

GENDER REASSIGNMENT SURGERY MODEL NCD

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I. Indications, Limitations of Coverage and/or Medical Necessity

The purpose of this National Coverage Determination is to implement the U.S. Department of Health and Human Services Departmental Appeals Board's 2014 decision overturning NCD 140.3 (Transsexual Surgery). The U.S. Department of Health and Human Services Departmental Appeals Board ("DAB") considered categories of evidence as outlined in the Medicare Integrity Program Manual § 13.7.1 when it determined that the previously extant prohibition on "transsexual surgery" in NCD 140.3 was unreasonable.¹ Implementing a policy to provide access to Gender Reassignment Surgery is centered in improving population health outcomes among transgender Medicare beneficiaries.

The Medicare Integrity Program Manual § 13.7.1 provides that NCDs should be based on published authoritative evidence and general acceptance by the medical community.

Summarized, this means treatments should follow:

- Evidence-based best practice derived from definitive studies such as meta-analyses, randomized clinical trials, or clinical evidence
- Best practice as accepted by the medical community, as supported by sound medical evidence based on:
 - Scientific data or research studies published in peer-reviewed medical journals;
 - Consensus of expert medical opinion (i.e., recognized authorities in the field); or
 - Medical opinion derived from consultations with medical associations or other health care experts.

The Integrity Manual further provides that "NCDs which challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall be based on sufficient evidence to convincingly refute evidence presented in support of coverage." As such, a categorical exclusion of any particular procedure must be based on current, patient-centered clinical evidence, and not based on individual opinion or anecdote.

The Medicare Benefit Policy manual defines cosmetic surgical procedures as those treatments directed at improving appearance, but provides as an exception surgeries needed for therapeutic purposes which coincidentally also serve some cosmetic purpose.² The essential purpose of transition-related treatment is to therapeutically treat Gender Dysphoria, not to improve a person's appearance. The evaluation of medical necessity must therefore be individualized to each patient and take into account the totality of the patient's total gendered appearance and transition-related needs. Transgender people have unique clinical needs that are distinct from those of non-transgender people, and individualized assessments should be based on their symptoms, functionality, and the total gendered appearance. All of the surgical procedures used to treat transgender patients by definition are designed to change the physical appearance of the body to have the gendered characteristics of the other physical sex. However, the purpose of

¹ See HHS DAB NCD 140.3, Transsexual Surgery, Docket No. A-13-87, Decision No. 2576 (May 30, 2014) (the "NCD 140.3 Decision").

² Cosmetic surgery includes any surgical procedure directed at improving appearance, except when required for the prompt (i.e., as soon as medically feasible) repair of accidental injury or for the improvement of the functioning of a malformed body member. For example, this exclusion does not apply to surgery in connection with treatment of severe burns or repair of the face following a serious automobile accident, or to surgery for therapeutic purposes which coincidentally also serves some cosmetic purpose. Medicare Benefit Policy Manual, Chapter 16 – General Exclusions from coverage 120 - Cosmetic Surgery (Rev. 1, 10-01-03) A3-3160, HO-260.11, B3-2329.

such procedures is not to make patients more attractive, but to make them appear as much as possible like members of the sex to which they are transitioning. Ultimately, the clinical purpose is to treat the gender dysphoria that arises from having a physical body that is not congruent with their gender identity. Thus the surgeries that by CMS definition are cosmetic are also covered under the Medicare Benefit Policy Manual (see footnote 2, above) and is thus a surgery for therapeutic purposes which coincidentally also serves some cosmetic purpose.

True randomized studies may not be feasible and may be unethical in the context of gender-affirming surgery.^{3,4,5} In its decision invalidating the NCD, however, the Departmental Appeals Board stated that the general acceptance of the medical necessity of such surgeries in the international medical community provided a sound scientific basis for coverage despite the lack of randomized studies.⁶ The Departmental Appeals Board held that “[r]egardless of whether” evidence regarding the medical necessity of gender-affirming surgery “meets the first option for meeting the evidentiary standard set forth in the guidance . . . it clearly meets the second option because it indicates a consensus among researchers and mainstream medical organizations that transsexual surgery is an effective, safe and medically necessary treatment for transsexualism.” Professional organizations supporting treatment for Gender Dysphoria, including Gender Reassignment Surgery, include American Medical Association, American Academy of Family Physicians, the Endocrine Society, American Psychiatric Association, American Psychological Association, American College of Obstetricians and Gynecologists, and the American Public Health Association.⁷

The World Professional Association for Transgender Health (WPATH) is broadly recognized as the worldwide authority on transgender health issues.⁸ The Departmental Appeals Board concluded that the WPATH Standards of Care have attained widespread acceptance in the medical community and are accepted by federal courts as the generally accepted protocols for the treatment of Gender Dysphoria.⁹ In accordance with the findings of the DAB, the provisions of this NCD have been reviewed to ensure that they do not conflict with the operable WPATH Standards of Care (Version 7, 2011).

Gender Identity Disorder (GID) or Gender Dysphoria (GD) is the formal diagnosis used to describe persons who experience significant and persistent distress between the individual’s

³ De Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *The Journal of Sexual Medicine*. 2011;8(8):2276–2283.

⁴ Drescher J, Byne W. Gender dysphoric/gender variant (GD/GV) children and adolescents: Summarizing what we know and what we have yet to learn. *Journal of homosexuality*. 2012;59(3):501–510.

⁵ Murad MH, Elamin MB, Garcia MZ, et al. Hormonal therapy and sex reassignment: a systematic review and meta-analysis of quality of life and psychosocial outcomes. *Clinical Endocrinology*. 2010;72(2):214–231.

⁶ “NCD 140.3 Decision” at 20.

⁷ Lambda Legal. *Professional Organization Statements Supporting Transgender People in Health Care*. Lambda Leg. 2013. Accessed from: https://www.lambdalegal.org/sites/default/files/publications/downloads/fs_professional-org-statements-supporting-trans-health_4.pdf.

⁸ See, e.g., *Glenn v. Brumby*, 724 F. Supp. 2d 1284, 1289 n.4 (N.D. Ga. 2010), *aff’d*, 663 F.3d 1312 (11th Cir. 2011) (recognizing WPATH’s published statements as “accepted in the medical community”); American Medical Association House of Delegates, “Removing Financial Barriers to Care for Transgender Patients,” Resolution 122, A-08 (2008), http://www.tgender.net/taw/ama_resolutions.pdf (characterizing WPATH as “the leading international, interdisciplinary professional organization devoted to the understanding and treatment of gender identity disorders”).

⁹ “NCD 140.3 Decision” at 22-23.

physical sex and their gender identity. While the DSM-V and ICD-10 classify it as a mental health diagnosis, the WHO's draft of ICD-11 removes this diagnosis from the mental health section and provides a new name for the condition (gender incongruence) and classifies it in conditions related to sexual health. Treatment for Gender Dysphoria often includes mental health counseling, medical treatment with cross-gender hormones, and surgeries, but the exact combination must be individualized to each patient. In the U.S., the American Psychiatric Association permits a diagnosis of Gender Dysphoria in adults or adolescents if the diagnostic criteria in the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) are met. The criteria are:

- A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least six month's duration, as manifested by at least two of the following:
1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics; OR
 2. 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
 3. A strong desire for the primary and/or secondary sex characteristics of the other gender; OR
 4. A strong desire to be of the other gender or some alternative gender different from one's assigned gender; OR
 5. A strong desire to be treated as the other gender or some alternative gender different from one's assigned gender; OR
 6. 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; AND
- B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Categories of Gender Reassignment Surgery

The category of Gender Reassignment Surgery (GRS) includes:

1. Breast/chest surgeries;
2. Genital surgeries;
3. Other surgeries.

For the Male-to-Female (MTF) patient, surgical procedures may include the following:

1. Breast/chest surgery: mammoplasty
2. Genital surgery: orchiectomy, penectomy, vaginoplasty, clitoroplasty, vulvoplasty; labiaplasty, urethroplasty, prostatectomy
3. Other procedures: facial reconstruction surgery, liposuction, lipofilling, voice surgery, thyroid cartilage reduction, electrolysis or laser hair removal, hair reconstruction

For the Female-to-Male (FTM) patient, surgical procedures may include the following:

1. Breast/chest surgery: subcutaneous mastectomy, nipple grafts, chest reconstruction
2. Genital surgery: hysterectomy/salpingo-oophorectomy, metoidioplasty, phalloplasty (employing a pedicled or free vascularized flap), reconstruction of the fixed part of the

urethra, vaginectomy, vulvectomy, scrotoplasty, implantation of erectile and/or testicular prostheses

3. Other procedures: voice surgery (rare), liposuction, lipofilling

Indications of Coverage

Gender Reassignment Surgery is reasonable and necessary when the patient demonstrates:

1. Persistent, well-documented Gender Dysphoria;
2. Capacity to make a fully informed decision and to consent for treatment;
3. Age of majority in a given country (if younger, follow the Standards of Care for children and adolescents);
4. If significant medical or mental health concerns are present, they must be reasonably well controlled.
5. For genital surgeries only: 12 continuous months of hormone therapy as appropriate to the patient's gender goals, unless hormones are not clinically indicated for the individual.

For breast/chest surgeries:

Hormone therapy is not a prerequisite for FTM patients. For MTF patients, it is recommended that MTF patients undergo feminizing hormone therapy (minimum 12 months) prior to breast augmentation surgery, unless clinically contraindicated.

These criteria do not apply to patients who are having these procedures for medical indications other than Gender Dysphoria.

Limitations of Coverage

No surgery should be performed while a patient is actively psychotic. Excluded procedures include lipectomy of upper limbs, neck, and head; excision of excessive skin and subcutaneous tissue from abdomen, thigh, leg, hip, buttock, arm, forearm or hand.

II. Documentation Requirements

One referral from a qualified mental health professional is needed for breast/chest surgery.¹⁰

Two referrals from qualified mental health professionals who have independently assessed the patient are needed for genital surgeries. If the first referral is from the patient's psychotherapist, the second referral may be from a person who has only had an evaluative role with the patient, whether mental health professional or primary care provider. Two separate letters, or one letter signed by both (e.g., if practicing within the same clinic) may be sent. Each referral letter, however, is expected to cover the same topics in the areas outlined below.

The recommended content of the referral letters for surgery is as follows:

1. The client's general identifying characteristics;
2. Results of the client's psychosocial assessment, including any diagnoses;

¹⁰ Qualified mental health professionals include certified and licensed: psychiatrists, clinical psychologists, psychiatric nurse practitioners, psychiatric physician assistants, psychotherapists/counselors, and social workers, or any health professional with behavioral health training and experience.

3. The duration of the mental health professional's relationship with the client, including the type of evaluation and therapy or counseling to date;
4. An explanation that the criteria for surgery have been met, and a brief description of the clinical rationale for supporting the patient's request for surgery;
5. A statement that informed consent has been obtained from the patient;
6. A statement that the treating professional is available for coordination of care and welcomes a phone call to establish this.

III. Providers of Gender Reassignment Surgery

Physicians who provide surgical treatments for Gender Dysphoria should have appropriate credentials and training for the procedures they provide. Commonly these surgeons are board certified gynecologists, general surgeons, plastic surgeons, otorhinolaryngologists, and urologists. Surgeons who perform genital surgeries should have specialized competence in genital reconstructive techniques as indicated by documented supervised training with a more experienced surgeon.

IV. Common CPT Codes

This list provides common CPT codes associated with Gender Reassignment Surgeries; it is not intended to be exhaustive.

14021	ADJACENT TISSUE TRANSFER OR REARRANGEMENT, SCALP, ARMS AND/OR LEGS; DEFECT 10.1 SQ CM TO 30.0 SQ
14060	ADJACENT TISSUE TRANSFER OR REARRANGMENT 10 SQ CM OR LESS
15770	AUTOLOGOUS FAT TRANSFER TO FACE
15776	PUNCH GRAFT FOR HAIR TRANSPLANT; MORE THAN 15 PUNCH GRAFTS
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
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
19303	MASTECTOMY, SIMPLE, COMPLETE
19304	MASTECTOMY, SUBCUTANEOUS

- 19316 MASTOPEXY
- 19325 MAMMAPLASTY, AUGMENTATION; WITH PROSTHETIC 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 (EG, 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)
- 21208 OSTEOPLASTY, FACIAL BONES; AUGMENTATION (AUTOGRAFT, ALLOGRAFT, OR PROSTHETIC IMPLANT)
- 21209 OSTEOPLASTY, FACIAL BONES; REDUCTION
- 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)
- 53420 URETHROPLASTY, 2-STAGE RECONSTRUCTION OR REPAIR OF PROSTATIC OR MEMBRANOUS URETHRA; FIRST STAGE
- 53425 URETHROPLASTY, 2-STAGE RECONSTRUCTION OR REPAIR OF PROSTATIC OR MEMBRANOUS URETHRA; SECOND STAGE
- 53430 URETHROPLASTY, RECONSTRUCTION OF FEMALE URETHRA
- 53430 URETHROPLASTY
- 54125 AMPUTATION OF PENIS; COMPLETE
- 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
- 55175 SCROTOPLASTY
- 55180 SCROTOPLASTY; COMPLICATED

- 55866 LAPAROSCOPY, SURGICAL PROSTATECTOMY, RETROPUBIC RADICAL, INCLUDING NERVE SPARING, INCLUDES ROBOTIC ASSISTANCE, WHEN PERFORMED
- 55899 UNLISTED SURGERY OF THE MALE GENITAL SYSTEM, FOR METOIDIOPLASTY and PHALLOPLASTY
- 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
- 57106 VAGINECTOMY, PARTIAL REMOVAL OF VAGINAL WALL;
- 57110 VAGINECTOMY, COMPLETE REMOVAL OF VAGINAL WALL;
- 57110 COLPECTOMY/VAGINECTOMY
- 57291 CONSTRUCTION OF ARTIFICIAL VAGINA; WITHOUT GRAFT
- 57292 CONSTRUCTION OF ARTIFICIAL VAGINA; WITH GRAFT
- 57295 REVISION (INCLUDING REMOVAL) OF PROSTHETIC VAGINAL GRAFT; VAGINAL APPROACH
- 57296 REVISION (INCLUDING REMOVAL) OF PROSTHETIC VAGINAL GRAFT; OPEN ABDOMINAL APPROACH
- 57335 VAGINOPLASTY FOR INTERSEX STATE
- 57426 REVISION (INCLUDING REMOVAL) OF PROSTHETIC VAGINAL GRAFT, LAPAROSCOPIC APPROACH
- 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)
- 58275 VAGINAL HYSTERECTOMY, WITH TOTAL OR PARTIAL VAGINECTOMY;
- 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)
- 58720 SALPINGO-OOPHORECTOMY, COMPLETE OR PARTIAL, UNILATERAL OR BILATERAL (SEPARATE PROCEDURE)

V. ICD-9 and ICD-10 Codes

ICD-9:

- 302.5 Trans-sexualism
- 302.6 Gender identity disorder in children
- 302.85 Gender identity disorder in adolescents or adults

ICD-10:

- F64.1 Gender identity disorder in adolescence and adulthood
- 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

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