

# GENDER DYSPHORIA TREATMENT

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  - [Physical, Occupational \(OptumHealth Care Solutions Arrangement\) and Speech Therapy including Cognitive/Neuropsychological Rehabilitation for New Jersey Small Group Members](#)
  - [Rhinoplasty and Other Nasal Surgeries](#)

- Related Optum Guideline**
- [Gender Dysphoria](#)

## INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

## CONDITIONS OF COVERAGE

Applicable Lines of Business/Products	This policy applies to Oxford Commercial plan membership.
Benefit Type	General Benefits Package
Referral Required (Does not apply to non-gatekeeper products)	No
Authorization Required (Precertification always required for inpatient admission)	Yes <sup>1</sup>
Precertification with Medical Director Review Required	Yes <sup>1</sup>

Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	Outpatient, Inpatient
Special Considerations	<sup>1</sup> Precertification with review by a Medical Director or their designee is required.

## BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

### **Coverage Information**

Unless otherwise specified, if a plan covers treatment for Gender Dysphoria, coverage includes psychotherapy, cross-sex hormone therapy, puberty suppressing medications and laboratory testing to monitor the safety of hormone therapy. This benefit also includes certain surgical treatments listed in the [Coverage Rationale](#) section below. Also see the related policy titled [Gonadotropin Releasing Hormone Analogs](#) and the Optum Coverage Determination Guideline titled *Gender Dysphoria* (to access this guideline, go to: [Optum Provider Express > Clinical Resources > Guidelines/Policies/Manuals > Coverage Determination Guidelines](#)).

### **Limitations and Exclusions**

Certain treatments and services are not covered. Examples include, but are not limited to:

- Treatment received outside of the United States.
- Reproduction services, including, but not limited to, sperm preservation in advance of hormone treatment or Gender Dysphoria surgery, cryopreservation of fertilized embryos, oocyte preservation, surrogate parenting, donor eggs, donor sperm and host uterus (see the Reproduction exclusion in the member specific benefit plan document).
- Transportation, meals, lodging or similar expenses.
- Cosmetic procedures (see the policy titled [Cosmetic and Reconstructive Procedures](#) and the [Coverage Rationale](#) section).
- Reversal of genital surgery or reversal of surgery to revise secondary sex characteristics.

Benefits are limited to one sex transformation reassignment per lifetime which may include several staged procedures.

Coverage does not apply to members who do not meet the indications listed in the [Coverage Rationale](#) section.

### **Essential Health Benefits for Individual and Small Group**

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

## COVERAGE RATIONALE

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

### **Gender reassignment surgery may be indicated for individuals who provide the following documentation:**

- A written psychological assessment from at least one qualified behavioral health provider experienced in treating Gender Dysphoria\*, is needed for breast surgery. 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 (age of majority)
  - If significant medical or mental health concerns are present, they must be reasonably well controlled
- A written psychological assessment from at least two qualified behavioral health providers experienced in treating Gender Dysphoria\*, who have independently assessed the individual, is required for genital surgery. 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 (age of majority)
- If significant medical or mental health concerns are present, they must be reasonably well controlled
- Complete at least 12 months of successful continuous full-time real-life experience in the desired gender
- Complete 12 months of continuous cross-sex hormone therapy appropriate for the desired gender (unless medically contraindicated)
- Treatment plan that includes ongoing follow-up and care by a qualified behavioral health provider experienced in treating Gender Dysphoria\*.

\*See the Optum Coverage Determination Guideline titled *Gender Dysphoria* for provider qualification criteria (to access this guideline, go to: [Optum Provider Express > Clinical Resources > Guidelines/Policies/Manuals > Coverage Determination Guidelines](#)).

**When the above criteria are met, the following gender reassignment surgical procedures are medically necessary and covered as a proven benefit:**

#### **Male-to-Female (MtF)**

- Clitoroplasty (creation of clitoris)
- Labiaplasty (creation of labia)
- Orchiectomy (removal of testicles)
- Penectomy (removal of penis)
- Urethroplasty (reconstruction of female urethra)
- Vaginoplasty (creation of vagina)

#### **Female-to-Male (FtM)**

- Bilateral mastectomy or breast reduction\*\*
- Hysterectomy (removal of uterus)
- Metoidioplasty (creation of penis, using clitoris)
- Penile prosthesis
- Phalloplasty (creation of penis)
- Salpingo-oophorectomy (removal of fallopian tubes and ovaries)
- Scrotoplasty (creation of scrotum)
- Testicular prostheses
- Urethroplasty (reconstruction of male urethra)
- Vaginectomy (removal of vagina)
- Vulvectomy (removal of vulva)

\*\*Bilateral mastectomy or breast reduction may be done as a stand-alone procedure, without having genital reconstruction procedures. In those cases, the individual does not need to complete hormone therapy prior to procedure.

**Certain ancillary procedures, including but not limited to the following, are considered cosmetic and not medically necessary, when performed as part of gender reassignment:**

- Abdominoplasty – also see [Panniculectomy and Body Contouring Procedures](#)
- Blepharoplasty – also see [Blepharoplasty, Blepharoptosis and Brow Ptosis Repair](#)
- Body contouring (e.g., fat transfer, lipoplasty, panniculectomy) – also see [Panniculectomy and Body Contouring Procedures](#)
- Breast enlargement, including augmentation mammoplasty and breast implants
- Brow lift
- Calf implants
- Cheek, chin and nose implants
- Injection of fillers or neurotoxins – also see [Botulinum Toxin A and B](#)
- Face/forehead lift and/or neck tightening
- Facial bone remodeling for facial feminization
- Hair removal (e.g., electrolysis or laser)
- Hair transplantation
- Lip augmentation
- Lip reduction
- Liposuction (suction-assisted lipectomy) – also see [Panniculectomy and Body Contouring Procedures](#)
- Mastopexy
- Pectoral implants for chest masculinization
- Rhinoplasty – also see [Rhinoplasty and Other Nasal Surgeries](#)
- Skin resurfacing (e.g., dermabrasion, chemical peels, laser)

- Thyroid cartilage reduction/reduction thyroid chondroplasty/trachea shave (removal or reduction of the Adam's apple)
- Voice modification surgery – e.g., laryngoplasty, glottoplasty or shortening of the vocal cords
- Voice lessons and voice therapy

## DEFINITIONS

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

- 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 (DSM-5)]:

- 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.

## 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 the member specific benefit plan document 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 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

CPT Code	Description
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
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
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

CPT Code	Description
19303	Mastectomy, simple, complete
19304	Mastectomy, subcutaneous
19316	Mastopexy
19318	Reduction mammoplasty
19324	Mammoplasty, augmentation; without prosthetic implant
19325	Mammoplasty, augmentation; with prosthetic implant
19340	Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
19342	Delayed insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
19350	Nipple/areola reconstruction
20926	Tissue grafts, other (e.g., paratenon, fat, dermis)
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)
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



CPT Code	Description
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
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

CPT Code	Description
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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ICD-10 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 gender and assigned gender (DSM-5). Treatment options include behavioral therapy, psychotherapy, hormone therapy and surgery for gender reassignment, which can involve genital reconstruction surgery and breast/chest surgery. For the FtM patient, surgical procedures may include mastectomy, hysterectomy, salpingo-oophorectomy, vaginectomy, vulvectomy, scrotoplasty, urethroplasty, placement of testicular and/or penile prostheses and phalloplasty or metoidioplasty (alternative to phalloplasty). For the MtF patient, surgical procedures may include penectomy, vaginoplasty, clitoroplasty, labiaplasty, orchiectomy and urethroplasty.

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

## CLINICAL EVIDENCE

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)

A Hayes report concluded that, overall, the quality of the evidence on gender reassignment surgery for gender dysphoria was very low. (Hayes, 2014a; updated 2018) The evidence suggests positive benefits, but because of serious limitations, permits only weak conclusions. Limitations include small sample sizes, retrospective data, lack of randomization and control and a lack of objective and validated outcome measures.

- Patients who underwent chest/breast or genital surgery were generally pleased with the aesthetic results.
- Following gender reassignment surgery, patients reported decreased gender dysphoria, depression and anxiety and increased quality of life.
- The majority of gender reassignment surgery patients were sexually active, but the ability to orgasm varied across studies.
- Complications of surgery following gender reassignment surgery were common and could be serious.
- Rates of regret of surgery and suicide were very low following gender reassignment surgery.
- Data were too sparse to draw conclusions regarding whether gender reassignment surgery conferred additional benefits to hormone therapy alone.
- Data were too sparse to draw conclusions regarding whether outcomes vary according to which surgeries were performed.

A separate Hayes report concluded that, overall, the quality of the evidence on ancillary procedures for the treatment of gender dysphoria was very low. (Hayes, 2014b; updated 2018) There is some evidence that transgender patients are satisfied with the results of rhinoplasty and facial feminization surgery, but patient satisfaction with vocal cord surgery and voice training was mixed. The evidence has serious limitations, and the effect of these procedures on overall individual well-being is unknown.

- Patients who had rhinoplasty or facial feminization surgery were generally pleased with the results.
- Vocal cord procedures and voice training had variable outcomes. Although the fundamental frequency was reduced by all treatment methods, patient satisfaction with the outcome was mixed.
- Most of the studies did not report complications; however, there was a low rate of bone nonunion following facial surgery, and moderate rates of dysphagia or throat pain following cricothyroid approximation.

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.

Manrique et al (2018) conducted a systematic review of retrospective studies on the outcomes of MtF vaginoplasty to minimize surgical complications and improve patient outcomes for transgender patients. Forty-six studies met the authors eligibility criteria. A total of 3716 cases were analyzed. The results showed the overall incidence of complications as follows: 2% fistula, 14% stenosis and strictures, 1% tissue necrosis, and 4% prolapse. Patient-reported outcomes included a satisfaction rate of 93% with overall results, 87% with functional outcomes, and 90% with esthetic outcomes. Ability to have orgasm was reported in 70% of patients. The regret rate was 1%. The authors concluded that multiple surgical techniques have demonstrated safe and reliable means of MtF vaginoplasty with low overall complication rates and with a significant improvement in the patient's quality of life. Studies using different techniques in a similar population and standardized patient-reported outcomes are required to further analyze outcomes among the different procedures and to establish best-practice guidelines.

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.

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 1121 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.

Frey et al. (2016) conducted a systematic review of metoidioplasty and radial forearm flap phalloplasty (RFFP) in 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.

Using a retrospective chart review, Buncamper et al. (2016) assessed surgical outcome after penile inversion vaginoplasty. Outcome measures were intraoperative and postoperative complications, reoperations, secondary surgical procedures and possible risk factors. Of 475 patients who underwent the procedure, 405 did not have additional full-thickness skin grafts while 70 did have grafts. Median follow-up was 7.8 years. The most frequently observed intraoperative complication was rectal injury (2.3 percent). Short-term postoperative bleeding that required transfusion (4.8 percent), reoperation (1.5 percent) or both (0.4 percent) occurred in some cases. Major complications were three (0.6 percent) rectovaginal fistulas, which were successfully treated. Revision vaginoplasty was performed in 14 patients (2.9 percent). Comorbid diabetes was associated with a higher risk of local infection, and use of psychotropic medication predisposed to postoperative urinary retention. Successful vaginal construction without the need for secondary functional reoperations was achieved in the majority of patients.

Bouman et al. (2016) prospectively assessed surgical outcomes of primary total laparoscopic sigmoid vaginoplasty in 42 transgender women with penoscrotal hypoplasia. Mean follow-up time was  $3.2 \pm 2.1$  years. The mean operative duration was  $210 \pm 44$  minutes. There were no conversions to laparotomy. One rectal perforation was recognized during surgery and immediately oversewn without long-term consequences. The mean length of hospitalization was  $5.7 \pm 1.1$  days. One patient died as a result of an extended-spectrum beta-lactamase-positive necrotizing fasciitis leading to septic shock, with multiorgan failure. Direct postoperative complications that needed laparoscopic reoperation occurred in three cases (7.1 percent). In seven cases (17.1 percent), long-term complications needed a secondary correction. After 1 year, all patients had a functional neovagina with a mean depth of  $16.3 \pm 1.5$  cm.

Gaither et al. (2017) retrospectively reviewed the records of 330 MtF patients from 2011 to 2015, to assess surgical complications related to primary penile inversion vaginoplasty. Complications included granulation tissue, vaginal pain, wound separation, labial asymmetry, vaginal stenosis, fistula formation, urinary symptoms including spraying stream or dribbling, infection, vaginal fissure or vaginal bleeding. Median age at surgery was 35 years, and median followup in all patients was 3 months. The results showed that 95 of the patients presented with a postoperative complication with the median time to a complication being 4.4 months. Rectovaginal fistulas developed in 3 patients, and 30 patients required a second operation. Age, body mass index and hormone replacement therapy were not associated with complications. The authors concluded that penile inversion vaginoplasty is a relatively safe procedure. Most complications due to this surgery develop within the first 4 months postoperatively. Age, body mass index and hormone replacement therapy are not associated with complications and, thus, they should not dictate the timing of surgery.

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.

Murad et al. (2010) conducted a systematic review to evaluate the effects of hormone therapy on patients undergoing gender reassignment surgery. The authors identified 28 eligible studies, all of which were observational and most lacked controls. These studies enrolled 1833 participants with gender dysphoria (1093 MtF; 801 FtM). After gender reassignment surgery, individuals reported improvement in gender dysphoria (80%), psychological symptoms (78%), sexual function (72%) and quality of life (80%). The authors concluded that very low quality evidence suggests that gender reassignment, that includes hormonal interventions, is likely to improve gender dysphoria, psychological functioning and comorbidities, sexual function and overall quality of life.

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.

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.

A single-arm study by Weigert et al. (2013) evaluated patient satisfaction with breasts and psychosocial, sexual and physical well-being after breast augmentation in MtF individuals with gender dysphoria. Thirty-five patients were asked to complete the BREAST-Q Augmentation module questionnaire before surgery, at 4 months and later after surgery. A prospective cohort study was designed and postoperative scores were compared with baseline scores. Responses indicated significant improvements in satisfaction with surgery (+59 points), psychosocial well-being (+48 points) and sexual well-being (+34 points). No significant changes were reported for physical well-being. This study has several limitations including lack of a control group and subjective measures.

In a non-randomized study, Dhejne et al. (2011) evaluated mortality, morbidity and criminal rates after gender reassignment surgery in 324 individuals (MtF n=191; FtM n=133). Random population controls (10:1) were matched by birth year and birth sex or reassigned final sex. The authors reported substantially higher rates of overall mortality, death from cardiovascular disease and suicide, suicide attempts and psychiatric hospitalizations in sex-reassigned individuals (both MtF/FtM) compared to a healthy control population. FtMs had a higher risk for criminal convictions.

In a case control study, Kuhn et al. (2009) evaluated quality of life and general satisfaction in patients following gender reassignment surgery compared with healthy controls. Fifty-five individuals with gender dysphoria (52 MtF; 3 FtM) participated in the questionnaire-based study. Fifteen years after gender reassignment surgery, quality of life was lower in the domains of general health, role limitation, physical limitation and personal limitation. Overall satisfaction was lower in individuals with gender dysphoria compared with controls.

Kanhai et al. (2000) conducted a retrospective survey evaluating the effects of augmentation mammoplasty on MtF individuals with gender dysphoria. Of 164 questionnaires sent, 107 (65%) were evaluated. Average clinical follow-up was 4.8 years. The average time lapse between mammoplasty and filling out the questionnaire was 5.5 years. Seventeen of the 107 patients had undergone further augmentation mammoplasty, on average 57 months after the initial mammoplasty. Eighty patients (75%) indicated satisfaction with the final outcome of the mammoplasty. The remaining 27 patients (25%) were unhappy with the results of mammoplasty. This study has several limitations including a retrospective design and subjective measures.

### **World Professional Association for Transgender Health (WPATH)**

WPATH, formerly known as the Harry Benjamin International Gender Dysphoria Association, is an advocacy group devoted to transgender health. WPATH guidelines (2012) present eligibility and readiness criteria for transition-related treatment, as well as competencies of health care providers.

WPATH describes the transition from one gender to another in the following three stages:

1. Living in the gender role consistent with gender identity.
2. The use of cross-sex hormone therapy after living in the new gender role for at least three months.
3. Gender-affirmation surgery after living in the new gender role and using hormonal therapy for at least 12 months.

### **Professional Societies**

#### ***American College of Obstetrics and Gynecology (ACOG)***

An ACOG committee opinion (2017) provides guidance on health care for transgender adolescents. The document makes the following recommendations regarding surgery:

- Obstetrician-gynecologists should understand gender identity and be able to treat transgender patients or refer them appropriately for medical and surgical therapeutic options.
- Surgical management for transgender male patients is typically reserved for patients 18 years and older.
- For transgender male patients, phalloplasty may be performed when the patient reaches the age of majority.
- Transgender female patients who choose to undergo surgery for a neovagina may have vaginoplasty after the age of majority.
- Transgender patients should be counseled about fertility and fertility preservation prior to surgical treatment.

A separate ACOG committee opinion (2011) provides guidance on health care for transgender individuals. The document makes the following recommendations regarding surgery:

- Obstetrician-gynecologists should assist or refer transgender individuals for routine treatment and screening as well as hormonal and surgical therapies.
- Hormonal and surgical therapies should be managed in consultation with health care providers with expertise in specialized care and treatment of transgender persons.

#### ***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)



Gender reassignment 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. See the following website to search by product name. Available at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed June 5, 2018)

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#### POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
11/01/2018	<ul style="list-style-type: none"> <li>Updated coverage rationale; modified language to clarify certain ancillary procedures, including but not limited to [those listed in the policy], are considered cosmetic <b>and</b> not medically necessary when performed as part of gender reassignment</li> <li>Archived previous policy version SURGERY 103.9 T2</li> </ul>