a globally accepted standard of care, which is supported by evidence-based peer-reviewed scientific literature. Relevant outcomes must include multi-disciplinary mental, medical, surgical, and speech-therapy professionals to achieve the best results to match the individual's gender identity. In accordance with the member's Benefit Contract allowances for these services or Legislative directives, the evidence is sufficient to determine these services result in a meaningful improvement in the individual's net health outcome.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	11950, 11951, 11952, 11954, 11980, 11981, 11982, 11983, 15780, 15781, 15782, 15783, 15786, 15787, 15788, 15789, 15792, 15793, 15820, 15821, 15822, 15823, 15824, 15825, 15826, 15828, 15830, 15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839, 15876, 15877, 15878, 15879, 17380, 19301, 19303, 19304, 19316, 19318, 19324, 19325, 19340, 19342, 19350, 21120, 21121, 21122, 21123, 21125, 21127, 30400, 30410, 30420, 30430, 30435, 30450, 53430, 54125, 54400, 54401, 54405, 54406, 54408, 54410, 54411, 54415, 54416, 54417, 54520, 54660, 54690, 55175, 55180, 55970, 55980, 56625, 56800, 56805, 56810, 57106, 57107, 57110, 57111, 57291, 57292, 57295, 57296, 57335, 57426, 58150, 58180, 58260, 58262, 58275, 58280, 58285, 58290, 58291, 58541, 58542, 58543, 58544,

	58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573, 58661, 58720, 90845, 90846, 90847, 90849, 90853, 90863
HCPCS Codes	J1071, J2320, J3121, J3145, S0189

*Current Procedural Terminology (CPT®) ©2020 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) **does not** have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been **developed** since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change

12/01/2021	Document updated with literature review. The following change was made to Coverage: Modified statement on hair removal. No new references added.
01/15/2021	Document updated with literature review. Coverage unchanged. Added references 21 and 22.
05/01/2019	Document updated with literature review. Coverage unchanged. Several definitions added in Description section. Reference 7 added; none removed.
03/15/2018	Document updated with literature review. The following changes were made to coverage: 1) Clarification of the required referrals prior to any surgery or related service(s); 2) The new coverage statements for gender primary or secondary sexual characteristic revision surgeries – "When there is documented evidence of physical functional impairment, gender primary or secondary sexual characteristic revision procedures or services are considered medically necessary. When there is no documented evidence of physical functional impairment, gender primary or secondary sexual characteristics revision services are considered not medically necessary (refer to appropriate procedure-specific policy)"; and, 3) The new coverage statements for reversal of gender reassignment surgical procedures – "Reversal of any of the prior gender reassignment surgical procedure(s) or service(s) for gender primary or secondary sexual characteristics, the patient must meet the same criteria for gender dysphoria to have those reversal procedures considered medically necessary. If the criteria for gender dysphoria is not met, then reversal of any prior gender reassignment surgical procedure(s) or service(s) for gender primary or secondary sexual characteristics is considered not medically necessary." The following was removed from coverage: 1) "See related medical policies below for information regarding related procedures or services for non-gender reassignment services because other exclusions may apply"; and 2) the listing of all medical policies addressing non-surgical related services and surgical related services.
10/01/2016	Document updated with literature review. Coverage unchanged. Speech-language therapy recommendations included in Rationale.
11/06/2015	Document updated with literature review. Multiple coverage changes from experimental, investigational and/or unproven to medically necessary for primary and secondary gender reassignment surgeries and related services. Coverage statements added for those individuals reaching the age of majority. Rationale and References updated and reorganized.
07/01/2014	Document updated with literature review. Coverage unchanged. CPT/HCPCS code(s) updated.
03/15/2013	Document updated with literature review. Coverage unchanged. The following was added: Gender reassignment surgery and related services, for those members with a contract or a certificate of coverage that would allow for gender reassignment surgery, when specific criteria are met. Title

	changed from Gender Reassignment Surgery to Gender Assignment Surgery and Gender Reassignment Surgery with Related Services. Policy removed from no further review status.
04/01/2008	Policy reviewed without literature review; new review date only. This policy is no longer scheduled for routine literature review and update.
05/01/2006	New medical document