

Gender Dysphoria Treatment (for North Carolina Only)

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[Instructions for Use](#)

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Related Policies
• Breast Reconstruction (for North Carolina Only)
• Breast Reduction Surgery (for North Carolina Only)
• Brow Ptosis and Eyelid Repair (for North Carolina Only)
• Cosmetic and Reconstructive Procedures (for North Carolina Only)
• Habilitation and Rehabilitation Therapy (Occupational, Physical, and Speech) (for North Carolina Only)
• Panniculectomy and Body Contouring Procedures (for North Carolina Only)
• Rhinoplasty and Other Nasal Procedures (for North Carolina Only)

Application

This Medical Policy only applies to the state of North Carolina.

Coverage Rationale

Note: This Medical Policy does not apply to individuals with ambiguous genitalia or disorders of sexual development.

Surgical treatment for [Gender Dysphoria](#) may be indicated for individuals who provide the following documentation:

- For breast surgery (mastectomy, breast reduction, or breast augmentation), a written clinical assessment from at least one [Qualified Healthcare Professional](#) experienced in treating Gender Dysphoria* is required; the assessment must document that an individual meets **all** of the following criteria:
 - Persistent, well-documented Gender Dysphoria
 - Capacity to make a fully informed decision and to consent for treatment
 - Must be at least 18 years of age for breast augmentation
 - For mastectomy or breast reduction, individuals must be at least 18 years of age; however, individuals within one calendar year of turning 18 can be considered on a case-by-case basis
 - Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges
 - For breast augmentation, continued Gender Dysphoria following the completion of 12 months of continuous hormone therapy prior to the breast procedure is required
- For thyroid cartilage reduction and/or voice modification surgery (e.g., laryngoplasty, glottoplasty, or shortening of the vocal cords), a written clinical assessment from at least one [Qualified Healthcare Professional](#) experienced in treating Gender Dysphoria is required; the assessment must document that an individual meets **all** of the following criteria:
 - Persistent, well-documented Gender Dysphoria

- Capacity to make a fully informed decision and to consent for treatment
- Must be at least 18 years of age
- Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges
- Completion of 6 months of continuous hormone therapy prior to surgery is required for voice masculinization
- For voice modification surgery, documentation of presurgical voice lessons and/or therapy
- For genital surgery, a written clinical assessment from at least two Qualified Healthcare Professionals experienced in treating Gender Dysphoria, who have independently assessed the individual, is required; the assessment must document that an individual meets **all** of the following criteria:
 - Persistent, well-documented Gender Dysphoria
 - Capacity to make a fully informed decision and to consent for treatment
 - Must be at least 18 years of age
 - Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges
 - Complete at least 12 months of successful continuous full-time real-life involvement in the identified gender
 - Complete 12 months of continuous hormone therapy appropriate for the experienced gender (unless medically contraindicated or not indicated for gender)
 - Treatment plan that includes ongoing follow-up and care by a Qualified Healthcare Professional experienced in treating Gender Dysphoria

When the [above criteria](#) are met, the following surgical procedures and/or therapies to treat Gender Dysphoria are medically necessary and covered as a proven benefit:

- Bilateral mastectomy or breast reduction
- Breast augmentation with breast implants or fat transfer
- Clitoroplasty (creation of clitoris)
- Hysterectomy (removal of uterus)
- Labiaplasty (creation of labia)
- Metoidioplasty (creation of penis, using clitoris)
- Orchiectomy (removal of testicles)
- Penectomy (removal of penis)
- Penile prosthesis
- Phalloplasty (creation of penis)
- Salpingo-oophorectomy (removal of fallopian tubes and ovaries)
- Scrotoplasty (creation of scrotum)
- Testicular prostheses
- Thyroid cartilage reduction/reduction thyroid chondroplasty/tracheal shave (removal or reduction of the Adam's apple)
- Urethroplasty (reconstruction of female urethra)
- Urethroplasty (reconstruction of male urethra)
- Vaginectomy (removal of vagina)
- Vaginoplasty (creation of vagina)
- Voice lessons and/or voice therapy (with or without surgery)
- Voice modification surgery (e.g., laryngoplasty, glottoplasty, or shortening of the vocal cords)
- Vulvectomy (removal of vulva)

Gender affirming surgery is considered an irreversible intervention. Although infrequent, reversal of prior gender affirming surgery may be covered when the medical necessity criteria for the requested treatment above are met.

Certain ancillary procedures, including but not limited to the following, are considered cosmetic and not medically necessary when performed as part of surgical treatment for Gender Dysphoria (check the federal, state, or contractual requirements for benefit coverage*):

- Abdominoplasty [also refer to the Medical Policy titled [Panniculectomy and Body Contouring Procedures \(for North Carolina Only\)](#)]
- Blepharoplasty [also refer to the Medical Policy titled [Brow Ptosis and Eyelid Repair \(for North Carolina Only\)](#)]
- Body contouring (e.g., fat transfer, lipoplasty, panniculectomy) [also refer to the Medical Policy titled [Panniculectomy and Body Contouring Procedures \(for North Carolina Only\)](#)]
- Brow lift
- Calf implants
- Cheek, chin, and nose implants

- Face/forehead lift and/or neck tightening
- Facial bone remodeling for facial feminization
- Hair transplantation
- Injection of fillers or neurotoxins
- Laser or electrolysis hair removal not related to genital reconstruction
- Lip augmentation
- Lip reduction
- Liposuction (suction-assisted lipectomy) [also refer to the Medical Policy titled [Panniculectomy and Body Contouring Procedures \(for North Carolina Only\)](#)]
- Mastopexy
- Pectoral implants for chest masculinization
- Rhinoplasty [also refer to the Medical Policy titled [Rhinoplasty and Other Nasal Procedures \(for North Carolina Only\)](#)]
- Skin resurfacing (e.g., dermabrasion, chemical peels, laser)

Definitions

Gender Dysphoria in Adolescents and Adults: A disorder characterized by the following diagnostic criteria [Diagnostic and Statistical Manual of Mental Disorders, 5th edition, Text Revision (DSM-5-TR™)]:

- A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by **at least two** of the following:
 - A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)
 - A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
 - A strong desire for the primary and/or secondary sex characteristics of the other gender
 - A strong desire to be of the other gender (or some alternative gender different from one's assigned gender)
 - A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender)
 - A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender)
- The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning

Gender Dysphoria in Children: A disorder characterized by the following diagnostic criteria [Diagnostic and Statistical Manual of Mental Disorders, 5th edition, Text Revision (DSM-5-TR™)]:

- A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by **at least six** of the following (**one of which must be criterion A1**):
 - A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender)
 - In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing
 - A strong preference for cross-gender roles in make-believe play or fantasy play
 - A strong preference for the toys, games, or activities stereotypically used or engaged in by the other gender
 - A strong preference for playmates of the other gender
 - In boys (assigned gender), a strong rejection of typically masculine toys, games, and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities
 - A strong dislike of one's sexual anatomy
 - A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender
- The condition is associated with clinically significant distress or impairment in social, school or other important areas of functioning

Qualified Healthcare Professional:

- Documented credentials from a relevant licensing board
- A minimum of a master's degree or equivalent training in a clinical field relevant to the assessment and treatment of Gender Dysphoria
- Knowledge and experience in treating Gender Dysphoria

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
11950	Subcutaneous injection of filling material (e.g., collagen); 1 cc or less
11951	Subcutaneous injection of filling material (e.g., collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (e.g., collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (e.g., collagen); over 10.0 cc
14000	Adjacent tissue transfer or rearrangement, trunk; defect 10 sq cm or less
14001	Adjacent tissue transfer or rearrangement, trunk; defect 10.1 sq cm to 30.0 sq cm
14041	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10.1 sq cm to 30.0 sq cm
15734	Muscle, myocutaneous, or fasciocutaneous flap; trunk
15738	Muscle, myocutaneous, or fasciocutaneous flap; lower extremity
15750	Flap; neurovascular pedicle
15757	Free skin flap with microvascular anastomosis
15758	Free fascial flap with microvascular anastomosis
15769	Grafting of autologous soft tissue, other, harvested by direct excision (e.g., fat, dermis, fascia)
*15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
*15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
*15773	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate
*15774	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)
*15775	Punch graft for hair transplant; 1 to 15 punch grafts
*15776	Punch graft for hair transplant; more than 15 punch grafts
15780	Dermabrasion; total face (e.g., for acne scarring, fine wrinkling, rhytids, general keratosis)
15781	Dermabrasion; segmental, face
15782	Dermabrasion; regional, other than face
15783	Dermabrasion; superficial, any site (e.g., tattoo removal)
15788	Chemical peel, facial; epidermal
15789	Chemical peel, facial; dermal
15792	Chemical peel, nonfacial; epidermal
15793	Chemical peel, nonfacial; dermal
15819	Cervicoplasty
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid

CPT Code	Description
*15824	Rhytidectomy; forehead
*15825	Rhytidectomy; neck with platysmal tightening (platysmal flap, P-flap)
*15826	Rhytidectomy; glabellar frown lines
*15828	Rhytidectomy; cheek, chin, and neck
*15829	Rhytidectomy; superficial musculoaponeurotic system (SMAS) flap
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh
15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg
15834	Excision, excessive skin and subcutaneous tissue (includes lipectomy); hip
15835	Excision, excessive skin and subcutaneous tissue (includes lipectomy); buttock
15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm
15837	Excision, excessive skin and subcutaneous tissue (includes lipectomy); forearm or hand
15838	Excision, excessive skin and subcutaneous tissue (includes lipectomy); submental fat pad
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area
*15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (e.g., abdominoplasty) (includes umbilical transposition and fascial plication) (List separately in addition to code for primary procedure)
*15876	Suction assisted lipectomy; head and neck
*15877	Suction assisted lipectomy; trunk
*15878	Suction assisted lipectomy; upper extremity
*15879	Suction assisted lipectomy; lower extremity
*17380	Electrolysis epilation, each 30 minutes
*17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
19303	Mastectomy, simple, complete
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19350	Nipple/areola reconstruction
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)
21121	Genioplasty; sliding osteotomy, single piece
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (e.g., wedge excision or bone wedge reversal for asymmetrical chin)
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)
21125	Augmentation, mandibular body or angle; prosthetic material
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)
21137	Reduction forehead; contouring only
21138	Reduction forehead; contouring and application of prosthetic material or bone graft (includes obtaining autograft)
21139	Reduction forehead; contouring and setback of anterior frontal sinus wall
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)
21175	Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (e.g., plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)

CPT Code	Description
21179	Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)
21180	Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21209	Osteoplasty, facial bones; reduction
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
21270	Malar augmentation, prosthetic material
*21899	Unlisted procedure, neck or thorax
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
*31599	Unlisted procedure, larynx
*31899	Unlisted procedure, trachea, bronchi
53410	Urethroplasty, 1-stage reconstruction of male anterior urethra
53430	Urethroplasty, reconstruction of female urethra
54125	Amputation of penis; complete
*54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
*54401	Insertion of penile prosthesis; inflatable (self-contained)
*54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54406	Removal of all components of a multi-component, inflatable penile prosthesis without replacement of prosthesis
*54408	Repair of component(s) of a multi-component, inflatable penile prosthesis
*54410	Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session
*54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54415	Removal of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis, without replacement of prosthesis
*54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session
*54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
*54660	Insertion of testicular prosthesis (separate procedure)
54690	Laparoscopy, surgical; orchiectomy
55175	Scrotoplasty; simple
55180	Scrotoplasty; complicated
*55970	Intersex surgery; male to female
*55980	Intersex surgery; female to male

CPT Code	Description
56625	Vulvectomy simple; complete
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
57110	Vaginectomy, complete removal of vaginal wall
57335	Vaginoplasty for intersex state
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)
58180	Supracervical abdominal hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)
58260	Vaginal hysterectomy, for uterus 250 g or less
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
58290	Vaginal hysterectomy, for uterus greater than 250 g
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58550	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral (separate procedure)
58940	Oophorectomy, partial or total, unilateral or bilateral
64856	Suture of major peripheral nerve, arm or leg, except sciatic; including transposition
64892	Nerve graft (includes obtaining graft), single strand, arm or leg; up to 4 cm length
64896	Nerve graft (includes obtaining graft), multiple strands (cable), hand or foot; more than 4 cm length
*67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
92508	Treatment of speech, language, voice, communication, and/or auditory processing disorder; group, 2 or more individuals

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Codes labeled with an asterisk (*) are not on the State of North Carolina Medicaid Fee Schedule and therefore may not be covered by the State of North Carolina Medicaid Program.

Diagnosis Code	Description
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified
Z87.890	Personal history of sex reassignment

Description of Services

Gender Dysphoria is a condition in which there is a marked incongruence between an individual's experienced/expressed/alternative gender and assigned gender (DSM-5-TR). Gender-affirming care encompasses a range of social, psychological, behavioral, and medical interventions to support an individual's gender identity. Treatment options include behavioral therapy, psychotherapy, hormone therapy, and surgery for gender transformation. Surgical treatments for Gender Dysphoria may include the following: clitoroplasty, hysterectomy, labiaplasty, mastectomy, orchiectomy, penectomy, phalloplasty or metoidioplasty (alternative to phalloplasty), placement of testicular and/or penile prostheses, salpingo-oophorectomy, scrotoplasty, urethroplasty, urethroplasty, vaginectomy, vaginoplasty, and vulvectomy.

Other terms used to describe surgery for Gender Dysphoria include gender affirming surgery, sex transformation surgery, sex change, sex reversal, gender change, transsexual surgery, transgender surgery, and sex reassignment.

Clinical Evidence

Almazan et al. (2021) conducted a secondary analysis of the 2015 United States Transgender Survey (USTS) that included 27,715 transgender and gender diverse (TGD) people to evaluate whether gender-affirming surgeries were associated with better mental health outcomes including psychological distress, substance use and suicide risk when compared to TGD people who do not undergo gender-affirming surgeries. The survey was conducted across all 50 states, Washington, DC, US territories and US military bases abroad. The exposure group included respondents who indicated they had undergone 1 or more gender-affirming surgeries at least 2 years prior to submitting survey responses. This group was compared to respondents who indicated a desire to undergo 1 or more types of gender-affirming surgeries but denied having had any gender-affirming surgeries. Of the 27,715 respondents, 3,559 (12.8%) indicated they had undergone 1 or more gender-affirming surgeries at least 2 years prior to the survey while 59.2% (n = 16,401) indicated a desire to undergo a gender-affirming surgery but had not done so as of the time they responded to the survey. Demographics of the respondents to the survey showed that 81.1% (n = 16,182) were between the ages of 18 and 44 years, 82.1% (n = 16,386) identified as white, 38.8% (n = 7,751) identified as transgender women, 32.5% (n = 6,489) identified as transgender men and 26.6% (n = 5,300) identified as nonbinary. After adjusting for sociodemographic factors, the authors concluded that the analysis showed TGD people with a history of gender-affirming surgery had significantly lower odds of past-month psychological distress, past-year tobacco smoking, and past-year suicidal ideation compared with TGD people who did not have any gender-affirming surgery. Limitations noted by the authors included the nonprobability sampling of the database, the self-reporting structure of the measures, and the risk of confounding. The authors concluded that the study showed a positive association between gender-affirming surgery and improved mental health outcomes for TGD people who seek gender affirming surgical interventions.

Scandurra et al. (2019) performed a systematic review assessing the health of nonbinary and genderqueer (NBGQ) individuals compared to binary transgender (BT) and cisgender individuals. Eleven studies were included in the review. Results related to the difference in health between NBGQ and BT were mixed, with some finding a better health status while others a worse one. Results related to the differences in health between NBGQ and cisgender individuals highlighted higher health needs in NBGQ individuals compared with cisgender counterparts. The authors noted the need for research expansion in terms of both methodology and research contents.

Wernick et al. (2019) conducted a systematic review of the psychological benefits of gender-affirming surgery. Thirty-three studies were included in the analysis. Overall, most of the studies comparing pre- and post-operative data on quality of life, body image/satisfaction, and overall psychological functioning among individuals with gender dysphoria suggested that gender-affirming surgery leads to multiple, significant psychological benefits. Of the studies comparing psychological well-being between individuals who did or did not undergo surgery, most demonstrated a trend of better mental health among individuals who underwent surgery compared with those who did not. The authors encouraged future research to focus on standardizing the assessment of psychological functioning pre- and post-gender-affirming surgery to gather

longitudinal data that will allow for more definitive conclusions to be made about factors that contribute to the psychological benefits of surgery.

A Hayes report on sex reassignment surgery (2018; updated 2022) for the treatment of gender dysphoria made the following conclusions:

- Studies suggest that following sex reassignment surgery, patients reported decreased gender dysphoria and improved body image satisfaction. However, results were mixed regarding effects of sex reassignment surgery on quality of life and psychological symptoms.
- Few studies compare outcomes in patients who received sex reassignment surgery with stand-alone hormone therapy. The results of these studies suggest that sex reassignment surgery may improve gender dysphoria, quality of life, body image and psychological symptoms to a greater extent than hormone therapy alone. However, the results were conflicting.
- Few studies compared outcomes in patients who received different components of sex reassignment surgery. For most outcome measures, there was only a single study available. This evidence is therefore insufficient to support definitive conclusions regarding the comparative effectiveness of different components of sex reassignment surgery for treating gender dysphoria.
- Not all studies reported all outcomes; the following findings therefore do not inform overall incidence of complications. Following sex reassignment surgery, there were very low rates of regret of surgery (0% to 6% per study) and suicide (2% to 3% per study). Complications following sex reassignment surgery were common, and some were serious.

An ECRI special report systematically reviewed the clinical literature to assess the efficacy of treatments for gender dysphoria. The authors identified limited evidence from mostly low-quality retrospective studies. Evidence on gender reassignment surgery was mostly limited to evaluations of MtF individuals undergoing vaginoplasty, facial feminization surgery and breast augmentation. Outcomes included mortality, patient satisfaction, physical well-being, psychological-related outcomes, quality of life, sexual-related outcomes, suicide, and adverse events. Concluding remarks included the need for standardized protocols and prospective studies using standardized measures for correct interpretation and comparability of data (ECRI, 2016).

Breast Surgery

Oles et al. (2022) performed a systematic review of gender-affirming surgery publications to assess outcomes and outcome assessment tools. Part 1 of the review encompasses non-genital procedures such as chest feminization, chest masculinization and voice surgery. Patient-centered outcomes included survival, function, symptoms, and health-related quality of life. Outcome data was pooled to assess reported complications, satisfaction, and other outcome rates. A total of 406 cohort publications were included. The lack of consistent use of the same outcome measures and validated gender-affirming surgery-specific instruments represent the two primary barriers to high-quality research. The authors address current methodologic limitations in the literature and what dimensions must be included in assessing surgical success. Addressing gaps in the literature will promote evidence-based practices and lead to improved surgical techniques.

Sijben et al. (2021) analyzed complications, surgical trends, and long-term follow-up of breast augmentations in 527 transgender women and nonbinary individuals. A total of nine studies were included, most were of retrospective design. Reoperations due to short-term complications were infrequent. Reoperations due to long-term complications included implant rupture (5.7%), capsular contracture (4.9%), aesthetic problems (3.8%), low-grade infection (0.4%) or seroma (0.6%). Follow-up time ranged from 30 days to 5.5 years.

Cohen et al. (2019) conducted a systematic review of surgical options and associated outcomes for transmasculine top surgery. Twenty-two studies were included (n = 2,447). The authors reported that future research is needed to improve patient selection, surgical decision making, and patient-reported outcomes for different chest contouring techniques.

Thyroid Cartilage Reduction/Voice Modification Surgery

In a 2023e (updated 2024) evolving evidence review, Hayes evaluated Wendler glottoplasty (WG) surgery for voice feminization in patients with gender dysphoria. Six poor- to very poor-quality studies were identified along with one systematic review with meta-analysis of 13 poor quality studies, and one guideline. The conclusion is that WG may achieve improvement in vocal qualities when combined with voice therapy, however, due to heterogeneity in surgical techniques and lack of organizational support for a recommended surgical modality, no recommendation can be made of a single approach.

Schwarz et al. (2023) performed a systematic review and meta-analysis evaluating speech therapy and phonosurgery for transgender women. There were 16 studies included in the review. The relationship between therapy time and post-

treatment frequency gain was not significant. The authors found that the type of sample collected significantly influenced the voice frequency gain. The authors also noted that both phonosurgery and voice feminization therapy showed an increase in voice frequency with phonosurgery having significantly more fundamental frequency gain compared to speech therapy alone. Limitations of the review include a low quality of evidence based on the lack of randomized controlled trials, small sample sizes, and various methods of collecting voice frequency.

Hayes (2022a, updated 2023) performed an evidence review for feminizing voice and communication therapy for gender dysphoria and identified one poor- and four very poor-quality clinical studies, one systematic review that only included 2 clinical studies, and two expert-opinion guidelines. All clinical studies had a small sample size, lacked comparison groups, and did not report clear benefits or advantages in patient-oriented outcomes. There are two RCTs underway examining feminizing voice therapy.

Hayes (2022b, updated 2023) performed an evidence review for masculinizing voice and communication therapy for gender dysphoria and identified one poor-quality clinical study, no systematic reviews, and two expert opinion-based guidelines. The clinical study identified appeared to suggest that masculinizing voice therapy is associated with improvement in patient satisfaction; however, evidence is extremely sparse and low in quality. There is one randomized controlled trial that is underway examining voice therapy.

Gray and Courey (2019) reported that many male to female (MtF) patients require initial or sustained voice therapy with or without phonosurgery to achieve voice goals. A study comparing voice outcomes after Wendler glottoplasty with and without voice therapy found that voice therapy was associated with higher pitch, improved self-evaluation, and increased perception of feminine voice. The authors also noted that hormone therapy is recommended for at least six months prior to further voice intervention.

Van Damme et al. (2017) conducted a systematic review of the effectiveness of pitch-raising surgery performed in MtF transsexuals. Twenty studies were included: eight using cricothyroid approximation, six using anterior glottal web formation and six using other surgery types or a combination of surgical techniques. A substantial rise in postoperative frequency was identified. The majority of patients seemed satisfied with the outcome. However, none of the studies used a control group and randomization process. Further investigation regarding long-term results using a stronger study design is necessary.

Genital Surgery

Wang et al. (2022) performed a systematic review and meta-analysis to evaluate the outcomes for different phalloplasty surgical techniques. There were 39 articles included in the analysis which consisted of 19 case series, 3 cross-sectional studies, and 17 retrospective cohort studies for a total of 1,731 patients. The most common type of reconstruction was radial forearm free flap (75.1%). The overall complication rate for phalloplasty was 76.5% with urethral complications being common (fistula 34.1% and stricture 25.4%). Only 14 of the 39 studies reported on functional outcomes. Of those studies, most patients (93.9%) reported having tactile sensation and ability to void while standing (92.2%) and 59.93% reported erogenous sensation/sexual function. Aesthetic outcomes were reported in 6.3% of patients with mean length achieved of 12.26 cm and mean circumference of 10.18 cm. The authors conclude that the evidence available for phalloplasty surgical techniques and expected outcomes is weak and lacking. Future research is needed to develop standardized core outcomes and improve clinical decision making.

Bustos et al. (2021) conducted a systematic review and meta-analysis of the complications and patient-reported outcomes in transfemale vaginoplasty. This was an updated systematic review and included data compiled from the previous systematic review by Manrique et al. (2018). There were 57 studies included in the review and 52 studies included in the meta-analysis with a total of 4,680 cases. Results including any surgical technique showed a complication rate of 1% for fistula, 11% for stenosis and/or strictures, 4% for tissue necrosis, and 3% for prolapse. The patient-reported satisfaction rate was 91% for overall, functional, and aesthetic outcomes with 76% of patients reporting the ability to achieve orgasm. There was a regret rate of 2%. The average neovaginal depth was 9.4 cm for the penile skin inversion and 15.3 cm for the intestinal vaginoplasty. The authors noted that in general, the quality of the studies was either low or moderate with the majority being retrospective with no control group. They conclude that transfemale vaginoplasty is an important component of a comprehensive surgical treatment for transfemale patients with gender dysphoria and there will likely be an increase in demand for these procedures, therefore, continued surgical training, clinical/surgical experience, and research outcomes are necessary to provide the best care possible for this population. (Publications by Bouman 2016, Buncamper 2016, Gaither 2018, and Manrique 2018, which were previously cited in this policy, are included in this systematic review).

Dreher et al. (2018) conducted a systematic review and meta-analysis to evaluate the epidemiology, presentation, management, and outcomes of neovaginal complications in the MtF transgender reassignment surgery patients. Selected

studies reported on 1,684 patients with an overall complication rate of 32.5% and a reoperation rate of 21.7% for non-esthetic reasons. The most common complication was stenosis of the neo-meatus (14.4%). Wound infection was associated with an increased risk of all tissue-healing complications. Use of sacrospinous ligament fixation (SSL) was associated with a significantly decreased risk of prolapse of the neovagina. The authors concluded that gender-affirmation surgery is important in the treatment of gender dysphoric patients, but there is a high complication rate in the reported literature. Variability in technique and complication reporting standards makes it difficult to assess the accurately the current state of MtF gender reassignment surgery. Further research and implementation of standards is necessary to improve patient outcomes.

Frey et al. (2016) conducted a systematic review of metoidioplasty and radial forearm flap phalloplasty (RFFP) in female to male (FtM) transgender genital reconstruction. Eighteen studies were included: 7 for metoidioplasty and 11 for RFFP. The quality of evidence was low to very low for all included studies. In studies examining metoidioplasty, the average study size and length of follow-up were 54 patients and 4.6 years, respectively [1 study did not report (NR)]. Eighty-eight percent underwent a single-stage reconstruction, 87% reported an aesthetic neophallus (3 NR) and 100% reported erogenous sensation (2 NR). Fifty-one percent of patients reported successful intercourse (3 NR) and 89% of patients achieved standing micturition (3 NR). In studies examining RFFP, the average study size and follow-up were 60.4 patients and 6.23 years, respectively (6 NR). No patients underwent single-stage reconstructions (8 NR). Seventy percent of patients reported a satisfactorily aesthetic neophallus (4 NR) and 69% reported erogenous sensation (6 NR). Forty-three percent reported successful penetration of partner during intercourse (6 NR) and 89% achieved standing micturition (6 NR). Compared with RFFP, metoidioplasty was significantly more likely to be completed in a single stage, have an aesthetic result, maintain erogenous sensation, achieve standing micturition, and have a lower overall complication rate. The authors reported that, although the current literature suggests that metoidioplasty is more likely to yield an "ideal" neophallus compared with RFFP, any conclusion is severely limited by the low quality of available evidence.

Despite the significant increase in genital gender affirming surgery (GAS) within the past 50 years, there is limited data regarding hair removal practices in preparation for genital GAS. Genital GAS involves reconstruction of the genitals to match a patient's identified sex. The use of hair-bearing flaps in this procedure may result in postoperative intra-vaginal and intra-urethral hair growth and associated complications, including lower satisfaction with genital GAS. In 2016, Zhang et al. conducted a literature review, recommendations from experience, and a practical laser hair removal (LHR) approach to hair removal prior to genital GAS.

Horbach et al. (2015) conducted a systematic review of vaginoplasty techniques in MtF individuals with gender dysphoria. Twenty-six studies were included (mostly retrospective case series of low to intermediate quality). Outcome of the penile skin inversion technique was reported in 1,461 patients and bowel vaginoplasty in 102 patients. Neovaginal stenosis was the most frequent complication in both techniques. Sexual function and patient satisfaction were overall acceptable, but many different outcome measures were used. Quality of life was only reported in one study. Comparison between techniques was difficult due to the lack of standardization. The authors concluded that the penile skin inversion technique is the most researched surgical procedure. Outcome of bowel vaginoplasty has been reported less frequently but does not seem to be inferior. The available literature is heterogeneous in patient groups, surgical procedure, outcome measurement tools and follow-up. There is a need for prospective studies with standardized surgical procedures, larger patient groups and longer follow-up periods. Uniformity in outcome measurement tools such as validated questionnaires and scores for sexual function and quality of life is mandatory for correct interpretation and comparability of data.

Bouman et al. (2014) conducted a systematic review of surgical techniques and clinical outcomes of intestinal vaginoplasty. Twenty-one studies were included (n = 894). All studies had a retrospective design and were of low quality. Prevalence and severity of procedure-related complications were low. The main postoperative complication was introital stenosis, necessitating surgical correction in 4.1% of sigmoid-derived and 1.2% of ileum-derived vaginoplasties. Neither diversion colitis nor cancer was reported. Sexual satisfaction rate was high, but standardized questionnaires were rarely used. Quality of life was not reported. The authors concluded that prospective studies, using standardized measures and questionnaires, are warranted to assess functional outcomes and quality of life.

Djordjevic et al. (2013) evaluated 207 patients who underwent single-stage metoidioplasty, comparing two different surgical techniques of urethral lengthening. The procedure included lengthening and straightening of the clitoris, urethral reconstruction and scrotoplasty with implantation of testicular prostheses. Buccal mucosa graft was used in all cases for dorsal urethral plate formation and joined with one of the two different flaps: longitudinal dorsal clitoral skin flap (n = 49) (group 1) and labia minora flap (n = 158) (group 2). The median follow-up was 39 months. The total length of reconstructed urethra ranged from 9.1 to 12.3 cm in group 1 and from 9.4 to 14.2 cm in group 2. Voiding while standing was significantly better in group 2 (93%) than in group 1 (87.82%). Urethral fistula occurred in 16 patients in both groups. Overall satisfaction was noted in 193 patients. The authors concluded that combined buccal mucosa graft and labia minora flap was the method of choice for urethroplasty in metoidioplasty, minimizing postoperative complications.

Sutcliffe et al. (2009) systematically reviewed five individual procedures for MtF gender reassignment surgery: clitoroplasty, labiaplasty, orchiectomy, penectomy and vaginoplasty. Further evaluations were made of eight surgical procedures for FtM gender reassignment surgery: hysterectomy, mastectomy, metoidioplasty, phalloplasty, salpingo-oophorectomy, scrotoplasty/placement of testicular prostheses, urethroplasty and vaginectomy. Eighty-two published studies (38 MtF; 44 FtM) were included in the review. For MtF procedures, the authors found no evidence that met the inclusion criteria concerning labiaplasty, penectomy or orchiectomy. A large amount of evidence was available concerning vaginoplasty and clitoroplasty procedures. The authors reported that the evidence concerning gender reassignment surgery in both MtF and FtM individuals with gender dysphoria has several limitations including lack of controlled studies, lack of prospective data, high loss to follow-up and lack of validated assessment measures. Some satisfactory outcomes were reported, but the magnitude of benefit and harm for individual surgical procedures cannot be estimated accurately using the current available evidence.

Ancillary Surgery/Procedures

In a 2023a (updated 2024) evolving evidence review, Hayes evaluated combination facial feminization surgery in patients with gender dysphoria. There were eleven very poor- to poor-quality studies with 10 being retrospective designs, five systematic reviews, and four guidelines identified. The overall conclusion is that facial feminization surgery has the potential to safely improve satisfaction and quality of life; however, data are lacking for mental health outcomes, patient and third-party perception of femininity, and longer-term follow-up. The quality of the evidence creates difficulty evaluating interventions and is unlikely to improve.

A Hayes (2023c, updated 2024) evolving evidence review evaluated gender-affirming hair removal for patients with gender dysphoria. There were two very poor- to poor-quality prospective studies identified, no systematic reviews, and three guidelines identified of which 1 performed a systematic review of the literature. The two low-quality studies suggest clearance of hair is at least moderately effective and highly satisfactory when modality is properly selected but not guaranteed to be 100% permanent for any modality. Better laser hair removal results may be attained if no mechanical epilation is done prior and no adverse events were reported. The overall conclusion is that there is minimal support for gender-affirming hair removal based on clinical studies as data is lacking or nonexistent for efficacy of hair removal treatment before versus after starting hormone therapy, adverse events/effects, pain, quality of life, and long-term follow-up.

Body-contouring procedures were evaluated in an evolving evidence review by Hayes (2023f). Hayes identified one small poor-quality study, one systematic review that included a single study of five patients and one guideline founded on a systematic review. Hayes noted that body-contouring procedures for patients with gender dysphoria are varied and highly customizable and that while such procedures may improve the quality of life through achievement of desired appearance, evidence on safety and efficacy is currently limited to a single poor-quality study of 2 related interventions. Higher-quality, randomized, comparative data from larger studies are needed by it is unlikely to be forthcoming due to the personalized nature of procedure selection based on desired appearance.

A panel of facial gender surgeons presented guidelines for screening, management, and surgical technique for patients undergoing facial gender surgery (Coon et al., 2022). The specific recommendations and position statements presented represent the panel's expert opinion based on collective experience and review of current evidence. Of the 21 studies included in the systematic review, 16 included some form of patient-centered outcomes. Thirteen studies included upper face procedures, primarily forehead; 14 studies described midface procedures, including rhinoplasty; 11 studies described lower face procedures, primarily genioplasty and mandibular osteotomy; and two studies did not specify. Most studies pointed to high rates of satisfaction and improved quality of life in patients who have undergone facial gender surgery; however, many cases were small cohorts or lacked effective instruments for assessing patient-reported outcomes. The panel also noted that nearly all articles originated from the same few experienced high-volume authors. Larger, multicenter, prospective studies with sufficient sample size are needed to advance the science further and to identify which patients would benefit the most from these procedures. Research priorities include better procedural outcomes data, more quality-of-life studies, and insight into variation in both patient and procedural subgroups.

Siringo, et al. (2022) performed a systematic review designed to critically appraise the literature, identify knowledge gaps, and inform future advancements in facial feminization surgical practice. Potential components of facial feminization surgery included frontal sinus setback, burring of the supraorbital ridge, hairline lowering, rhinoplasty, malar augmentation, genioplasty, mandibular angle reduction or alternative jaw contouring, and tracheal shave. A total of 23 articles were included in the review, including primary data pertaining to 3,554 patients who underwent 8,506 total procedures. Participants ranged in age from 18 to 73. Data on procedures, outcomes, patient age, follow-up time, complications, and patient satisfaction were collected. Information was categorized by facial thirds and then further stratified by facial feature. Most of the procedures addressed the upper facial third (hairline, forehead, and brow), comprising 49.1% of total procedures performed. Further categorization by facial feature revealed that the most commonly

addressed feature was the forehead (34.6% of procedures), followed by the nose (12.8%) and the chin (12.2%). The authors reported that facial feminization surgery was found to be safe, whether conducted in a single stage or as a staged procedure. Patients reported high satisfaction and better gender congruency after facial feminization procedures. The use of validated and specific patient-reported outcome measures and standardization of follow-up would better inform patients' postoperative quality of life. Future investigations focused on the timing and coordination of procedures, as well as the development of patient-reported outcome measures, might better guide these surgeries moving forward. Author noted limitations include potential for bias in data interpretation and variations in the extent of information regarding surgical techniques and features addressed. Further research is needed to establish best surgical practice and gauge patient satisfaction beyond the length of average follow-up.

Morrison et al. (2016) conducted a systematic review of the facial feminization surgery literature. Fifteen studies were included, all of which were either retrospective or case series/reports. The studies covered a variety of facial feminization procedures. A total of 1,121 patients underwent facial feminization surgery, with seven complications reported, although many studies did not explicitly comment on complications. Satisfaction was high, although most studies did not use validated or quantified approaches to address satisfaction. The authors noted that further studies are needed to better compare different techniques to more robustly establish best practices. Prospective studies and patient-reported outcomes are needed to establish quality of life outcomes for patients.

Adolescents

Hayes (2023b, updated 2024) conducted an evidence review for FtM gender-affirming surgical (GAS) procedures for adolescents with gender dysphoria. There were three clinical studies included in the review that were of poor to very poor quality, no systematic reviews were identified, and three evidence-based guidelines with expert opinion. Evidence suggests that masculinizing chest GAS may provide psychological and social benefits for transgender adolescent boys, however, uncertainty remains for this age group due to lack of long-term follow-up, lack of validated structure outcome assessments, no studies evaluating efficacy and safety of genital GAS, and no studies evaluating reversal rates after GAS. The overall conclusion is that there is unclear to minimal support for FtM GAS in adolescents. Additionally, because randomization of treatment is inappropriate in this patient population, it is unlikely that there will be higher-quality studies forthcoming.

Hayes (2023d, updated 2024) conducted an evidence review for MtF GAS procedures for adolescents with gender dysphoria. There were no clinical studies or systematic reviews identified for this population and only three evidence-based guidelines with expert opinion were identified. It was determined that the evidence for efficacy and safety of vaginoplasty gender-affirming surgery is unclear in this population. Additionally, given that there are no current or ongoing studies specifically aimed at this population, high-quality studies are unlikely to be forthcoming as randomization of treatment is inappropriate in this population.

Thompson et al. (2023) performed a systematic review to evaluate the treatment of adolescent gender dysphoria focusing on the types of treatment, age when different treatment types are instituted, and outcomes measured. There were 19 articles included in the review which were observational cohort studies, usually using retrospective record review, with significant overlap of study samples. The authors note that GAS was not routinely offered in this young population. Two articles reported cases for GAS. One reporting 14 adolescents undergoing a mastectomy at an average age of 17.2 years old and one reporting 14 patients undergoing mastectomy and 1 vaginoplasty with a mean age of 18 years old. Most changes to health parameters were inconclusive. The authors note a lack of evidence on treatment for GD in adolescents further identifying the impossibility to draw definitive conclusions regarding the safety of treatment.

Mahfouda et al. (2019) conducted a systematic review of the available published evidence on gender-affirming hormone and surgical interventions in transgender children and adolescents, amalgamating findings on mental health outcomes, cognitive and physical effects, side-effects, and safety variables. The small amount of available data suggests that when clearly indicated in accordance with international guidelines, gender-affirming hormone therapy and chest wall masculinization in transgender males are associated with improvements in mental health and quality of life. Evidence regarding surgical vaginoplasty in transgender females younger than age 18 years remains extremely scarce and conclusions cannot yet be drawn regarding its risks and benefits in this age group. Further research on an international scale is urgently warranted to clarify long-term outcomes on psychological functioning and safety.

World Professional Association for Transgender Health (WPATH)

In Standards of Care version 8, WPATH offers standards for promoting optimal healthcare and guidance for the treatment of transgender and gender diverse individuals. Recommendation statements were developed based on data derived from independent systematic literature reviews, where available, background reviews and expert opinions (Coleman et al., 2022).

Clinical Practice Guidelines

American Academy of Pediatrics (AAP)

In a 2018 policy statement entitled Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents, the AAP states the following regarding surgery: Surgical approaches may be used to feminize or masculinize features, such as hair distribution, chest, or genitalia, and may include removal of internal organs, such as ovaries or the uterus (affecting fertility). These changes are irreversible. Although current protocols typically reserve surgical interventions for adults, they are occasionally pursued during adolescence on a case-by case basis, considering the necessity and benefit to the adolescent's overall health and often including multidisciplinary input from medical, mental health, and surgical providers as well as from the adolescent and family (Rafferty et al, 2018).

American College of Obstetrics and Gynecology (ACOG)

An ACOG committee opinion (2021) provides guidance on health care for transgender and gender diverse individuals. The document does not make specific recommendations regarding surgery but does provide an overview of surgical procedures and education for clinicians who care for transgender patients before and after surgery.

Endocrine Society

Endocrine Society practice guidelines (Hembree et al., 2017) addressing endocrine treatment of gender-dysphoric/gender-incongruent persons makes the following recommendations regarding surgery for sex reassignment and gender confirmation:

- Suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country (Recommendation based on low quality evidence).
- A patient pursue genital gender-affirming surgery only after the mental health practitioner (MHP) and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being (Strong recommendation based on low quality evidence).
- Surgery is recommended only after completion of at least one year of consistent and compliant hormone treatment unless hormone therapy is not desired or medically contraindicated (Ungraded Good Practice Statement).
- The physician responsible for endocrine treatment medically clears individual for surgery and collaborates with the surgeon regarding hormone use during and after surgery (Ungraded Good Practice Statement).
- Recommend that clinicians refer hormone treated transgender individuals for genital surgery when (Strong recommendation based on very low quality evidence):
 - The individual has had a satisfactory social role change
 - The individual is satisfied about the hormonal effects
 - The individual desires definitive surgical changes
- Suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement (Recommendation based on very low quality evidence).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Gender transformation surgeries are procedures, and therefore, not subject to FDA regulation. However, medical devices, drugs, biologics, or tests used as a part of these procedures may be subject to FDA regulation. Refer to the following website to search by product name. Available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed October 3, 2024)

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Policy History/Revision Information

Date	Summary of Changes
01/01/2025	<p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information Archived previous policy version CSNCT0145.01

Instructions for Use

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