Gender Affirmation Surgery

Pl. Trial Ex. 058

Humana

Medical Coverage Policy

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Change Summary: Updated Description, Coverage Determination, Coverage Limitations, Provider Claims Codes, References

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State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. Refer to the CMS website. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from Humana.

Description

Gender dysphoria refers to discomfort or distress caused by a discrepancy between an individual's gender identity and the gender assigned at birth (and the associated gender role and/or primary and secondary sex characteristics). A diagnosis of gender dysphoria requires a marked difference between the individual's expressed/experienced gender and the gender others would assign him or her, and it must continue for at least 6 months. This condition may cause clinically significant distress or impairment in social, occupational or other important areas of functioning.[4]

Gender affirmation surgery is an umbrella term for reconstructive procedures performed to change primary and/or secondary sex characteristics in order to align anatomy and physical appearance with an individual's expressed gender identity.

Gender affirming surgeries may include, but are not limited to, the following:

- Breast augmentation (increase in breast size)
- Breast reduction (decrease in breast size)
- Clitoroplasty (creation of clitoris)
- Hysterectomy (removal of uterus)
- Labiaplasty (creation of labia)
- Mastectomy (removal of breasts)
- Metoidioplasty (creation of penis using clitoris)
- Nipple/areola reconstruction (redefines features of natural breasts)
- Orchiectomy (removal of testicles)
- Penectomy (removal of penis)
- Phalloplasty (creation of penis)
- Salpingo-oophorectomy (removal of fallopian tubes and ovaries)
- Scrotoplasty (creation of scrotum)
- Testicular prosthesis (artificial implant for testicles)
- Urethroplasty (reconstruction of urethra)
- Vaginectomy (removal of vagina)
- Vaginoplasty (creation of vagina)
- Vulvectomy (removal of vulva)

Additional procedures to enhance femininity or masculinity may be requested. Please refer to the Coverage Limitations section for examples of these procedures.

Gender affirmation surgeries are typically considered an irreversible type of intervention, depending on the type of procedures completed. However, some may require revision due to postoperative complications.

Coverage Determination

Any state mandates for gender affirmation surgery take precedence over this medical coverage policy.

Please refer to the member's applicable pharmacy benefit to determine benefit availability and the terms and conditions of coverage for medication for the treatment of gender dysphoria.

Services provided by a psychiatrist, psychologist or other behavioral health professionals are subject to the provisions of the applicable behavioral health benefit.

Gender Affirming Genital Surgery

Humana members may be eligible under the Plan for **gonadectomy** (eg, hysterectomy, orchiectomy, salpingo-oophorectomy) when **ALL** of the following criteria are met:

- 18 years of age or older; **AND**
- Persistent, well-documented diagnosis of gender dysphoria according to the DSM-5 with clinical notes submitted; **AND**
- Absence of a mental or physical impairment that would preclude a fully informed decision and/or consent; **AND**
- 12 continuous months of hormone therapy as appropriate to the individual's gender goals, when medically appropriate and not contraindicated; **AND**
- Two referral letters from qualified mental health professionals; one in a purely evaluative role **(please see Appendix B for specific referral letter requirements)**; **AND**
- Preoperative surgical clearance (within 3 months prior to the procedure) based on medical and psychological evaluation by a licensed healthcare professional to assess whether other coexisting conditions are regulated, maintained or managed without active exacerbations or concerns

Gender Affirming Genital Reconstructive Surgery

Humana members may be eligible under the Plan for **genital reconstructive surgery** (eg, clitoroplasty, labiaplasty, metoidioplasty, penectomy, phalloplasty, scrotoplasty, testicular prosthesis placement, urethroplasty, vaginectomy, vaginoplasty, vulvectomy) when **ALL** of the following criteria are met:

- 18 years of age or older; **AND**

- Persistent, well-documented diagnosis of gender dysphoria according to the DSM-5 with clinical notes submitted; **AND**
- Absence of a mental or physical impairment that would preclude a fully informed decision and/or consent; **AND**
- 12 continuous months of hormone therapy as appropriate to the individual's gender goals, when medically appropriate and not contraindicated; **AND**
- 12 continuous months* of living in a gender role that is congruent with their gender identity; **AND**
- Two referral letters from qualified mental health professionals, one in a purely evaluative role **(please see Appendix B for specific referral letter requirements)**; **AND**
- Preoperative surgical clearance (within 3 months prior to the procedure) based on medical and psychological evaluation by a licensed healthcare professional to assess whether other coexisting conditions are regulated, maintained or managed without active exacerbations or concerns

*The requirement for 12 continuous months of living in the desired gender role may or may not take place concurrently with the 12 continuous months of hormone therapy.

Humana members may be eligible under the Plan for **permanent hair removal by electrolysis or laser** when the following criteria are met:

- Criteria for gender affirming genital reconstructive surgery has been met; **AND**
- As preparation for genital reconstructive surgery which will require areas to be permanently without hair (eg, donor site tissue or tissue used for neopenis/ neovagina)

Gender Affirming Chest Surgery

Humana members may be eligible under the Plan for **gender affirming chest surgery** (eg, breast augmentation, breast reduction, mastectomy, nipple/areola reconstruction) when **ALL** of the following criteria are met:

- 18 years of age or older; **AND**
- Persistent, well-documented diagnosis of gender dysphoria according to the DSM-5 with clinical notes submitted; **AND**
- Absence of a mental or physical impairment that would preclude a fully informed decision and/or consent; **AND**
- Single letter of referral from a qualified mental health professional **(please see Appendix B for specific referral letter requirements)**; **AND**
- Preoperative surgical clearance (within 3 months prior to the procedure) based on medical and psychological evaluation by a licensed healthcare professional to assess whether other coexisting conditions are regulated, maintained or managed without active exacerbations or concerns

Revision of Gender Affirming Surgical Procedures

Humana members may be eligible under the Plan for **revision of gender affirming procedures** as a result of a surgical complication (eg, bleeding, hematoma, infection, injury to surrounding organs, mechanical complication [eg, fistula, malposition, strictures], remnant tissue, wound dehiscence).

Note: The criteria for **gender affirming surgery** are not consistent with the Medicare National Coverage Policy and therefore may not be applicable to Medicare members. Refer to the CMS website for additional information.

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **gender affirmation surgery** for any indications other than those listed above. All other indications are considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Humana members may **NOT** be eligible under the Plan for **revision of gender affirming surgical procedures** for any indications other than those listed above. All other indications are considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Humana members may **NOT** be eligible under the Plan for **reversal of gender affirming surgical procedures**. This is considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Humana members may **NOT** be eligible under the Plan for **procurement, cryopreservation, storage and/or thawing of embryos, oocytes, sperm or reproductive tissue** (eg, ovarian or testicular tissue). These are considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Humana members may **NOT** be eligible under the Plan for **any other procedures as part of gender affirmation surgery** including, but may not be limited to, the following:

- Abdominoplasty
- Blepharoplasty**
- Body contouring
- Brow lift**
- Calf implants
- Cheek implants
- Chin implants
- Face lift
- Facial bone reduction (eg, osteoplasty)
- Facial feminization/masculinization
- Forehead contouring or lift
- Gluteal implants
- Hair removal^ (eg, electrolysis, laser)
- Hair transplantation
- Injectable fillers (eg, collagen, fat or other biologic/synthetic material)
- Jaw reduction (eg, jaw contouring)

- Lip enhancement or reduction
- Liposuction
- Mastopexy
- Neck tightening
- Nose implants
- Pectoral implants
- Penile prosthesis (inflatable or noninflatable)**
- Redundant skin removal
- Rhinoplasty**
- Skin resurfacing (eg, chemical peel, dermabrasion)
- Thyroid cartilage reduction (eg, chondroplasty)
- Voice modification surgery (eg, cricothyroid approximation, laryngoplasty)
- Voice therapy

These procedures are considered cosmetic. Please refer to the member's individual certificate for the specific definition.

**While these procedures may not be covered under this Medical Coverage Policy, Humana members may be eligible for them when criteria are met. For information regarding coverage determination/limitations, please refer to Blepharoplasty, Blepharoptosis Repair and Brow Lift, Erectile Dysfunction and Peyronie's Disease Treatments, and Rhinoplasty/Septoplasty Medical Coverage Policies.

^Please refer to the Coverage Determination section for hair removal exception.

Background

Additional information about **gender dysphoria** may be found from the following websites:

- National Library of Medicine
- World Professional Association for Transgender Health

Medical Alternatives

Physician consultation is advised to make an informed decision based on an individual's health needs.

Provider Claims Codes

Any CPT, HCPCS or ICD codes listed on this medical coverage policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
11950	Subcutaneous injection of filling material (eg, collagen); 1 cc or less	**Not Covered**
11951	Subcutaneous injection of filling material (eg, collagen); 1.1 to 5.0 cc	**Not Covered**
11952	Subcutaneous injection of filling material (eg, collagen); 5.1 to 10.0 cc	**Not Covered**
11954	Subcutaneous injection of filling material (eg, collagen); over 10.0 cc	**Not Covered**
11960	Insertion of tissue expander(s) for other than breast, including subsequent expansion	**Not Covered if performed as part of gender affirmation surgery**
11970	Replacement of tissue expander with permanent implant	**Not Covered if used to report any procedure outlined in Coverage Limitations section**
11971	Removal of tissue expander without insertion of implant	**Not Covered if used to report any procedure outlined in Coverage Limitations section**
15775	Punch graft for hair transplant; 1 to 15 punch grafts	**Not Covered**
15776	Punch graft for hair transplant; more than 15 punch grafts	**Not Covered**
15780	Dermabrasion; total face (eg, for acne scarring, fine wrinkling, rhytids, general keratosis)	**Not Covered**
15781	Dermabrasion; segmental, face	**Not Covered**
15782	Dermabrasion; regional, other than face	**Not Covered**
15783	Dermabrasion; superficial, any site (eg, tattoo removal)	**Not Covered**
15788	Chemical peel, facial; epidermal	**Not Covered**

15789	Chemical peel, facial; dermal	**Not Covered**
15792	Chemical peel, nonfacial; epidermal	**Not Covered**
15793	Chemical peel, nonfacial; dermal	**Not Covered**
15819	Cervicoplasty	**Not Covered**
15820	Blepharoplasty, lower eyelid;	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Blepharoplasty, Blepharoptosis Repair and Brow Lift Medical Coverage Policy**
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Blepharoplasty, Blepharoptosis Repair and Brow Lift Medical Coverage Policy**

15822	Blepharoplasty, upper eyelid;	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Blepharoplasty, Blepharoptosis Repair and Brow Lift Medical Coverage Policy**
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Blepharoplasty, Blepharoptosis Repair and Brow Lift Medical Coverage Policy**
15824	Rhytidectomy; forehead	**Not Covered**
15825	Rhytidectomy; neck with platysmal tightening (platysmal flap, P-flap)	**Not Covered**
15826	Rhytidectomy; glabellar frown lines	**Not Covered**
15828	Rhytidectomy; cheek, chin, and neck	**Not Covered**
15829	Rhytidectomy; superficial musculoaponeurotic system (SMAS) flap	**Not Covered**

15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy	**Not Covered if performed as part of gender affirmation surgery**
15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh	**Not Covered**
15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg	**Not Covered**
15834	Excision, excessive skin and subcutaneous tissue (includes lipectomy); hip	**Not Covered**
15835	Excision, excessive skin and subcutaneous tissue (includes lipectomy); buttock	**Not Covered**
15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm	**Not Covered**
15837	Excision, excessive skin and subcutaneous tissue (includes lipectomy); forearm or hand	**Not Covered**
15838	Excision, excessive skin and subcutaneous tissue (includes lipectomy); submental fat pad	**Not Covered**
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area	**Not Covered**
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial plication) (List separately in addition to code for primary procedure)	**Not Covered**
15876	Suction assisted lipectomy; head and neck	**Not Covered**
15877	Suction assisted lipectomy; trunk	**Not Covered**
15878	Suction assisted lipectomy; upper extremity	**Not Covered**
15879	Suction assisted lipectomy; lower extremity	**Not Covered**
17380	Electrolysis epilation, each 30 minutes	
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue	**Not Covered if used to report any procedure outlined in Coverage Limitations section**
19303	Mastectomy, simple, complete	

19316	Mastopexy	**Not Covered if performed as part of gender affirmation surgery**
19318	Breast reduction	
19325	Breast augmentation with implant	
19328	Removal of intact breast implant	
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)	
19340	Insertion of breast implant on same day of mastectomy (ie, immediate)	
19342	Insertion or replacement of breast implant on separate day from mastectomy	
19350	Nipple/areola reconstruction	
19370	Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy	
19371	Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents	
19380	Revision of reconstructed breast (eg, significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)	
19396	Preparation of moulage for custom breast implant	
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)	**Not Covered**
21121	Genioplasty; sliding osteotomy, single piece	**Not Covered**
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (eg, wedge excision or bone wedge reversal for asymmetrical chin)	**Not Covered**
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)	**Not Covered**
21125	Augmentation, mandibular body or angle; prosthetic material	**Not Covered if performed as part of gender affirmation surgery**
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)	**Not Covered if performed as part of gender affirmation surgery**

21137	Reduction forehead; contouring only	**Not Covered**
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)	**Not Covered if performed as part of gender affirmation surgery**
21209	Osteoplasty, facial bones; reduction	**Not Covered**
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)	**Not Covered if performed as part of gender affirmation surgery**
21270	Malar augmentation, prosthetic material	**Not Covered**
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Rhinoplasty/Septoplasty Medical Coverage Policy**
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Rhinoplasty/Septoplasty Medical Coverage Policy**

30420	Rhinoplasty, primary; including major septal repair	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Rhinoplasty/Septoplasty Medical Coverage Policy**
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Rhinoplasty/Septoplasty Medical Coverage Policy**
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Rhinoplasty/Septoplasty Medical Coverage Policy**

30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Rhinoplasty/Septoplasty Medical Coverage Policy**
31599	Unlisted procedure, larynx	**Not Covered if performed as part of gender affirmation surgery**
31899	Unlisted procedure, trachea, bronchi	**Not Covered if performed as part of gender affirmation surgery**
53430	Urethroplasty, reconstruction of female urethra	
54125	Amputation of penis; complete	
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)	**Not Covered if performed as part of gender affirmation surgery**
54401	Insertion of penile prosthesis; inflatable (self-contained)	**Not Covered if performed as part of gender affirmation surgery**
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir	**Not Covered if performed as part of gender affirmation surgery**
54406	Removal of all components of a multi-component, inflatable penile prosthesis without replacement of prosthesis	**Not Covered if performed as part of gender affirmation surgery**
54408	Repair of component(s) of a multi-component, inflatable penile prosthesis	**Not Covered if performed as part of gender affirmation surgery**

54410	Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session	**Not Covered if performed as part of gender affirmation surgery**
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	**Not Covered if performed as part of gender affirmation surgery**
54415	Removal of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis, without replacement of prosthesis	**Not Covered if performed as part of gender affirmation surgery**
54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session	**Not Covered if performed as part of gender affirmation surgery**
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	**Not Covered if performed as part of gender affirmation surgery**
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;	
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);	
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)	
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)	
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;	
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Blepharoplasty, Blepharoptosis Repair and Brow Lift Medical Coverage Policy**
67901	Repair of blepharoptosis; frontalis muscle technique with suture or other material (eg, banked fascia)	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Blepharoplasty, Blepharoptosis Repair and Brow Lift Medical Coverage Policy**

67902	Repair of blepharoptosis; frontalis muscle technique with autologous fascial sling (includes obtaining fascia)	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Blepharoplasty, Blepharoptosis Repair and Brow Lift Medical Coverage Policy**
67903	Repair of blepharoptosis; (tarso) levator resection or advancement, internal approach	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Blepharoplasty, Blepharoptosis Repair and Brow Lift Medical Coverage Policy**

67904	Repair of blepharoptosis; (tarso) levator resection or advancement, external approach	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Blepharoplasty, Blepharoptosis Repair and Brow Lift Medical Coverage Policy**
67906	Repair of blepharoptosis; superior rectus technique with fascial sling (includes obtaining fascia)	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Blepharoplasty, Blepharoptosis Repair and Brow Lift Medical Coverage Policy**

67908	Repair of blepharoptosis; conjunctivo-tarso-Muller's muscle-levator resection (eg, Fasanella-Servat type)	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Blepharoplasty, Blepharoptosis Repair and Brow Lift Medical Coverage Policy**
67909	Reduction of overcorrection of ptosis	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Blepharoplasty, Blepharoptosis Repair and Brow Lift Medical Coverage Policy**

67911	Correction of lid retraction	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Blepharoplasty, Blepharoptosis Repair and Brow Lift Medical Coverage Policy**
67950	Canthoplasty (reconstruction of canthus)	**Not Covered if performed as part of gender affirmation surgery** **Members may be eligible for coverage when criteria are met. Refer to Blepharoplasty, Blepharoptosis Repair and Brow Lift Medical Coverage Policy**
89258	Cryopreservation; embryo(s)	**Not Covered**
89259	Cryopreservation; sperm	**Not Covered**
89335	Cryopreservation, reproductive tissue, testicular	**Not Covered**
89337	Cryopreservation, mature oocyte(s)	**Not Covered**
89342	Storage (per year); embryo(s)	**Not Covered**
89343	Storage (per year); sperm/semen	**Not Covered**
89344	Storage (per year); reproductive tissue, testicular/ovarian	**Not Covered**
89346	Storage (per year); oocyte(s)	**Not Covered**

89354	Thawing of cryopreserved; reproductive tissue, testicular/ovarian	**Not Covered**
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual	**Not Covered if performed as part of gender affirmation surgery**
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
C1789	Prosthesis, breast (implantable)	
C1813	Prosthesis, penile, inflatable	**Not Covered if performed as part of gender affirmation surgery**
C2622	Prosthesis, penile, noninflatable	**Not Covered if performed as part of gender affirmation surgery**
L8600	Implantable breast prosthesis, silicone or equal	
S4027	Storage of previously frozen embryos	**Not Covered**
S4030	Sperm procurement and cryopreservation services; initial visit	**Not Covered**
S4031	Sperm procurement and cryopreservation services; subsequent visit	**Not Covered**
S4040	Monitoring and storage of cryopreserved embryos, per 30 days	**Not Covered**

References

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Appendix A
DSM-5 Criteria for the Diagnosis of Gender Dysphoria in Adolescents and Adults[4]

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least six months' 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 in young adolescents, the anticipated secondary sex characteristics); **OR**

   2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics); **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

Appendix B
Referral Letter Requirements[27]

Minimum Credentials for a Qualified Mental Health Professional	Format for Referral Letters from a Qualified Mental Health Professional
1. Master's degree or equivalent in a clinical behavioral science field. This degree or a more advanced one should be granted by an institution accredited by the appropriate national or regional accrediting board. The mental health professional should have documented credentials from a relevant licensing board or equivalent; **AND** 2. Competence in using the DSM-5 and/or the International Classification of Disease for diagnostic purposes; **AND** 3. Ability to recognize and diagnose coexisting mental health concerns and to distinguish these from gender dysphoria; **AND** 4. Documented supervised training and competence in psychotherapy or counseling; **AND** 5. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria	1. Individual's general identifying characteristics; **AND** 2. Results of the individual's psychosocial assessment, including any diagnoses; **AND** 3. Duration of the mental health professional's relationship with the individual, including the type of evaluation and therapy or counseling to date; **AND** 4. An explanation that the World Professional Association for Transgender Health (WPATH) criteria for surgery have been met and a brief description of the clinical rationale supporting the individual's request for surgery; **AND** 5. A statement about the fact that informed consent has been obtained from the individual; **AND** 6. A statement that the mental health professional is available for the coordination of the care and welcomes a phone call to establish this

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Gender Dysphoria Hormone Therapy

PRODUCTS AFFECTED

Androgens: testosterone transdermal patch, testosterone topical gel, testosterone enanthate, testosterone cypionate, testosterone pellet for implant, methyltestosterone capsules, testosterone nasal gel, testosterone undecanoate Cap
Estrogens: Alora (estradiol transdermal patch), Delestrogen (estradiol valerate), Depo-Estradiol (estradiol cypionate), Estrace (estradiol oral tablet), Minivelle (estradiol transdermal patch) Vivelle (estradiol transdermal patch), Vivelle-Dot (estradiol transdermal patch)
Gonadotropin-Releasing Hormone Agonist: Fensolvi (leuprolide), Lupron Depot (leuprolide), Lupron Depot-Ped (leuprolide), Eligard (Leuprolide Acetate), Supprelin LA (histrelin acetate implant), Trelstar Mixject (triptorelin), Triptodur (triptorelin)
5-Alpha Reductase Inhibitor: Propecia tablets (finasteride) Aldosterone Receptor Antagonist: Aldactone (spironolactone)
Progestin: Depo-Provera (medroxyprogesterone acetate), Progesterone

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
Gender Dysphoria, Delayed Puberty

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc.

clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review.

A. PUBERTY SUPPRESSION
1. Documentation that the adolescent has started puberty (Tanner stage >G2/B2)
   AND
2. Less than 16 years of age
   AND
3. A definitive diagnosis of persistent gender dysphoria has been made and documented by a qualified mental health professional such as a licensed psychiatrist, psychologist or psychotherapist and all of the following are present: [ALL]
   a) The adolescent has demonstrated a long lasting and intense pattern of gender dysphoria
      AND
   b) Gender dysphoria worsened with the onset of puberty
      AND
   c) The disorder is not a symptom of another mental disorder

   AND
4. Recommendation for puberty suppression treatment has been made by a qualified health professional (as specified in 'Prescriber Requirements') who has confirmed the diagnosis of persistent gender dysphoria by the qualified mental health professional
   AND
5. Initial hormone therapy must be prescribed by an endocrinologist preceded by all of the following: [ALL]
   a) Documentation that the individual has the capacity to make a fully informed decision and to consent for treatment
      AND
   b) Documentation that the parents or caretakers or guardians have consented to the treatment and are involved in supporting the adolescent through the treatment process

B. GENDER DYSPHORIA
1. Age 16 years or older
   AND
2. Prescriber attests that the member has the capacity to make a fully informed decision and to consent for treatment
   AND
3. A definitive diagnosis of persistent gender dysphoria has been made and documented by a qualified mental health professional such as a licensed psychiatrist, psychologist, or psychotherapist and all of the following are present: [ALL]
   a. The desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatment
      AND
   b. The transsexual identity has been present persistently for at least two years
      AND
   c. The disorder is not a symptom of another mental disorder
      AND
   d. The disorder causes clinically significant distress or impairment in social, occupational, or other important areas of functioning

   AND
4. Hormone replacement treatment has been recommended as a result of the diagnosis of persistent gender dysphoria by an expert multidisciplinary team comprised of medical professionals and *mental health professional (MHP) specializing in the management of hormone therapy for gender dysphoria (preferred) **OR** by a qualified mental health professional as *defined by The Endocrine

Society (2017) or World Professional Association for Transgender Health (WPATH). *Refer to 'Prescriber Requirements' section
AND

5. Initial hormone therapy must be prescribed by a qualified health professional ('Prescriber Requirements') preceded by all of the following: [ALL] Documentation that the individual has lived as their new gender full-time for 3 months or more prior to the administration of hormones
AND
6. Documentation that he individual has demonstrable knowledge of the risks and benefits of hormone replacement
AND
7. LHRH agents are not covered following sex confirmation surgery
Note: All other FDA labeled indications for Estrogens, 5-Alpha Reductase Inhibitors, Aldosterone Receptor Antagonists, and Progestins are covered without Prior Authorization requirement

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:

1. Must submit documentation that member has been assessed by prescriber at least every 3 to 6 months for response to treatment, compliance, side effects (through regular monitoring of parameters such as height, weight, sitting height, Tanner stage, FH, FSH, estradiol/testosterone levels, renal/liver function, lipids, glucose, insulin, glycosylated hemoglobin, bone density, bone age, etc.), and discussion of treatment plan (e.g. hormone therapy, sex confirmation surgery)

DURATION OF APPROVAL:

Initial authorization: LHRH: 6 months or until time of sex confirmation surgery, whichever is shorter
Continuation of therapy: 12 months or until time of sex confirmation surgery, whichever is shorter
Testosterone: 6 months, Continuation of therapy: 12 months
All other therapies: Initial authorization- 12 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:

PUBERTY SUPPRESSION and GENDER DYSPHORIA: Prescribed by, or in consultation, with an 1) Endocrinologist, OR 2) expert multidisciplinary team comprised of medical professionals and *mental health professional (MPH) specializing in the management of hormone therapy for gender dysphoria (preferred) OR 3) qualified MPH as *defined by The Endocrine Society (2017) or World Professional Association for Transgender Health (WPATH) trained specialist (refer to definition below)

The Endocrine Society Clinical Practice Guideline (Hembree et al. 2017)

- Clinicians may add gender-affirming hormones after a multidisciplinary team has confirmed the persistence of gender dysphoria/gender incongruence and sufficient mental capacity to give informed consent to this partially irreversible treatment.
  - Advise that only trained mental health professionals (MHPs) who meet the following criteria should diagnose gender dysphoria (GD)/gender incongruence in ***adults:*** (1) competence in using the Diagnostic and Statistical Manual of Mental Disorders (DSM) and/or the International Statistical Classification of Diseases and Related Health Problems (ICD) for diagnostic purposes, (2) the ability to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (3) training in diagnosing psychiatric conditions, (4) the ability to undertake or refer for appropriate treatment, (5) the ability to psychosocially assess the person's understanding, mental health, and social conditions that can impact gender- affirming hormone therapy, and (6) a practice of regularly attending relevant professional meetings.
- Advise that only MHPs who meet the following criteria should diagnose GD/gender in-congruence in ***children and adolescents:*** (1) training in child and adolescent developmental psychology and psychopathology, (2) competence in using the DSM and/or the ICD for diagnostic purposes, (3) the ability to make a distinction between GD/gender incongruence and

conditions that have similar features (e.g., body dysmorphic disorder), (4) training in diagnosing psychiatric conditions, (5) the ability to undertake or refer for appropriate treatment, (6) the ability to psycho-socially assess the person's understanding and social conditions that can impact gender-affirming hormone therapy,
(7) a practice of regularly attending relevant professional meetings, and (8) knowledge of the criteria for puberty blocking and gender-affirming hormone treatment in adolescents.

WPATH Guidelines (2012)
*Competency of Mental Health Professionals (MPH) Working with **Children or Adolescents** with Gender Dysphoria (GD):* The following are recommended minimum credentials for MPHs who assess, refer, and offer therapy to children and adolescents presenting with GD: **1)** Meet the competency requirements for MPHs working with adults, as outlined (below); **2)**Trained in childhood and adolescent developmental psychopathology; and **3)** Competent in diagnosing and treating the ordinary problems of children and adolescents.

*Competency of MPHs Working with **Adults** Who Present with Gender Dysphoria (GD):* The training of MPHs competent to work with gender dysphoric adults' rests upon basic general clinical competence in the assessment, diagnosis, and treatment of mental health concerns. Clinical training may occur within any discipline that prepares MPHs for clinical practice, such as psychology, psychiatry, social work, mental health counseling, marriage and family therapy, nursing, or family medicine with specific training in behavioral health and counseling. The following are recommended minimum credentials for MPHs who work with adults presenting with GD: **1)** A master's degree or its equivalent in a clinical behavioral science field. This degree, or a more advanced one, should be granted by an institution accredited by the appropriate national or regional accrediting board. The MPH should have documented credentials from a relevant licensing board or equivalent for that country. **2)** Competence in using the Diagnostic Statistical Manual of Mental Disorders and/orthe International Classification of Diseases for diagnostic purposes; **3)** Ability to recognize and diagnose coexisting mental health concerns and to distinguish these from GD; **4)** Documented supervised training and competence in psychotherapy or counseling; **5)** Knowledgeable about gender- nonconforming identities and expressions, and the assessment and treatment of GD; **6)** Continuing education in the assessment and treatment of GD. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and GD. **7)** In addition to the minimum credentials above, it is recommended that MPHs develop and maintain cultural competence to facilitate their work with transsexual, transgender, and gender-nonconforming clients. This may involve, for example, becoming knowledgeable about current community, advocacy, and public policy issues relevant to these clients and their families. Additionally, knowledge about sexuality, sexual health concerns, and the assessment and treatment of sexual disorders is preferred.

AGE RESTRICTIONS:
PUBERTY SUPPRESSION: Tanner stage > G2/B2 through 16 years of age GENDER DYSPHORIA: 16 years of age or older

QUANTITY:
Per WPATH guidelines. See Appendix for specific regimen dosing.

PLACE OF ADMINISTRATION:
The recommendation is that oral and topical medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous and intramuscular injectable products be administered in a place of service that is a non-hospital facility-based location.

Drug and Biologic Coverage Criteria

The recommendation is that injectable implant medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable implant products be administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Injectable (intramuscular, subcutaneous, subcutaneous implant), topical, oral

DRUG CLASS:
Androgens, Estrogens, Antineoplastic Agent, Gonadotropin-Releasing Hormone Agonist, 5-Alpha Reductase Inhibitor, Progestins

FDA-APPROVED USES:
Androgens: Primary or Hypogonadotropic Hypogonadism (congenital or acquired), Delayed Puberty, Metastatic Breast Cancer
Estrogens: Menopause, Metastatic Breast Cancer, Hypogonadism, Post-menopausal osteoporosis, Advanced Androgen-Dependent Prostate Cancer (for palliation)
Gonadotropin-Releasing Hormone Agonist: Advanced prostate cancer, Endometriosis and Uterine leiomyomata fibroids, Central precocious puberty
5-Alpha Reductase Inhibitor: Benign prostatic hyperplasia, alopecia
Aldosterone Receptor Antagonist: Edema, Heart failure, Hyperaldosteronism, Hypertension Progestin: Contraception, Endometriosis, Endometrial carcinoma/hyperplasia, Renal cell carcinoma, Secondary Physiologic amenorrhea

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
A. Tanner Stages of Breast Development and Male External Genitalia [7]

The description of Tanner stages for breast development:
1. Prepubertal
2. Breast and papilla elevated as small mound; areolar diameter increased
3. Breast and areola enlarged, no contour separation
4. Areola and papilla form secondary mound
5. Mature; nipple projects, areola part of general breast contour

For penis and testes:
1. Prepubertal, testicular volume <4 mL
2. Slight enlargement of penis; enlarged scrotum, pink, texture altered, testes 4–6 mL
3. Penis longer, testes larger (8–12 mL)
4. Penis and glans larger, including increase in breadth; testes larger (12–15 mL), scrotum dark
5. Penis adult size; testicular volume > 15 ml

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Transsexualism also known as gender dysphoria is the condition in which a person with apparently normal somatic sexual differentiation of one gender is convinced that he or she is actually a member of the opposite gender. It is associated with an irresistible urge to be in the opposite gender hormonally,

anatomically, and psychosocially. According to the American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders (DSM-V) gender dysphoria is described as a condition in which an individual is intensely uncomfortable with their biological gender and strongly identifies with, and wants to be, the opposite gender. For a person to be diagnosed with gender dysphoria there must be a marked difference between the individual's expressed/experienced gender and the gender others would assign him or her, and it must continue for at least six months. In children, the desire to be of the other gender must be present and verbalized. This condition causes clinically significant distress or impairment in social, occupational, or other important areas of functioning. Gender dysphoria is manifested in a variety of ways, including strong desires to be treated as the other gender or to be rid of one's sex characteristics, or a strong conviction that one has feelings and reactions typical of the other gender. It is recommended that patients meet the DSM-5 and/or ICD-10 criteria to be diagnosed with gender dysphoria.[7]

The current ICD-10 criteria for transsexualism include: [10]

- The desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatments.
- The transsexual identity has been present persistently for at least two years.
- The disorder is not a symptom of another mental disorder or a genetic, intersex, or chromosomal abnormality.

The current DSM-5 criteria for gender dysphoria in adolescents and adults include[4,7]

A. Marked incongruence between one's experienced/expressed gender and natal gender of at least 6 months in duration, as manifested by at least two of the following:
    a. 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)
    b. 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
    c. A strong desire for the primary and/or secondary sex characteristics of the other gender
    d. A strong desire to be of the other gender (or some alternative gender different from one's designated gender)
    e. A strong desire to be treated as the other gender (or some alternative gender different from one's designated gender)
    f. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's designated gender)

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.
    Specify if:
    1. The condition exists with a disorder of sex development
    2. The condition is post transitional, in that the individual has transitioned to full- time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one sex- related medical procedure or treatment regimen – namely, regular sex hormone treatment or gender reassignment surgery confirming the desired gender (e.g., penectomy, vaginoplasty in natal males; mastectomy or phalloplasty in natal females).

The treatment of gender dysphoria requires a multidisciplinary team and stepwise approach to promote optimal health for individuals of this diverse population. The initial assessment of a patient with transsexualism is based on psycho-diagnostic instruments and ideally should be performed by a mental

health professional who is trained in using the DSM-5 or ICD criteria. "Gender affirmation" or "transitioning" is defined as the process of reflection, acceptance, and intervention. Counseling is essential before initiating hormonal or surgical treatment for gender affirmation. It is recommended that when or before hormone treatment starts, the individual should begin living in the role of the opposite gender. The World Professional Association for Transgender Health Standards of Care provides the following criteria for starting hormone therapy and for undergoing surgical procedures: diagnosis of persistent, well-documented gender dysphoria, the capacity to make a well-informed decision, the person must be of legal age; and any medical or mental issues are well controlled.

Medical management involves the suppression of puberty in the form of gonadotropin-releasing hormone agonists, followed by cross-sex hormone therapy to induce puberty by the age of 16. The two major goals of hormonal therapy are to reduce endogenous sex hormone levels and secondary sex characteristics of the individual's designated gender, and to replace endogenous sex hormone levels consistent with the individual's gender identity. [7,10]

Young adolescents with gender dysphoria may experience social distress due to pubertal changes. Gonadotropin-suppression or GnRH analogs are a reversible treatment option for adolescents with gender dysphoria which can be used up until the age of 16 to suppress puberty. It is suggested that pubertal hormone suppression should be started after girls or boys first exhibit physical changes of puberty during Tanner stages G2/B2 (See Appendix A). This option provides time for the individual to explore gender identity and treatment options before gender-affirming sex hormone treatments and/or surgery. Studies reveal that pubertal suppression in children with gender dysphoria tends to lead to improved psychological function in adolescence and early adulthood. Regardless, pubertal suppression may be associated with long-term side effects including but not limited to bone mineralization. Therefore, individuals and providers should weigh the risks and benefits before initiating pubertal suppression in adolescents.[7]

Hormone replacement can begin at or after the age of 16 years. The goal of treatment in female-to- male transsexual individuals is to stop menses and induce virilization, including a male pattern of sexual hair, male physical contours, and clitoral enlargement. The principal hormonal treatment is a testosterone preparation. For male-to-female transsexual individuals the goal is elimination of sexual hair growth, induction of breast formation, and a more female fat distribution are essential. To accomplish this, a near-complete reduction of the biological effects of androgens is required.

Puberty suppression treatment recommendations [7, 12]

A. Treatment consists of IM injections of GnRH agonists:
   a. Leuprolide 3.75 – 7 mg every month
   b. Histrelin implant 50 µg/day released over a period of 12 months.
B. The duration of treatment with GnRH agonists alone depends on when the individual reaches the age at which cross-sex hormone therapy can be added; typically, at the age of 16 years old

Hormone treatment recommendations: [7, 21]

A. There are different regimens to change secondary sex characteristics for transgender males. Parenteral, or transdermal preparations of testosterone can be used to achieve testosterone values in the normal male range, which is typically 320 to 1000 ng/dL. After the age of 40, transdermal formulations are recommended as they bypass first pass metabolism and seem to be associated with better metabolic profiles.

Testosterone for transgender males				
Parenteral		Transdermal		Implant
Testosterone enanthate	Testosterone cypionate	Testosterone gel 1.6%	Testosterone transdermal patch	Testopel®

100 – 200 mg/10 – 14 days or 50 – 100 mg/ week	50 – 100 mg/d	2.5 – 7.5 mg/d	75mg/pellet

A. The hormone regimen for transgender females is more complex. While estrogens are the choice of therapy for transgender females, monotherapy is typically not enough to reach testosterone levels in the female range (100 – 200 pg/mL and <50 ng/dL). Adjunctive anti- androgenic therapy may be necessary to achieve desirable androgen suppression. Transdermal preparations and injectable estradiol cypionate or valerate are advantageous in older transgender females who may be at higher risk for thromboembolic disease.

Estrogen for transgender females			
Oral	Transdermal	Parenteral	
Estradiol	Estradiol patch	Estradiol valerate	Estradiol cypionate
2-6 mg/d	0.025 – 0.2 mg/d *new patch placed Q3-5 d	5 – 30mg IM Q2 weeks	2 – 10mg IM Q week

Anti-androgens for transgender females					
Progesterone	Medroxyprogesterone acetate	GnRH agonist (leuprolide)	Histrelin implant	Spironolactone	Finasteride
20 – 60 mg PO daily	150mg IM Q3 months	3.75 – 7.5mg IM monthly	50 mg implanted Q 12 months	100 – 300 mg PO daily	1 mg PO daily

Surveillance recommendations:

For transgender men on Testosterone [7]

a. Monitor for virilizing and adverse effects every 3 months for the first year, then every 6-12 months.
b. Obtain baseline hematocrit and lipid profile and monitor every 3 months for the first year, then every 6 – 12 months.
    a. Monitor weight, blood pressure, and lipids regularly during visits
c. Obtain baseline bone mineral density if at risk for osteoporosis; routine screening after age 60, or earlier if sex hormone levels consistently low.
d. Monitor serum estradiol during the first 6 months and thereafter until uterine bleeding has ceased.
e. Monitor serum testosterone every 3 months until at, target levels, 320 – 1000 ng/dL
    a. Peak levels for parenteral testosterone measured 24-48 hours after injection.
f. Trough levels for parenteral measured before injection. If mastectomy was performed, conduct sub- and peri areolar annual breast examinations.
    a. If no mastectomy was performed, consider mammograms as recommended by the recommended by the American Cancer Society.

American Cancer Society For transgender women on Estrogen [7]

a. Monitor for feminizing and adverse effects every 3 months for the first year, then every 6-12 months.
b. Obtain baseline hematocrit and lipid profile and monitor at follow up visits.
c. Obtain baseline bone mineral density if at risk for osteoporosis; routine screening after age 60, or earlier if sex hormone levels consistently low.
d. Obtain prolactin at baseline, at 12 months after initiation of treatment, biennially thereafter.
e. Monitor serum testosterone every 3 months, target <50 ng/dL

f. Monitor serum estradiol every 3 months, target 100-200 pg/mL .
g. Obtain baseline serum potassium level and renal function, then every 3 months in the first year, and annually thereafter, when using Spironolactone.

Other considerations:[22-25]

A. Breast cancer:

i) FTM [female to male]: Intact breasts, routine screening as for natal females. Post- mastectomy: Yearly chest wall and axillary exams.
ii) MTF [male to female]: Screening in members >50 years with additional risk factors for breast cancer (estrogen therapy >5 years, family history, BMI >35).

B. Cervical cancer:

i) FTM: Cervix intact, routine screening as for natal females.

C. Prostate cancer:

i) MTF: Routine screening as for natal males.

D. Cardiovascular disease:

i) Screen for risk factors.

E. Diabetes mellitus:

i) MTF: Increased risk on estrogen.
ii) FTM: Routine screening.

Summary of Medical Evidence [8-12]

There are no randomized controlled trials evaluating the effectiveness of hormone treatment for gender dysphoria. Available evidence consists of cross-sectional studies where a group of transgender individuals, some of whom had undergone cross-sex hormone therapy and some of whom had not, responded to questionnaires. Sample sizes in these studies of adults ranged from 50 to 376. The studies most commonly evaluated quality of life (QOL) or functional status with instruments such as the SF-36 Health Survey (Quality Metric Inc.), mood-related conditions such as depression or anxiety, and/or psychosocial conditions such as perceived social support or partnership status. A variety of other behavioral and social outcomes were each assessed, and results were generally positive.18-24 A systematic review based on 28 studies (1833 participants; 1091 MtF and 801 FtM) published from 1996 to February 2008 included a meta-analysis of the QOL and psychosocial outcomes of hormone therapy. 80% of the study participants reported significant improvement in quality of life and reported significant improvement in psychiatric symptoms. [25]

Medically necessary criteria were developed according to the World Professional Association for Transgender Health Standards of Care, 7th version and the 2017 Endocrine Society clinical Practice Guidelines. [4, 7]

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

Members with an FDA labeled contraindication to an individual agent are excluded from coverage unless the prescriber provides an attestation of medical necessity

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J9217	Injection, leuprolide acetate (for depot suspension), 7.5mg
J1950	Injection, leuprolide acetate (for depot suspension), per 3.75mg
J3130	Injection, testosterone enanthate, up to 200 mg
J1380	Injection, estradiol valerate, up to 10 mg
J1000	Injection, depo-estradiol cypionate, up to 5 mg
J9226	Histrelin implant (Supprelin LA), 50 mg
J9225	Histrelin implant (Vantas), 50 mg
J1050	Injection, medroxyprogesterone acetate, 1 mg
J1951	Injection, leuprolide acetate for depot suspension, 0.25 mg
J3316	Injection, triptorelin, extended-release 3.75 mg
J3315	Injection, triptorelin pamoate, 3.75 mg

AVAILABLE DOSAGE FORMS:

Aldactone (spironolactone) oral tablets 25mg, 50mg, 100mg
Alora transdermal patch 0.025mg, 0.05mg, 0.075mg, 0.1mg
Delesrogen (valerate) injectable solution 10mg/mL,
20mg/mL,40mg/mL Depo-estradiol (cypionate) injectable solution
5mg/mL
Androderm transdermal patch 2mg, 4mg
AndroGel packet 1.62% (1.25g, 2.5g), gel pump 1.62%
Delatestryl (enanthate) injectable solution 200mg/mL
Depo-Provera (medroxyprogesterone acetate) suspension for injection 150mg/mL
Progesterone oral capsules 100mg
Depo-Testosterone (cypionate) injectable solution 100mg/mL, 200mg/Ml
Testopel pellet for implantation 75mg
Eligard 7.5 mg SC every 1 month, 22.5 mg SC every 3 months, 30 mg SC every 4 months, 45 mg SC every 6 months,
Estrace oral tablet 0.5mg, 1mg, 2mg
Fensolvi (6 Month) KIT 45MG
Finasteride oral tablets 1mg
Lupron Depot 3.75 mg (monthly), 7.5 mg (monthly)
Lupron Depot 11.25 mg (3 months), 22.5 mg (3 month)
Lupron Depot 30 mg (4 months), Lupron Depot 45 mg (6 months)
Lupron Depot -Ped (3 month) 11.25 mg, 30 mg
Supprelin LA implant 50mg
Lupron Depot-Ped (monthly) 7.5 mg, 11.25 mg, 15 mg
Minivelle/Vivelle/Vivelle-Dot transdermal patch 0.025mg, 0.0375mg, 0.05mg, 0.075mg, 0.1mg,
Progesterone oil for injection 50mg/ml
Trelstar Mixject SUSR 3.75MG
Trelstar Mixject SUSR 11.25MG

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Products Affected Required Medical Information Quantity Place of Administration Route of Administration Coding/Billing Information Available Dosage Forms References	Quarter 3 2022
Q2 2022 Established tracking in new format	Historical changes on file

Molina Clinical Policy
Gender Affirmation Treatment and Procedures (Marketplace): Policy No. 216c

Last Approval: 2/8/2023
Next Review Due By: February 2024

Pl. Trial Ex. 060

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Transgender refers to an individual whose sex assigned at birth (e.g., typically based on external genitalia) does not match their gender identity (one's psychological sense of their gender). **Gender dysphoria** (previously gender identity disorder) may occur in some individuals; this includes the psychological distress resulting from an incongruence between one's sex assigned at birth and one's gender identity. Gender dysphoria frequently starts in childhood however some may not experience it until adolescence or later. To have multiple domains of gender affirmation, someone who is transgender may seek affirmation in all, or some, in the following ways (APA, 2020):

- Socially (changing their name and pronouns);
- Legally (changing gender markers on government-issued documents);
- Medically (pubertal suppression or gender-affirming hormones [GAHs]); and/or
- Surgically (vaginoplasty, facial feminization surgery, breast augmentation, masculine chest reconstruction, etc.)

Gender identity is unlike **gender expression.** Gender identity refers to an individual's psychological sense of their gender – gender expression refers to the way in which one presents to the world in a gendered way. For example, in the United States, wearing a dress is a feminine form of gender expression while wearing a suite is a masculine form. Culturally defined expectations vary across time and culture. An individual's gender expression does not always align with their gender identity. Gender identity is also unlike **sexual orientation** which refers to the type of individual someone is sexually attracted to.; those who are transgender have the same diversity of sexual orientations as those who are cisgender. (APA, 2020).

NOTE: For common terms used when discussing gender dysphoria and gender care, please refer to the *Supplemental Information* section below.

Levin et al. (2021) note that awareness of an individual's gender identity begins very early in life. Consciousness of physical differences occurs between the 1 and 2 years of age; by age 3, children are able to identify themselves as a boy or a girl and by age 4 a child's gender identity is stable. A child's gender identity becomes more established during middle childhood and can be reflected in their interest in playing more exclusively with those of their own gender as well as taking interest in acting like, looking like, and having things similar to same-sex peers. Some children may display gender-role confusion – for example, a boy may lack interest in traditionally masculine activities and identify with females and/or feminine traits. The same can occur for girls who may identify more with males and/or masculine traits. Due to this conflict about one's gender, the child may dislike the parts of themselves that is a boy or a girl; resolution occurs by the time a child completes adolescence however some may continue to experience dysphoria and seek treatment to transition to the opposite gender.

According to federal and state population studies from 2016, approximately 1.3 million adults (0.5% of the total population) and 300,000 youths in the United States identify as transgender (UCLA, 2022; ACOG, 2021). The majority of those who identify as transgender are concentrated in the Western and Southern regions of the United States. In terms of race or ethnicity, adults who are American Indian and Alaska Native Resources (AIAN) account for 0.9% of the population followed by Latinx (0.7%), Black (0.6%), White (0.5%), and Asian (0.5%); all other races account for an

additional 1%. Among youth identifying as transgender, the highest percentages were found among AIAN (1.8%) and Latinx (1.8%) populations followed by those who are Black (1.4%), White (1.3%), and Asian (1.0%); all other races account for an additional 1.5%. Based on data from the Centers for Disease Control and Prevention's Behavioral Risk Factor Surveillance System, differences were not statistically significant among racial and ethnic groups. However, previous research indicates that more people who identify as transgender are Latinx, AIAN, and Asian than White. (UCLA, 2022).

Cedars Sinai (2020) conducted a study that included 210 adults (155 transgender women, 55 transgender men) who sought gender-affirming surgery. Results showed that gender dysphoria was first experience by age 7 in 73% of transgender women and 78% of transgender men. Before starting social transition and/or hormonal therapy, transgender women waited 27 years on average while transgender men waited 23 years. These findings indicate that individuals who received counseling and support services earlier likely would have lessened the distress and negative health effects that many transgender individuals encounter as well as improved overall quality of life.

Etiology of Gender Dysphoria

Research is ongoing however gender dysphoria may originate from a complex biopsychosocial link. Growing research also shows a correlation between gender dysphoria and childhood abuse, neglect, maltreatment, and physical or sexual abuse. Those with gender dysphoria and higher rates of body dissatisfaction typically have a poor prognosis with respect to mental health. These individuals also report higher rates of depression, suicidal ideations, and substance use. (Garg et al., 2021).

History and Physical

Patients typically present to a primary care physician, endocrinologist, or mental health provider. It is essential that the healthcare team document a good history of the patient and should include a developmental history including their childhood, education status, academic performance, social support, history of trauma (mental, physical, sexual), legal history, and if they are currently married, have a partner, or have children. A patient's psychiatric history should include any previous suicide attempts, self-injury behavior, and previous inpatient psychiatric condition(s), including if the patient has a psychiatrist or a psychotherapist and any past psychiatric treatment / medication use. Substance use should also be noted (Garg et al., 2021).

Treatment and Management

Due to more social acceptance and improved access to care, this population is presenting earlier before puberty whereas in the past individual's may have presented at adulthood or late adolescence. Providers should make necessary referrals according to the unique needs of the patient in an effort to build support. For children, individual, family, and group therapy is recommended to explore and counsel on issues stemming from gender preference. For adolescents, the anticipation of puberty is a concern; hormonal treatment and psychotherapy should be considered simultaneously. For adults, options include psychotherapy as well as hormonal and surgical treatments. Counseling is recommended to begin prior to starting treatment and should include, at minimum: (Garg et al., 2021)

- **Care Team.** A comprehensive approach with an endocrinologist and mental health providers.
- **Expectations.** While transgender hormonal and surgical treatment options will be helpful in addressing the patient's external appearance to align with their gender identity, providers should discuss unrealistic expectations sufficiently. A supportive system of peers, friends, and family is also helpful.
- **Treatment Risks.** Providers should discuss potential risks including venous thromboembolism, bone mineral density changes, and pubertal suppression.
- **Fertility Preservation.** Prior to initiation of hormonal and surgical treatment, the patient may lose the ability to reproduce. Providers should discuss fertility preservation with the patient.
- **Sexual Health.** Higher rates of sexually transmitted infections, including HIV, which are higher in this population.

It is important that providers understand that treatment options can be influenced by expectations of one's family or culture as well as the opinion of health professionals, insurance coverage, and the availability of services. Phenotypic

interventions may be appropriate and include social transition and affirmation (e.g., living partially or completely in the preferred gender role by adapting hairstyle, clothing, pronouns, and possibly a new name) and hormonal interventions to suppress endogenous puberty and/or alter secondary sexual characteristics. Primary care providers should make available education, support, and referral to mental health providers as applicable especially when there is evidence of gender dysphoria; coexisting anxiety, depression, or suicidality; or serious interpersonal conflicts with peers or family (e.g., bullying). Medical interventions typically progress from reversible (e.g., social transition, pubertal suppression) to partially reversible interventions (e.g., GAHs) to irreversible interventions (e.g., surgical interventions). Proper attention and early intervention, as well as support of the individual's family and peers, will increase the safety and health of transgender youth. (Olson-Kennedy & Forcier, 2022).

Additional information can be found below in the *Summary of Medical Evidence* section, including a summary of the World Professional Association for Transgender Health (WPATH) *Standards of Care*.

Surgical Procedures for Transgender Individuals

(Coleman et al., 2022; ACOG, 2021)

Masculinizing surgical procedures (female-to-male [FtM]) may include the following:

- **Breast or Chest Surgery.** Subcutaneous mastectomy, creation of a male chest.
- **Genital Surgery.** Hysterectomy (with or without salpingo-oophorectomy), reconstruction of the fixed part of the urethra, which can be combined with a metoidioplasty or with a phalloplasty (employing a pedicled or free vascularized flap), vaginectomy, scrotoplasty, and implantation of erection or testicular prostheses.
- **Nongenital, Nonbreast Surgical Interventions.** Voice surgery (rare), liposuction, lipofilling, pectoral implants, and various aesthetic procedures.

Feminizing surgical procedures male-to-female (MtF) may include the following:

- **Breast or Chest Surgery.** Augmentation mammoplasty (implants/lipofilling).
- **Genital Surgery.** Penectomy, orchiectomy, vaginoplasty, clitoroplasty, vulvoplasty.
- **Non-Genital, Non-Breast Surgical Interventions.** Facial feminization surgery, liposuction, lipofilling, voice surgery, thyroid cartilage reduction, gluteal augmentation (implants/lipofilling), hair reconstruction, and various aesthetic procedures.

Health Disparities for Transgender Youth

Levine et al. (2013) note a lack of research on transgender youth in the areas of medical, mental health, and substance abuse issues. The population also experiences family and/or peer rejection, harassment, trauma, abuse, legal problems, educational problems, poverty and homelessness. Transgender people face extremely high rates of verbal harassment and physical violence both at home and school. Mental health issues faced by transgender youth including depression and suicidality, anxiety, body image distortion, substance abuse, and post-traumatic stress disorder.

Healthy People 2030 is focused on collecting data on LGBT health issues and specifically improving the health of LGBT adolescents. Research shows that LGBT adolescents are especially at risk for being bullied, having suicidal thoughts, and using illegal drugs. (DHHS, n.d.). Objectives of Healthy People 2030 include:

- **Adolescents** with the goal of reducing bullying of LGBT students.
- **Drug and Alcohol Abuse** with the aim of reducing the proportion of LGBT students who have used illicit drugs.
- **Mental Health and Mental Disorders** with a focus on the reduction of suicidal thoughts in LGBT students.
- **Public Health Infrastructure** which includes increasing the number of national surveys to obtain data on LGNT populations and increasing the number of states, territories, and DC that include sexual orientation and gender identity questions in the Behavioral Risk Factor Surveillance System.
- **Sexually Transmitted Infections** with a focus on reduction in new HIV diagnoses and infections as well as increasing the linkage to HIV medical care and knowledge of HIV status and increase the proportion of those age 13 years and over living with diagnosed HIV infection who are virally suppressed. The objective also aims to reduce the rates of syphilis in men who have sex with men.

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COVERAGE POLICY

Marketplace

Please note that there may be State Marketplace mandates and Health Plan regulations regarding coverage of gender dysphoria treatment.

Refer to the members *Evidence of Coverage (EOC)* and *Schedule of Benefits (SOB)* documents to determine coverage

This policy addresses the surgical treatment of gender dysphoria. For specific hormone therapy criteria, please see *Pharmacy PA Criteria: Gender Dysphoria Hormone Therapy (Policy Number C17908-A)*. The following Molina Clinical Policies are also available: *Breast Implant Removal (MCP-315)* and *Blepharoplasty (MCP-204)*.

Please see the *Appendix* section at the end of this policy for additional State coverage information.

Initial Criteria

1. Surgical treatment **may be considered medically necessary** when **ALL** of the following criteria are met:
   a. Member is age 18 years or older; **AND**
   b. A gender reassignment treatment plan is created specific to the Member; **AND**
   c. Member has the capacity to make a fully informed decision and to consent for treatment; **AND**
   d. Member has a documented diagnosis of gender dysphoria as defined by the *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition, Text Revision (DSM-V-TR)* including a marked incongruence between one's experienced/expressed gender and assigned gender of at least six months' duration as manifested by at least **TWO** of the following:
      i. 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); **OR**
      ii. 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); **OR**
      iii. A strong desire for the primary and/or secondary sex characteristics of the other gender; **OR**
      iv. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender); **OR**
      v. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender); **OR**
      vi. 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

   e. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning as evidenced by documentation from a behavioral health professional as defined by the World Professional Association for Transgender Health (WPATH)**. Documentation should indicate that the Member meets **ALL** of the following clinical criteria:
      i. Diagnosis of gender dysphoria; **AND**
      ii. Co-morbid psychiatric or other medical conditions are stable, and the Member is clinically cleared to undergo surgery; **AND**
      iii. Completion of twelve (12) months of continuous, full-time, real-life experience (e.g., the act of fully adopting a new or evolving gender role or gender presentation in everyday life) in the experienced gender; **AND**
      iv. While the duration of needed treatment and number of sessions is up to the discretion of the behavioral health professional, documentation in the medical record should reflect the Member's

understanding of all applicable medical, pharmaceutical, and behavioral health therapies (including risks and complications).

AND

f. When medically indicated, there is documentation that the Member has participated in six (6) consecutive months of gender affirming hormone therapy of the experienced gender continuously and responsibly (e.g., screenings and follow-ups with the professional provider). Any Member contraindications should be documented.

NOTE: The purpose of mental health evaluations and referral letters for surgery is to ensure that the Provider(s) responsible for the care of the Member understand the Member's medical history.

** To avoid delays in medical necessity determinations, Providers may request sample referral letters from the surgeon and/or hospital. The following suggestions align with WPATH guidance: (Coleman et al., 2022).

1. Letter must be written at least twelve (12) months prior to the date of the Member's surgery consult. To ensure best surgery outcomes, the timeframe may be shortened dependent upon the nature of the Member's treatment plan; **AND**
2. For Members undergoing mastectomy (male chest contouring), breast augmentation, hysterectomy, laryngeal shave, and most facial surgeries, one letter is needed to document satisfaction of any applicable criteria. For Members undergoing metoidioplasty, phalloplasty, and vaginoplasty, two letters are required; **AND**
3. Letters should include the following:
   a. Member identifying information (e.g., general identification [age, sex/gender, relationship status, race/ethnicity] and reason surgery is being sought); **AND**
   b. Duration and nature of the therapeutic relationship with the Member, including evaluation, treatment type, and duration; **AND**
   c. Explanation of how the Member meets criteria and a brief clinical reason to support the Member's surgery. This includes the Member's capacity to make an informed decision and consent about treatment. For Member's undergoing genital surgery, six (6) of continuous cross gender hormone therapy should be documented unless there are contraindications and/or the Member is unable/unwilling to use hormones; **AND**
   d. Summary of the Member's psychosocial assessment that includes, but is not limited to: diagnoses; chronological history of the Member's cross-gender feelings; initial and current gender and any sexual, psychiatric (personality, developmental), and/or substance abuse diagnoses; **AND**
   e. Background related to family, development, education and occupation, relational and social history; **AND**
   f. Documentation of Member's current psychiatric stability and if the diagnosis is controlled; **AND**
   g. Medication listing (medical and psychiatric) including dosage, starting date, and prescribing Provider; **AND**
   h. Expected support level from the Member's family, friends, colleagues, etc.; **AND**
   i. Legal status of gender change (including name and gender) on identification (e.g., birth certificate, driver's license passport); **AND**
   j. Qualifications of the evaluator and/or letter author including appropriate level of education, supervision, training and State credentials to treat individuals with gender dysphoria and who seek treatment (including continuing education opportunities); experience utilizing the *DSM-V-TR*; the ability to recognize and diagnose co-morbid behavioral health concerns and differentiate from gender dysphoria; and a strong understanding of gender non-conforming identities and expressions (including how to assess and treat individuals with gender dysphoria).

2. Surgical procedures **may be considered medically necessary** when applicable criteria are met for **ANY/ALL** of the following:

   a. For Male-to-Female (MtF) procedures:

   - Breast Augmentation Mastoplasty when indicated by **ALL** of the following:
     i. Referral letter from a qualified behavioral health Provider confirming **ALL** of the following:
        - Member has a documented diagnosis of persistent gender dysphoria; **AND**
        - Member has an understanding of potential risks, harms, and irreversibility of procedure; **AND**
        - Member has full decision-making capacity to give fully informed consent; **AND**
        - There is documented appropriateness for the proposed surgery (e.g., clinical rationale supporting the request for surgery); **AND**
        - Appropriate psychosocial assessment confirms that comorbid mental health issues are absent or under control. This includes, but is not limited to, substance abuse, major depression, and bipolar disorder.
     ii. Member has undergone at least six (6) months of continuous hormone therapy consistent with gender dysphoria treatment goals (e.g., estrogen) or reason for contraindication, as documented by a Provider (e.g., endocrinologist, primary care).

OR

- Orchiectomy when indicated by **ALL** of the following:
  i. Two referral letters from mental health professionals who have independently assessed patient, one of whom is acting in a purely evaluative capacity (not involved in long-term care), with each letter attesting to **ALL** of the following:
     - Member has a documented diagnosis of persistent gender dysphoria; **AND**
     - Member has an understanding of potential risks, harms, and irreversibility of procedure; **AND**
     - Member has full decision-making capacity to give fully informed consent; **AND**
     - There is documented appropriateness for the proposed surgery (e.g., clinical rationale supporting the request for surgery); **AND**
     - Appropriate psychosocial assessment confirms that comorbid mental health issues are absent or under control. This includes, but is not limited to, substance abuse, major depression, and bipolar disorder.
  ii. Member has undergone at least six (6) months of continuous hormone therapy consistent with gender dysphoria treatment goals (e.g., estrogen) or reason for contraindication, as documented by a Provider (e.g., endocrinologist, primary care).

OR

- Genital Reconstructive Surgery (e.g., vaginoplasty, penectomy, labioplasty, clitoroplasty)
  i. Two referral letters from mental health professionals who have independently assessed patient, one of whom is acting in a purely evaluative capacity (not involved in long-term care), with each letter attesting to **ALL** of the following:
     - Member has a documented diagnosis of persistent gender dysphoria; **AND**
     - Member has an understanding of potential risks, harms, and irreversibility of procedure; **AND**
     - Member has full decision-making capacity to give fully informed consent; **AND**
     - There is documented appropriateness for the proposed surgery (e.g., clinical rationale supporting the request for surgery); **AND**
     - Appropriate psychosocial assessment confirms that comorbid mental health issues are absent or under control. This includes, but is not limited to, substance abuse, major depression, and bipolar disorder.
  ii. Member has undergone at least six (6) months of continuous hormone therapy consistent with gender dysphoria treatment goals (e.g., estrogen) or reason for contraindication, as documented by a Provider (e.g., endocrinologist, primary care).
  iii. Documentation that the Member has lived in the gender role consistent with their gender identity for at least 12 months.

OR

- Voice Disorders when the Member meets **ALL** of the following:
  i. Diagnosis of voice disorder; **AND**
  ii. Evidence of voice-gender incongruence (if the Member is undergoing voice rehabilitation).

Additional procedures that **may be considered medically necessary** include:

- Electrolysis (when required for vaginoplasty)**; OR**
- Mammaplasty**; OR**
- Prostatectomy**; OR**
- Urethroplasty**; OR**
- Vulvoplasty.

OR

b. For Female-to-Male (FtM) procedures:

- Mastectomy when medically necessary as indicated by referral letter from a qualified behavioral health Provider confirming **ALL** of the following:

i. Member has a documented diagnosis of persistent gender dysphoria; **AND**
ii. Member has an understanding of potential risks, harms, and irreversibility of procedure; **AND**
iii. Member has full decision-making capacity to give fully informed consent; **AND**
iv. There is documented appropriateness for the proposed surgery (e.g., clinical rationale supporting the request for surgery); **AND**
v. Appropriate psychosocial assessment confirms that comorbid mental health issues are absent or under control. This includes, but is not limited to, substance abuse, major depression, and bipolar disorder.

OR

- Oophorectomy when medically necessary (usually with hysterectomy and salpingectomy) and when **ALL** of the following are met:
  iv. Two referral letters from mental health professionals who have independently assessed patient, one of whom is acting in a purely evaluative capacity (not involved in long-term care), with each letter attesting to **ALL** of the following:
    - Member has a documented diagnosis of persistent gender dysphoria; **AND**
    - Member has an understanding of potential risks, harms, and irreversibility of procedure; **AND**
    - Member has full decision-making capacity to give fully informed consent; **AND**
    - There is documented appropriateness for the proposed surgery (e.g., clinical rationale supporting the request for surgery); **AND**
    - Appropriate psychosocial assessment confirms that comorbid mental health issues are absent or under control. This includes, but is not limited to, substance abuse, major depression, and bipolar disorder.
  v. Member has undergone at least six (6) months of continuous hormone therapy consistent with gender dysphoria treatment goals (e.g., testosterone) or reason for contraindication, as documented by a Provider (e.g., endocrinologist, primary care).

OR

- Genital Reconstructive Surgery (e.g., vaginectomy, metoidioplasty, scrotoplasty, phalloplasty, urethroplasty, placement of testicular prosthesis)
  i. Two referral letters from mental health professionals who have independently assessed patient, one of whom is acting in a purely evaluative capacity (not involved in long-term care), with each letter attesting to **ALL** of the following:
    - Member has a documented diagnosis of persistent gender dysphoria; **AND**
    - Member has an understanding of potential risks, harms, and irreversibility of procedure; **AND**
    - Member has full decision-making capacity to give fully informed consent; **AND**
    - There is documented appropriateness for the proposed surgery (e.g., clinical rationale supporting the request for surgery); **AND**
    - Appropriate psychosocial assessment confirms that comorbid mental health issues are absent or under control. This includes, but is not limited to, substance abuse, major depression, and bipolar disorder.
  ii. Member has undergone at least six (6) months of continuous hormone therapy consistent with gender dysphoria treatment goals (e.g., testosterone) or reason for contraindication, as documented by a Provider (e.g., endocrinologist, primary care).
  iii. Documentation that the Member has lived in the gender role consistent with their gender identity for at least 12 months.

OR

- Voice Disorders when the Member meets **ALL** of the following:
  i. Diagnosis of voice disorder; **AND**
  ii. Evidence of voice-gender incongruence (if the Member is undergoing voice rehabilitation).

- Breast Reconstruction**; OR**

- Electrolysis (when required for phalloplasty)**; OR**
- Hysterectomy**; OR**
- Salpingo-oophorectomy**; OR**
- Vulvectomy.

c. Members undergoing **reconstructive chest surgery** (e.g., initial mastectomy, breast augmentation) must have **ONE** letter of recommendation from a qualified behavioral health Provider.

NOTE: Certain post-mastectomy services related to breast reconstruction and treatment of physical complications from mastectomy including nipple-areola reconstruction may be covered by the Women's Health and Cancer Rights Act (WHCRA), 29 U.S. Code § 1185b.

d. Members undergoing **hysterectomy, salpingo-oophorectomy, orchiectomy** must have documentation of:
- At least six (6) months of continuous hormonal sex reassignment therapy; **AND**
- Two (2) recommendations for gender reassignment surgery by qualified mental health providers must be submitted to the surgeon performing the genital surgery.

e. Members undergoing **reconstructive genital surgery** must have the following:
- Documentation of at least six (6) months of continuous hormonal sex reassignment therapy; **AND**
- Recommendation for surgery by two qualified mental health professionals; documentation must be submitted to the surgeon performing surgery. (If the first referral is from the Member's psychotherapist, the second referral should be from an individual who has had only an evaluative role with the Member); **AND**
- Documentation that the Member has lived for at least 12 continuous months in a gender role that corresponds with their gender identity.

Additional Services

The following **may be considered medically necessary** for Members undergoing gender affirming procedures:

1. *Behavioral Health.* Services including, but not limited to, counseling for gender dysphoria and related psychiatric conditions (e.g., anxiety, depression).
2. *Hormonal Therapy.* This includes, but is not limited to androgens, anti-androgens, GnRH analogues*, estrogens, and progestins. Prior authorization requirements may apply. Please reference *Pharmacy PA Criteria: Gender Dysphoria Hormone Therapy (Policy Number C17908-A)*.
3. *Laboratory Testing.* For the monitoring of prescribed hormonal therapy.
4. *Age-Related, Gender-Specific Services.* This includes, but is not limited to, preventive health (as applicable to the Member's biological anatomy such as cancer screenings [e.g., cervical, breast, prostate]) and treatment of the prostate.

Limitations

Marketplace defines cosmetic surgery as services that are intended primarily to change or improve a Member's physical appearance that would be considered within normal anatomic variation and **are not covered.** The following procedures and services for the treatment of gender dysphoria **may be considered cosmetic and/or not medically necessary**, including but not limited to:

- Blepharoplasty – removal of redundant skin of upper and/or lower eyelids and protruding periorbital fat
- Chin Augmentation – reshaping or enhancing the size of the chin
- Collagen Injections

- Cricothyroid Approximation – voice modification that raises the vocal pitch by simulating contractions of the cricothyroid muscle with sutures
- Facial Feminizing Procedures
- Hair Removal / Hair Transplantation outside of that for indications noted in 2a. or 2b. above.
- Laryngoplasty – reshaping of laryngeal framework (voice modification surgery)
- Liposuction – removal of fat
- Lip Reduction / Enhancement – decreasing/enlarging lip size
- Mastopexy – breast lift
- Rhinoplasty – reshaping of nose
- Rhytidectomy – face lift

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

[1]Oles et al. (2022) performed the first systematic review of available gender-affirming surgery publications (including all procedures) to analyze outcomes reported in the literature as well as methods used for outcome assessment. While some procedures have been long performed, data is limited for each and requires a review of the literature to understand current knowledge and to steer needed future research. The systematic review was conducted following Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines to identify all outcomes measures gender-affirming surgery cohorts. In total, 15,186 references were identified, 4162 papers advanced to abstract review, and 1826 underwent full-text review; upon review, there were 406 cohort publications. Of non-genitoplasty titles, 35 were mastectomy, 6 mammoplasty, 21 facial feminization, and 31 voice/cartilage. Although 59% of non-genitoplasty papers addressed PCOs in some form, only 4.3% used instruments partially validated in transgender patients. Overall, data were reported heterogeneously and were biased towards high-volume centers. The authors present a comprehensive list of outcome instruments which offers an ideal starting basis for discussions between patients and providers regarding deficiencies that require attention. In addition, consistent use of the same outcome measures and validated gender-affirming surgery-specific instruments are needed as they represent two primary barriers to high-quality research where improvement efforts should be focused.

[2]Oles et al. (2022) also performed a systematic review focusing on genital reconstruction. Gender affirming surgery results were analyzed in a multidimensional way, involving complication rates and anatomic (e.g., vaginal depth), functional (e.g., urinary), and psychosocial outcomes. Of the total references identified (as noted above), there were 406 GAS cohort publications (171 vaginoplasty, 82 phalloplasty, 16 metoidioplasty, 23 oophorectomy/vaginectomy, and 21 with multiple procedures). Although 69% of genitoplasty papers addressed patient-centered outcomes, only 1% used metrics validated in the transgender population. Forty-three different outcome instruments were used. No instrument was used in more than 15% of published series and 38 were used in only one or two publications. Overall, the review identified high patient satisfaction for genital procedures however there was little concordance between study methods – nearly 90% of patient-focused outcome metrics appeared once or twice. The authors suggest standardization of outcome instruments and measurement methods by taking a patient-inclusive, multidisciplinary approach to improve quality of care.

Akhavan et al. (2021) analyzed data from the literature that were specific to gender-affirming mastectomies, vaginoplasty, vulvaplasty, mastectomy, metoidioplasty, and phalloplasty. The review found that gender affirmation surgery is generally safe and complication rates are low for gender-affirming mastectomy and breast augmentation; complication rates for genital surgeries are also considerable low. Surgery can decrease rates of gender dysphoria, depression, and suicidality as well as greatly improve quality-of-life measures. Gaps exist in the research with respect to female-to-male surgery as well as surgical complication rates for genital surgery, facial masculinization and feminization, and patient-reported outcomes.

Almazan et al. (2021) evaluated associations between gender affirming surgeries and mental health outcomes (e.g.,

psychological distress, substance use, and suicide risk). A secondary analysis of data was conducted from the 2015 U.S. Transgender Survey, which includes the largest existing data set across the 50 states and Washington, D.C. The focus of the survey is on the surgical and mental health experiences of transgender individuals. Data of the 27,715 adults that participated in 2015 were analyzed between November 1, 2020, and January 3, 2021.Over 12% (3559 participants) endorsed undergoing one or more types of gender affirming surgery at least two years prior to submitting survey responses; almost 60% (16,401 participants) endorsed a desire to undergo one or more types of gender affirming surgery but denied undergoing any of these. Upon adjusting the data for sociodemographic factors and exposure to other types of gender-affirming care, undergoing one or more types of gender affirming surgery was associated with lower past-month psychological distress, past-year smoking, and past-year suicidal ideation.

Eftekhar et al. (2020) conducted a systematic review and meta-analysis on the quality of life (QoL) of the transgender population post transsexual surgery. Of the nearly 500 articles initially identified (published through December 2019), eight articles were selected for meta-analysis – this included 1099 patients. The mean of QoL in transgender individuals was 70.45 based on World Health Organization Quality of Life (WHOQoL-BREF) and The 36-item short form of the Medical Outcomes Study questionnaire (SF36). Further analysis indicated that the weighted mean QoL in male to female and female to male indicate that the mean QoL in female to male was 57.54 and 62.47 in male to female (based on SF36 questionnaire). The weighted mean QoL in female to male was 69.99 and 70.65 in male to female (based on WHOQoL-BREF questionnaire). Analysis results support approaches to gender reassignment.

Weinforth et al. (2019) performed a systematic literature to assess the available date on QoL following male-to-female reassignment surgery. A total of 13 articles (1101 study participants) were reviewed; the number of trans women in each study ranged from 3 to 247 and had a mean age of 39.9 years (range of 18-76). Seven questionnaires were utilized used to analyze participants QoL following surgery. Results show that gender reassignment surgery benefits emotional well- being, sexuality, and general QoL. In addition, participants reported "freedom from pain", "fitness", and "energy". Some studies identified worsening in some patients following surgery however, overall improved QoL was reported.

Chest Surgery

Cohen et al. (2019) performed a literature review using PubMed for articles related to patients who were transgender female to male. Often, chest contouring is the first surgery that patients undergo and helps individuals assimilate into their new gender role. While there are different techniques to create an aesthetic male chest, it requires adjustment of breast tissue volume, proper nipple-areolar complex placement, and abolishment of the inframammary fold. Consensus on the preferred technique is varied. The authors identified 67 unique articles – 22 met inclusion criteria; 2447 unique patients were analyzed. The authors found that further research is needed with respect to patient selection, surgical decision making, and patient-reported outcomes for various chest contouring techniques. Specific research is needed regarding the ideal nipple-areolar complex shape, size, and location.

Tolstrup et al. (2020) performed a systemic comprehensive literature review using PubMed, EMBASE, CINAHL, PsycINFO, Scopus and the Cochrane Library to identify studies that evaluated gender-confirming chest surgery in a non-cis gender population. Outcome measures were reviewed. A total of 849 records were found; 47 were included in the review. Feminizing gender-confirming chest surgery was analyzed in 11 studies while masculinizing gender-confirming chest surgery was evaluated in 39 studies. Categories of patient-reported outcomes were used in 29 studies and included aesthetic outcome, functional outcome and mental health parameters. In conclusion, the summary of outcome domains and classifications found large variations in outcome evaluation between studies. While several studies reported on similar outcome categories, there was a high level of heterogeneity of domains and classifications of outcomes. Future research should focus on the evaluation of outcomes with an effort to streamline reporting and compare surgical outcomes between studies.

Genital Surgery

Nassiri et al. (2020) performed a systematic review to evaluate the effect of gender reassignment surgery on the development of urethral complication. A total of 879 articles published up until June 2019 were included and identified the Pubmed, Scopus, Embase, and Web of Science databases. Following examination and removal of articles that were not pertinent to the review, 32 studies were examined which included a total of 3463 patients. Female-to-male

(FtM) surgery and male-to-female (MtF) surgery was discussed in 23 and 10 studies, respectively (one study discussed both). Differing patterns of complications were observed in FtM and MtF surgeries; increased complications were noted FtM surgeries due to the larger size of the neourethra. Complications related to meatal stenosis (a concern in MtF surgery) ranged from 4 to 40%; meatotomy for repair was often required. Stricture and fistulization are often reported complications following FtM surgery; studies reporting on fistulae involving the urethra found that 19 to 54% of fistulae resolved spontaneously without further surgical intervention. The authors concluded that high rates of complications are reported in the medical literature which emphasizes the need for proper patient education regarding risks and benefits of surgery.

Rooker et al. (2019) conducted a comprehensive literature review to analyze and aggregate reported characteristics and outcomes of penile prosthesis implantation in the trans masculine patient. Penile prostheses are often used to achieve erectile rigidity after phalloplasty in trans masculine patients. Due to the delicate nature of the neophallus and lack of native erectile tissue, complications and challenges are of concern. While novel phalloplasty and prosthesis insertion techniques have been developed, none have proven superior. The authors used the Medline, EMBASE, and Cochrane Registry databases; articles through February 2019 were included. Studies included and analyzed those prosthesis outcomes in patients who received a neophallus as part of a gender-affirming procedure. A total of 23 journal articles (retrospective or case series/reports) were reviewed – this included 1,056 patients who underwent phalloplasty and 792 who received a penile prosthesis. Over 83% of the prostheses were inflatable versus 16% were non-inflatable. The number of cylinders used for each prosthesis was 61% (single-cylinder) and 39% (double-cylinder). Follow-up duration had a mean of 3.0 years. Complications were reported by 36% of patients who received a prosthesis; at follow-up 60% of patients had their original implant present and 84% reported achieving penetration. While prosthesis implantation in gender-affirming operations may pose a significant risk of complication, this is a reasonable and useful method to achieve rigidity necessary for sexual intercourse.

Massie et al. (2018) performed a retrospective chart review of a single surgeon's experience with penile inversion vaginoplasty (performed from July 2014 to June 2016). Information analyzed included patient demographic data, postoperative complications, and patient-reported outcome data. The data were correlated by binary logistic regression to identify predictors of postoperative complications and patient satisfaction. Penile inversion vaginoplasty is the current gold standard procedure for MtF transgender patients undergoing gender-confirming genital surgery. While data concerning complications have been extensively reported in the medical literature, studies regarding patient-reported outcomes are limited. The aim of the study was to report postoperative complications and patient-reported outcomes based on the largest cohort in the United States undergoing penile inversion vaginoplasty. A total of 117 patients underwent penile inversion vaginoplasty. Common complications included granulation tissue (26%), intravaginal scarring (20%), and prolonged pain (20%). A majority of patients (94%) reported that they felt positive about their genitals and would have the surgery again. Over 70% of patients reported resolution of their gender dysphoria. Predictors of patient dissatisfaction included intravaginal scarring, prolonged pain, excessive external scarring, loss of sensation, and hematoma/excessive bleeding. Regardless of the moderate complication risks, patient satisfaction is very high following penile inversion vaginoplasty.

Studies and Trials

Surgical Treatment

There are no randomized controlled trials evaluating the effectiveness of surgical treatment of gender dysphoria (GD). Available evidence consists of cohort studies comparing outcomes in patients that underwent sex reassignment surgery (SRS) versus transgendered patients that had not undergone SRS. In addition, cross-sectional studies were also reviewed that compared outcomes in transgendered patients who had undergone SRS versus those who had not undergone SRS. Most of the studies did not explicitly state inclusion and exclusion criteria. Sample sizes ranged from 35 to 376 patients. Follow-up time since SRS varied widely across studies and ranged from one month to seven years. There is insufficient evidence to establish definitive patient selection criteria for SRS to treat GD. Professional groups recommend that SRS be restricted to individuals who are referred for sex reassignment services by a qualified behavioral health professional, and that while one referral is sufficient for breast or chest surgery, two independent referrals should be required for genital SRS. Individuals who have medical contraindications to surgery should not undergo SRS. (Heylens et al., 2014; Weigert et al., 2013; Berry et al., 2012; Motmans et al., 2012; Dhejne et al., 2011; Ainsworth & Spiegel, 2010).

Hormone Treatment

There are no randomized controlled trials evaluating the effectiveness of hormone treatment for gender dysphoria. Available evidence consists of cross-sectional studies where a group of transgender individuals, some of whom had undergone gender affirming hormone therapy and some of whom had not, responded to questionnaires. Sample sizes in these studies of adults ranged from 50 to 376. The studies most commonly evaluated quality of life (QOL) or functional status with instruments such as the SF-36 Health Survey (QualityMetric Inc.), mood-related conditions such as depression or anxiety, and/or psychosocial conditions such as perceived social support or partnership status. A variety of other behavioral and social outcomes were assessed; results were generally positive. (Colizzi et al., 2014; Fisher et al., 2014; Costantino et al., 2013; Gorin-Lazard et al., 2013; Wierckx et al., 2013; Gorin-Lazard et al., 2012). A systematic review based on 28 studies (1833 participants; 1091 MtF and 801 FtM) published from 1996 to February 2008 included a meta-analysis of the QOL and psychosocial outcomes of hormone therapy. 80% of the study participants reported significant improvement in quality of life and reported significant improvement in psychiatric symptoms. (Murad et al., 2010).

Cardiovascular Risks

Schutte et al. (2022) conducted an exploratory study to evaluate the cardiovascular risks and gender-affirming hormone therapy (specifically markers of inflammation and hemostasis). A total of 48 trans women and 47 trans men were included (ages 18 to 50); participants had no history of cardiovascular events. Trans women were using estradiol patches plus cyproterone acetate (CPA) and trans men were using testosterone gel. Measurements were performed for all participants before and after 3 and 12 months of hormone therapy. The study found an increase in platelet activation and coagulation marker concentrations in trans women using transdermal estradiol plus CPA. No increase was noted in the trans men. Concentrations of inflammatory markers were less in trans women and increased in trans men. Hormone therapy is shown to affect hemostasis in transgender persons and therefore may be a catalyst to the presence of increased cardiovascular risk.

Swe et al. (2022) reviewed limited, non-randomized studies suggesting that transgender women on gender affirming hormone therapy (GAHT) have increased risks of myocardial infarction, ischemic stroke and venous thromboembolism (or VTE). Conversely, evidence does not demonstrate an increased cardiovascular risk in transgender men receiving GAHT. Evidence also demonstrates an improvement in gender dysphoria and quality of life. Monitoring for standard cardiovascular risk factors is recommended for transgender individuals who are receiving GAHT – this includes. Providers should adhere to current guidelines regarding lifestyle programs and preventive screenings.

Children and Adolescents

The American Academy of Child and Adolescent Psychiatry (AACAP) posted a literature review conducted on gender dysphoria in childhood and adolescence.

- Aitken et al. (2016) examines self-harm, suicidal ideation, and suicidal behavior (by parent report). Children with gender dysphoria show an increase in self-harm and suicidality as age progressed.
- Dheine et al. (2016) provides an overview of existing studies on psychiatric disorders in transgender patients. This population has an increased risk of psychiatric morbidity however, symptoms improve with gender affirming care and mental health care.
- Durwood et al. (2017) researchers of the TransYouth Project analyzed depression, anxiety, and self-worth in children age 9-14 who had socially transitioned. Results showed that transgender children had similar rates of depression and marginally higher rates of anxiety.
- Olson et al. (2016) examined depression and anxiety in transgender children who have socially transitioned. Research showed that when support was received for their gender identities, normative rates of depression were found as well as decreased anxiety.

Tordoff et al. (2022) conducted a study of 104 youths aged 13 to 20 years (mean age 15.8) – 61% were transmasculine individuals, 26% were transfeminine individuals, and 10% were nonbinary or gender fluid individuals, and 3% responded "I don't know" or did not respond to the gender identity question. Baseline data show that 57% of all participants had moderate to severe depression, 50% had moderate to severe anxiety, and 43% reported self-harm or suicidal thoughts. By the conclusion of the study, 66% received puberty blockers, GAHs, or both – 34% did not receive either intervention.

The authors found that gender affirming interventions decrease levels of depression and suicidality over a 12-month time. This supports existing data to suggest that gender affirming care increases well-being among transgender youth.

National and Specialty Organizations

World Professional Association for Transgender Health (WPATH)

Since 1979, WPATH has published the internationally accepted *Standards of Care* guidelines. The Standards aim to provide clinical guidance for health professionals assisting transgender and gender diverse (TGD) individuals with access to safe and effective pathways for achieving lasting comfort with their gendered selves. The objective is to maximize an individual's overall physical health, psychological well-being, and self-fulfillment. Assistance may include primary care, gynecologic and urologic care, reproductive options, voice and communication therapy, mental health services (e.g., assessment, counseling, psychotherapy), and hormonal and surgical treatments. After initial publication in 1980, the Standards were updated in 1981, 1990, 1998, 2001, 2011, 2012, and 2022 – current chapters include:

1. Terminology*
2. Global Applicability
3. Population Estimates
4. Education*
5. Assessment of Adults*
6. Adolescents*
7. Children*
8. Nonbinary*
9. Eunuchs*
10. Intersex
11. Hormone Therapy
12. Surgery and Postoperative Care and Follow-Up
13. Voice and Communication
14. Primary Care
15. Reproductive Health
16. Sexual Health*
17. Mental Health

* New chapter for 2022

Appendices include Methodology; Glossary; Gender-Affirming Hormonal Treatments; Summary Criteria for Hormonal and Surgical Treatments for Adults and Adolescents; and Gender-Affirming Surgical Procedures (Coleman et al., 2022).

A summary of the new chapters and recommendations are included below (Coleman et al., 2022).

- **Education.** An overview is provided of education surrounding gender affirming care as well as recommendations for those at the governmental, nongovernmental, institutional and provider levels. The aim of education is to increase access to competent, compassionate health care as well as encourage a broader discussion between educators and health care professionals.

- **Assessment of Adults.** This chapter includes assessments for gender-affirming medical and surgical treatments (GAMSTs). Recommendations are centered around the proper licensure of Providers as well as continuing education and skill to identify co-existing mental health or other psychosocial concerns and how they differ from gender dysphoria, incongruence, and diversity – physical health conditions should also be evaluated for any impact to the outcome of a GAMST. Recommendations also focus when to recommend GAMSTs and how to ensure fulfillment of diagnostic criteria prior to treatments (in regions requiring a diagnosis to access care).

- **Adolescents.** A new chapter was included on the population due to the significant increase in referrals as well as an increase of studies focused on adolescent gender diversity-related care, and specific developmental and

gender affirming care issues. Recommendations are centered around the assessment process of adolescents requiring GAMSTs as well as how to work with youth and their families.

- **Children.** Developmentally appropriate psychosocial practices and therapeutic approaches for prepubescent gender diverse children are included.
- **Non-Binary.** A chapter is included discussing the broad description of the term "nonbinary" and its usage from a biopsychosocial, cultural, and intersectional perspective. The importance of access to gender-affirming care, specific gender-affirming medical interventions, and appropriate level of support is discussed.
- **Eunuchs.** A new chapter was included on individuals who identify as eunuch (individuals assigned male at birth and wish to eliminate masculine physical features, masculine genitals, or genital functioning). The unique needs of the population are explored.
- **Sexual Health.** The impact of sexual health on physical and psychological well-being for transgender people is explored with respect to sexual functioning, pleasure, and satisfaction.

The **American Academy of Child and Adolescent Psychiatry (AACAP)** published practice principles that address issues faced by children and adolescents who identify as gay, lesbian, bisexual, gender nonconforming, or gender discordant. The following principles focus on cultural competence, research needs, and ethics (Adelson & AACAP, 2012):

1. **Principle 1.** All children and adolescents should complete a comprehensive diagnostic evaluation that is age-appropriate and assesses their psychosexual development.
2. **Principle 2.** Confidentiality must be upheld when assessing sexual and gender minority youth.
3. **Principle 3.** With respect to the individual's sexual orientation, gender nonconformity, and gender identity, family dynamics should be assessed as they relate to cultural values of the individual, their family, and community.
4. **Principle 4.** Providers should assess the individual for commonly encountered situations by this population that can increase the risk of psychiatric diagnoses.
5. **Principle 5.** Providers should focus on establishing healthy psychosexual development in sexual and gender minority youth. This includes protecting their full capacity for identity formation and adaptive functioning.
6. **Principle 6.** Providers should understand that evidence does not exist that one's sexual orientation can be altered via therapy (and that such attempts may be harmful).
7. **Principle 7.** Providers should be aware of current literature supporting the natural course of gender discordance and associated psychopathology and how it impacts the selection of treatment goals and modalities.
8. **Principle 8.** Providers should be available as a liaison with schools, community agencies, and other health care providers to advocate for the unique needs of this population and their families.
9. **Principle 9.** Mental health providers should be knowledgeable of community and professional resources for sexual and gender minority youth.

The **American Academy of Pediatrics (AAP)** (2021) published a policy statement on *Office-Based Care for Lesbian, Gay, Bisexual, Transgender, and Questioning Youth.* The AAP notes that pediatricians should provide factual, current, nonjudgmental information in a confidential manner to lesbian, gay, bisexual, transgender, and questioning (LGBTQ) youth. Particular attention should also be paid to the effects of homophobia and heterosexism that can contribute to increased mental health issues for sexual minority youth. Providers should acknowledge and affirm their patient's feelings of gender dysphoria; referral to a qualified mental health professional is vital to assist the patient as well as educate them and assess their readiness for transition. Those who receive the right assistance and care are more likely to live a healthy, productive life as they go through adolescence and enter young adulthood. The AAP (2018) also published a policy statement on *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents.* Highlights include the need for more formal training, standardized treatment and research that focuses on safety and medical outcomes.

The AAP also published a policy statement titled *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents* (Rafferty et al., 2018). The statement aims to bring attention to the need for more formal training, standardized treatment, and research on safety and medical outcomes surrounding the care of

transgender individuals. Concepts and challenges faced by providers, as well as families and loved ones, are discussed and potential solutions are provided to promote the health and positive development of youth that identify as transgender to eliminate discrimination and stigma.

The **American College of Obstetricians and Gynecologists (ACOG)** published *Committee Opinion Committee No. 823: Health Care for Transgender and Gender Diverse Individuals* in 2021 to provide clinical guidance to obstetrician–gynecologists caring for transmasculine and transfeminine patients to offer inclusive patient care. In addition, ACOG notes that most medications used for gender transition are common and can be safely prescribed by a variety of health care professionals when given proper appropriate training and education. This includes, but is not limited to, obstetrician–gynecologists, family or internal medicine physicians, endocrinologists, psychiatrists, and advanced practice clinicians. Additional recommendations include discussion of fertility and parenting desires, prior to starting hormone therapy or gender affirmation surgery. Patients should also know that gender-affirming hormone therapy is not effective contraception; sexually active individuals should be educated about contraceptive options if they do not wish to become pregnant or cause pregnancy in others. Finally, to lead preventive medical care, any anatomical structure present that warrants screening should be screened, regardless of the patient's gender identity.

The **American Psychiatric Association (APA)** (2017) published *A Guide for Working with Transgender and Gender Nonconforming Patients*. Sections include:

- History and Epidemiology
- Definitions of Gender, Sex, and Sexual Orientation and Pronoun Usage
- Gender Dysphoria Diagnosis
- Medical Treatment and Surgical Interventions
- Best Practices
- Writing Letters of Support to Insurers and Surgeons
- Gender-Affirming Therapy
- Terminology
- Resources and References

In addition, the APA (2015) published *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People*. A total of 16 guidelines were developed to aid providers with affirmative psychological practice across the lifespan of the population. The guidelines are categorized in five clusters: (1) foundational knowledge and awareness; (2) stigma, discrimination, and barriers to care; (3) lifespan development; (4) assessment, therapy, and intervention; and (5) research, education, and training.

The **Endocrine Society** published the *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline* (Hembree et al., 2017). Recommendations are summarized below:

- Adolescents who meet diagnostic criteria for gender dysphoria/gender incongruence should initially undergo treatment to suppress pubertal development.
- Pubertal hormone suppression should start after girls and boys first exhibit physical changes of puberty.
- GnRH analogues should be used to suppress pubertal hormones (where indicated).
- Adolescents requesting sex hormone treatment should begin with a gradual increasing dose schedule. This should be initiated following confirmation by a multidisciplinary team as well as informed consent by the patient (which is often established by age 16). The Society notes that while some studies show administration of hormones before age 13.5 to 14, a multidisciplinary team should evaluate for final determination.
- Approval for gender affirming surgery should be given only after completion of at least 1 year of consistent and compliant hormone treatment unless hormone therapy is not desired or medically contraindicated.
- Genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old.
- Puberty blocking and gender-affirming hormone treatment in pre-pubertal children with gender dysphoria/gender incongruence is not recommended.

The Endocrine Society (2009) also published a clinical practice guideline titled *Endocrine Treatment of Transsexual Persons* which focuses on gender dysphoria and provides a standard of care for supporting transgender individuals. Recommendations include evidence that treatment of gender dysphoria is medically necessary. Sections include:

1. Diagnostic Procedure
2. Treatment of Adolescents
3. Hormonal Therapy for Transsexual Adults
4. Adverse Outcome Prevention and Long-Term Care
5. Surgery for Sex Reassignment

The **Endocrine Society** and the **Pediatric Endocrine Society** (2020) published a position statement on *Transgender Health* in support of medical interventions for transgender youth and adults. This includes puberty suppression, hormone therapy, and medically indicated surgery which are considered safe and effective when properly monitored and established as the standard of care. Patients should also undergo necessary screenings related to medically necessary surgeries.

The **Society for Adolescent Health and Medicine (SAHM)** published a *Position Paper on Promoting Health Equity and Nondiscrimination for Transgender and Gender-Diverse Youth* (2020) that encourages Providers treating adolescent and young adults to receive training in providing culturally effective, evidence-based care for transgender youth. The SAHM states that additional research on gender-affirming health care is needed and advocates for policies that protect the rights of transgender youth to limit barriers to healthcare. The SAHM aligns with other professional organizations and promotes the call for gender affirmation as a mainstay of treatment and is opposed to the notion that diversity in gender is pathological.

SUPPLEMENTAL INFORMATION

The following are terms related to gender care (Coleman et al., 2022; Perzanowski et al., 2020; Rafferty et al., 2018).

Term	Definition
Affirmed Gender	When one's true gender identity, or concern about their gender identity, is communicated to and validated from others as authentic
Agender	A term that is used to describe one who does not identify as having a particular gender.
Cisgender	Used to describe an individual who identifies and expresses a gender that is consistent with the culturally defined norms of the sex they were assigned at birth.
Eunuch	Individuals assigned male at birth and wish to eliminate masculine physical features, masculine genitals, or genital functioning
FTM **(affirmed male; trans male)**	Used to describe individuals who were assigned female sex at birth but who have a gender identity and/or expression that is asserted to be more masculine.
Gender Dysphoria	A concept designated in the *DSM-V-TR* as clinically significant distress or impairment related to a strong desire to be of another gender, which may include desire to change primary and/or secondary sex characteristics. Not all transgender or gender diverse people experience dysphoria.
Gender Expression	The external way an individual expresses their gender (e.g., clothing, hair, mannerisms, voice/speech patterns, activities, or social roles).
Gender Identity	An individual's deep internal sense of being female, male, a combination of both, somewhere in between, or neither, resulting from a multifaceted interaction of biological traits, environmental factors, self-understanding, and cultural expectations.
Gender Identity Disorder	A psychiatric diagnosis (previously defined in the *DSM-V-TR* that was changed to "gender dysphoria" in the *DSM-V-TR*). Primary criteria include a strong, persistent gender affirming identification and significant distress and social impairment. This diagnosis is no longer appropriate for use and may lead to stigma – the term may be found in older research.
Gender Perception	How others interpret a person's gender expression.
Gender Diverse	An umbrella term to describe individuals with gender identities and/or expressions that vary

Term	Definition
	from expected developmental norms; includes individuals who identify as multiple genders or with no gender at all.
MTF (affirmed female; trans female)	Used to described individuals who were assigned male sex at birth but who have a gender identity and/or expression that is asserted to be more feminine.
Nonbinary	Individuals whose gender identity is neither girl/woman nor boy/man.
Sex	Assignment made at birth, usually male or female, based on external genital anatomy; may be based on internal gonads, chromosomes, or hormone levels.
Sexual Orientation	Describes the types of individuals toward whom a person has emotional, physical, and/or romantic attachments.
Transgender	An umbrella term describing individuals whose gender identity does not align in a traditional sense with the gender they were assigned at birth. It may also be used to refer to a person whose gender identity is binary and not traditionally associated with that assigned at birth.

The following are terms related to diagnoses (Garg et al., 2021):

Other Specified Gender Dysphoria applies to presentations in which symptoms characteristic of gender dysphoria that cause clinically significant distress or impairment in social, occupational, or other important areas of functioning predominate but do not meet the full criteria for gender dysphoria. The "other specified gender dysphoria" category is used in situations in which the clinician chooses to communicate the specific reason that the presentation does not meet the criteria for gender dysphoria. This is done by recording “other specified gender dysphoria” followed by the specific reason (e.g., “brief" gender dysphoria).

Unspecified Gender Dysphoria applies to presentations in which symptoms characteristic of gender dysphoria that cause clinically significant distress or impairment in social, occupational or other important areas of functioning predominate but do not meet the full criteria for gender dysphoria. The "unspecified gender dysphoria" category is used in situations in which the clinician chooses not to specify the reason that the criteria are not met for gender dysphoria and includes presentations in which there is insufficient information to make a more specific diagnosis.

Differential Diagnoses for gender dysphoria include: autogynephilia; body dysmorphic disorder; gynandromorphophilia; intersex states; psychosis; paraphilic disorders; self-amputation; schizophrenia; and transvestitism.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
55970	Intersex surgery; male to female
19325	Breast augmentation with implant
54125	Amputation of penis; complete
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
54690	Laparoscopy, surgical; orchiectomy
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
57291	Construction of artificial vagina; without graft
57292	Construction of artificial vagina; with graft
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
55980	Intersex surgery; female to male
19303	Mastectomy, simple, complete
53410	Urethroplasty, 1-stage reconstruction of male anterior urethra

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
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
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
54660	Insertion of testicular prosthesis (separate procedure)
55175	Scrotoplasty; simple
55180	Scrotoplasty; complicated
56625	Vulvectomy simple; complete
57106	Vaginectomy, partial removal of vaginal wall
57110	Vaginectomy, complete removal of vaginal wall
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)

The following CPT codes may be considered Cosmetic Procedures and non-covered:

Blepharoplasty	
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

Body Contouring	
15769	Grafting of autologous soft tissue, other, harvested by direct excision (eg, 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)
Breast Lift and Reconstruction	
19316	Mastopexy
19350	Nipple/areola reconstruction
Brow Lift	
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
Calf Implant	
27656	Repair, fascial defect of leg
Cheek, Malar, Pectoral Implant	
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
Chin/Nose Implants, Chin Recontouring	
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
21270	Malar augmentation, prosthetic material
Collagen Injections	
11950	Subcutaneous injection of filling material (eg, collagen); 1 cc or less
11951	Subcutaneous injection of filling material (eg, collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (eg, collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (eg, collagen); over 10.0 cc
Dermabrasion and Peels	
15780	Dermabrasion; total face (eg, for acne scarring, fine wrinkling, rhytids, general keratosis
15781	Dermabrasion; segmental, face
15782	Dermabrasion; regional, other than face
15783	Dermabrasion; superficial, any site (eg, tattoo removal)
15788	Chemical peel, facial; epidermal
15789	Chemical peel, facial; dermal
15792	Chemical peel, nonfacial; epidermal
15793	Chemical peel, nonfacial; dermal
Face and Neck Tightening	
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
Facial Bone Reduction	
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21209	Osteoplasty, facial bones; reduction
Forehead Reduction and Contouring	
21137	Reduction forehead; contouring only
21138	Reduction forehead; contouring and application of prosthetic material or bone graft (includes obtaining autograft)

Hair Removal	
17380	Electrolysis epilation, each 30 minutes
Hair Transplant	
15775	Punch graft for hair transplant; 1 to 15 punch grafts
15776	Punch graft for hair transplant; more than 15 punch grafts
Jaw Reduction, Contouring, Augmentation	
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)
Laryngoplasty	
31599	Unlisted procedure, larynx
Lip Lift and Lip Filling	
40799	Unlisted procedure, lips
Liposuction-Lipectomy	
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
15876	Suction assisted lipectomy; head and neck
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity
Rhinoplasty	
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)
Thyroid Reduction Chondroplasty	
31750	Tracheoplasty; cervical
Voice Modification	
31899	Unlisted procedure, trachea, bronchi

HCPCS Codes – None.

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

Molina Clinical Policy
Gender Affirmation Treatment and Procedures (Marketplace): Policy No. 216c
Last Approval: 2/8/2023
Next Review Due By: February 2024

APPROVAL HISTORY

2/8/2023	Policy reviewed, changed the duration of hormone therapy for adults from 12 months to 6 months per WPATH 8 update; included updates to national and specialty organizations, including WPATH 8.
4/13/2022	New policy.

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Evidence Based Reviews and Publications

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Pl. Trial Ex. 061

United Healthcare

UnitedHealthcare® Commercial
Medical Policy

Gender Dysphoria Treatment (for Commercial Only)

Policy Number: 2023T0580N
Effective Date: April 1, 2023

Instructions for Use

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Application

This Medical Policy applies to all UnitedHealthcare Commercial benefit plans.

Coverage Rationale

See Benefit Considerations

Notes:

- This Medical Policy does not apply to individuals with ambiguous genitalia or disorders of sexual development.
- This Medical Policy does not apply to fully-insured group plans in California. Refer to the Benefit Interpretation Policy titled Gender Dysphoria (Gender Identity Disorder) Treatment: CA.
- This Medical Policy does not apply to fully-insured group plans in the state of Washington. Refer to the Benefit Interpretation Policy titled Gender Dysphoria (Gender Identity Disorder) Treatment: WA.

Surgical treatment for Gender Dysphoria may be indicated for individuals who provide the following documentation:

- For mastectomy/breast reduction surgery, a written psychological assessment from at least one Qualified Behavioral Health Provider 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 (age of majority)
  - Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges
- For genital surgery, 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. 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)
  - 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 experienced 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 Behavioral Health Provider experienced in treating Gender Dysphoria
- For plans that specifically provide coverage for breast augmentation, thyroid cartilage reduction, and/or voice modification surgery (e.g., laryngoplasty, glottoplasty or shortening of the vocal cords), a written psychological assessment from at least one Qualified Behavioral Health Provider 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 (age of majority)
  - Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges
  - For breast augmentation, completion of 12 months of continuous hormone therapy prior to the breast procedure is required

When the above criteria are met, the following surgical procedures to treat Gender Dysphoria are medically necessary and covered as a proven benefit:

- Bilateral mastectomy or breast reduction
- Clitoroplasty (creation of clitoris)
- Hysterectomy (removal of uterus)
- Labiaplasty (creation of labia)
- Laser or electrolysis hair removal in advance of genital reconstruction prescribed by a physician for the treatment of Gender Dysphoria
- 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
- Urethroplasty (reconstruction of female urethra)
- Urethroplasty (reconstruction of male urethra)
- Vaginectomy (removal of vagina)
- Vaginoplasty (creation of vagina)
- Vulvectomy (removal of vulva)

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:

Refer to the Benefit Considerations section as member specific benefit plan language may vary.
Note: For fully insured group policies in New York, refer to the Benefit Considerations section for more information.

- Abdominoplasty (also refer to the Medical Policy titled Panniculectomy and Body Contouring Procedures)
- Blepharoplasty (also refer to the Medical Policy titled Brow Ptosis and Eyelid Repair)
- Body contouring (e.g., fat transfer, lipoplasty, panniculectomy) (also refer to the Medical Policy titled Panniculectomy and Body Contouring Procedures)
- Breast enlargement, including augmentation mammaplasty and breast implants*
- Brow lift

- Calf implants
- Cheek, chin and nose implants
- Injection of fillers or neurotoxins (also refer to the Medical Benefit Drug Policy titled Botulinum Toxins A and B)
- Face/forehead lift and/or neck tightening
- Facial bone remodeling for facial feminization
- Laser or electrolysis hair removal not related to genital reconstruction
- Hair transplantation
- Lip augmentation
- Lip reduction
- Liposuction (suction-assisted lipectomy) (also refer to the Medical Policy titled Panniculectomy and Body Contouring Procedures)
- Mastopexy
- Pectoral implants for chest masculinization
- Rhinoplasty (also refer to the Medical Policy titled 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*

*Some plans may provide coverage for these services. Refer to the Benefit Considerations section as member specific benefit plan language may vary.

Documentation Requirements

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 documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT Codes*	Required Clinical Information
Gender Dysphoria Treatment	

14000, 14000, 14001, 14041, 15734, 15738, 15750, 15757, 15758, 15769, 15771, 15773, 15820, 15821, 15822, 15823, 15830, 15847, 15877, 15878, 15879, 17999, 19303, 19316, 19318, 19325, 19340, 19342, 19350, 21121, 21123, 21125, 21127, 21137, 21138, 21139, 21172, 21175, 21179, 21180, 21208, 21209, 21210, 30400, 30410, 30420, 30430, 30435, 30450, 53410, 53430, 54125, 54400, 54401, 54405, 54520, 54660, 54690, 55175, 55180, 55970, 55980, 56625, 56800, 56805, 57110, 57335, 58150, 58180, 58260, 58262, 58290, 58291, 58541, 58542, 58543, 58544, 58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573, 58661, 58720, 58940, 64856, 64892, 64896, 67900	Medical notes documenting the following:
	• The history of medical conditions requiring treatment or surgical intervention
	• A well-defined physical/physiologic abnormality resulting in a medical condition that requires treatment
	• Recurrent or persistent functional deficit caused by the abnormality
	• Clinical studies/tests addressing the physical/physiologic abnormality confirming its presence and degree to which it causes impairment
	• Color photos, where applicable, of the physical and/or physiological abnormality
	• Physician plan of care with proposed procedures and whether this request is part of a staged procedure
	• A written psychological assessment from at least two Qualified Behavioral Health Providers experienced in treating Gender Dysphoria, who have independently assessed the individual. The assessment should include all of the following:
	  ○ The member is capable to make a fully informed decision and to consent for treatment
	  ○ The member 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
	  ○ The member has completed at least 12 months of successful continuous full-time real-life experience in the desired gender
	  ○ The member has completed 12 months of continuous cross-sex hormone therapy appropriate for the desired gender (unless medically contraindicated)

CPT Codes*	Required Clinical Information
Gender Dysphoria Treatment	
	• A treatment plan that includes ongoing follow-up and care by a Qualified Behavioral Health Provider experienced in treating Gender Dysphoria

*For code descriptions, refer to the Applicable Codes section.

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. 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:
   1. 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)].
   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 in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)].
   3. A strong desire for the primary and/or secondary sex characteristics of the other gender.
   4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
   5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
   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).
B. 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. 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):
   1. 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).
   2. 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.
   3. A strong preference for cross-gender roles in make-believe play or fantasy play.
   4. A strong preference for the toys, games or activities stereotypically used or engaged in by the other gender.
   5. A strong preference for playmates of the other gender.
   6. 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.
   7. A strong dislike of ones' sexual anatomy.
   8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.
B. The condition is associated with clinically significant distress or impairment in social, school or other important areas of functioning.

Qualified Behavioral Health Provider:

- Recommended minimum credentials for behavioral health providers working with adults presenting with gender dysphoria (World Professional Association for Transgender Health [WPATH] Guidelines, version 7, 2012):
  - A minimum of a master's degree or its equivalent in a clinical behavioral science field. This degree should be granted by an institution accredited by the appropriate national or regional accrediting board. The behavioral health provider should have documented credentials from a relevant licensing board;
  - Competence in using the current version of the Diagnostic Statistical Manual of Mental Disorders (DSM) and/or the International Classification of Diseases (ICD) for assessment and diagnostic purposes;
  - Ability to recognize and diagnose coexisting mental health concerns and to distinguish these from gender dysphoria;

- Documented supervised training and competence in psychotherapy or counseling;
- Knowledgeable about gender nonconforming identities and expressions, and the evaluation and treatment of gender dysphoria;
- Continuing education in the assessment and treatment of gender dysphoria;
- Develop and maintain cultural competence to facilitate their work with transsexual, transgender, and gender nonconforming clients.

- Recommended minimum credentials for behavioral health providers working with children or adolescents presenting with gender dysphoria (WPATH Guidelines, version 7, 2012):
  - Meet the competency requirements for behavioral health providers working with adults, as outlined above;
  - Trained in childhood and adolescent developmental psychopathology;
  - Competent in diagnosing and treating the ordinary problems of children and adolescents.

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 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

CPT Code	Description
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
19303	Mastectomy, simple, complete
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19340	Insertion of breast implant on same day of mastectomy (i.e., immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
19350	Nipple/areola reconstruction
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)

CPT Code	Description
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
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

CPT Code	Description
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
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

CPT Code	Description
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

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). 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.

Benefit Considerations

Coverage Information

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.

This medical policy does not apply to fully-insured group plans in California. Refer to the Benefit Interpretation Policy titled Gender Dysphoria (Gender Identity Disorder) Treatment: CA

This Medical Policy does not apply to fully-insured group plans in the state of Washington. Refer to the Benefit Interpretation Policy titled Gender Dysphoria (Gender Identity Disorder) Treatment: WA.

Unless otherwise specified, if a plan covers treatment for Gender Dysphoria, coverage includes psychotherapy, gender-affirming hormone therapy, puberty suppressing medications, laboratory testing to monitor the safety of hormone therapy and surgical treatments listed in the Coverage Rationale section. Note: All plans may not cover all of the listed surgical treatments. Also, refer to the Drug Policy titled Gonadotropin Releasing Hormone Analogs.

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 (refer to the Reproduction exclusion in the member specific benefit plan document)
- Transportation, meals, lodging or similar expenses
- Cosmetic procedures (refer to the Medical Policy titled Cosmetic and Reconstructive Procedures and the Coverage Rationale section). See below for additional information on New York fully insured group policies.
- Reversal of genital surgery or reversal of surgery to revise secondary sex characteristics

Coverage does not apply to members who do not meet the indications listed in the Coverage Rationale section above.

For Fully Insured Group Policies in New York Only

Certain ancillary procedures may be considered cosmetic and not medically necessary when performed as part of surgical treatment for Gender Dysphoria. Clinical review for medical necessity of ancillary procedures is conducted on a case-by-case basis.

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 = 6489) 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.

Cohen et al. (2019) conducted a systematic review of surgical options and associated outcomes for transmasculine top surgery. Twenty-two studies were included (n = 2447). The authors reported that future research is needed to improve patient selection, surgical decision making, and patient-reported outcomes for different chest contouring techniques.

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 suggest 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.

A Hayes report on sex reassignment surgery (2018; updated 2021) 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.

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.

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 follow-up 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. Rectoneovaginal 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.

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).

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) rectoneovaginal 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 ±2.1 years. The mean operative duration was 210 ±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 ±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 ±1.5 cm.

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.

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.

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.

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 is currently reviewing their Standards of Care with an anticipated release date for their update of 2022.

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

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

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 July 12, 2022)

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Policy History/Revision Information

Date	Summary of Changes

04/01/2023	Title/Template Update
	• Updated template to specify this policy applies to UnitedHealthcare Commercial plans only (no change to coverage guidelines):
	  ○ Modified title
	  ○ Added *Application* section
	Supporting Information
	• Archived previous policy version 2022T0580M

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies 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.

EPSDT - A Guide for States:
Coverage in the Medicaid Benefit for Children and Adolescents

Early and Periodic Screening, Diagnostic and Treatment (EPSDT)

JUNE 2014

Available at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Early-and-Periodic-Screening-Diagnostic-and-Treatment.html

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I. INTRODUCTION

The Medicaid program's benefit for children and adolescents is known as Early and Periodic Screening, Diagnostic and Treatment services, or EPSDT. EPSDT provides a comprehensive array of prevention, diagnostic, and treatment services for low-income infants, children and adolescents under age 21, as specified in Section 1905(r) of the Social Security Act (the Act). The EPSDT benefit is more robust than the Medicaid benefit for adults and is designed to assure that children receive early detection and care, so that health problems are averted or diagnosed and treated as early as possible. The goal of EPSDT is to assure that individual children get the health care they need when they need it – the right care to the right child at the right time in the right setting.

EPSDT's goal is to assure that individual children get the health care they need when they need it – the right care to the right child at the right time in the right setting.

States share responsibility for implementing the benefit, along with the Centers for Medicare & Medicaid Services (CMS). States have an affirmative obligation to make sure that Medicaid-eligible children and their families are aware of EPSDT and have access to required screenings and necessary treatment services.[1] States also have broad flexibility to determine how to best ensure such services are provided. In general, they either administer the benefit outright (through fee for service arrangements) or provide oversight to private entities with whom they have contracted to administer the benefit (e.g., managed care entities). States must arrange (directly or through delegations or contracts) for children to receive the physical, mental, vision, hearing, and dental services they need to treat health problems and conditions. Through the EPSDT benefit, children's health problems should be addressed before they become advanced and treatment is more difficult and costly.

[1] CMS, State Medicaid Manual §§ 5010, 5121, 5310 (requiring states to "[a]ssure that health problems found are diagnosed and treated early, before they become more complex and their treatment more costly,. . . that informing methods are effective, . . . [and] that services covered under Medicaid are available.")

EPSDT entitles enrolled infants, children and adolescents to any treatment or procedure that fits within any of the categories of Medicaid-covered services listed in Section 1905(a) of the Act if that treatment or service is necessary to "correct or ameliorate" defects and physical and mental illnesses or conditions.[2] This includes physician, nurse practitioner and hospital services; physical, speech/language, and occupational therapies; home health services, including medical equipment, supplies, and appliances; treatment for mental health and substance use disorders; treatment for vision, hearing and dental diseases and disorders, and much more. This broad coverage requirement results in a comprehensive, high-quality health benefit for children under age 21 enrolled in Medicaid.

Children's health problems should be addressed before they become advanced and treatment is more difficult and costly.

States report annually to CMS certain data about their delivery of services under the EPSDT benefit.[3] The reporting is made on the CMS Form 416. CMS and states use this data to monitor EPSDT performance.

This guide is intended to help states, health care providers and others to understand the scope of services that are covered under EPSDT so that they may realize EPSDT's goals and provide the best possible child and adolescent health benefit through their Medicaid programs. While it does not establish new EPSDT policy, this guide serves the important purpose of compiling into a single document various EPSDT policy guidances that CMS has issued over the years.

This guide outlines:

- ✓ EPSDT's screening requirements, including when interperiodic screening should be provided;
- ✓ Scope of services covered under EPSDT;
- ✓ EPSDT's requirements governing dental, vision, and hearing services;
- ✓ Permissible limitations on service coverage under EPSDT;

[2] Section 1905(r)(5) of the Social Security Act.
[3] Sections 1902(a)(43)(D) and 2108(e) of the Social Security Act; CMS, State Medicaid Manual § 2700.4.

- ✓ States' responsibilities to assure access to EPSDT services and providers;
- ✓ Assistance to states as they work with managed care plans to provide the best child health benefit possible; and
- ✓ Notice and appeal procedures required when services are denied, reduced or terminated.

II. PERIODIC AND INTERPERIODIC SCREENINGS

EPSDT covers regular screening services (check-ups) for infants, children and adolescents. These screenings are designed to identify health and developmental issues as early as possible. States have the responsibility to ensure that all eligible children (and their families) are informed of both the availability of screening services, and that a formal request for an EPSDT screening service is not required. States must provide or arrange for screening services both at established times and on an as-needed basis. Covered screening services are medical, mental health, vision, hearing and dental. Medical screenings has five components:

- ✓ Comprehensive health and developmental history that assesses for both physical and mental health, as well as for substance use disorders;4
- ✓ Comprehensive, unclothed physical examination;
- ✓ Appropriate immunizations, in accordance with the schedule for pediatric vaccines established by the Advisory Committee on Immunization Practices;
- ✓ Laboratory testing (including blood lead screening appropriate for age and risk factors);5 and
- ✓ Health education and anticipatory guidance for both the child and caregiver.6

Under the Act, states must establish a periodicity schedule for each type of screening service: medical, vision, hearing, and dental. The periodicity schedules set the frequency by which certain services should be provided and will be covered.[7] The schedules are not prescribed by federal law, but should be based on current standards of pediatric medical and dental practice, and states are required to consult with recognized medical and dental organizations involved in child health care to assist in developing their periodicity schedules. One commonly used source is Bright Futures (developed by the American Academy of Pediatrics), which, for example, suggests that developmental screenings be conducted when children are ages 9 months, 18 months, and 30 months. The American Academy of Pediatric Dentistry (AAPD) has published a recommended periodicity schedule for dental services for children and adolescents. States should review their EPSDT periodicity schedules regularly to keep them up to date.

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[4] CMS issued an Informational Bulletin on March 27, 2013, discussing Prevention and Early Identification of Mental Health and Substance Use Conditions in Children and informing states about resources available to help them meet the needs of children under EPSDT.

[5] CMS issued guidance on June 22, 2012 to align blood lead screening for Medicaid children with recommendations of the Centers for Disease Control and Prevention (CDC). After providing data that demonstrates that universal screening is not the most effective approach to identifying childhood exposure to lead, a state may request to implement a targeted lead screening plan rather than continue universal screening of all Medicaid-eligible children ages 1 and 2.

[6] Section 1905(r)(1)(B) of the Social Security Act.

[7] 42 C.F.R. § 441.58; CMS, State Medicaid Manual §§ 5110, 5140.

States should review their EPSDT periodicity schedules regularly to keep them up to date.

EPSDT also requires coverage of medically necessary "interperiodic" screening outside of the state's periodicity schedule. Coverage for such screenings is required based on an indication of a medical need to diagnose an illness or condition that was not present at the regularly scheduled screening or to determine if there has been a change in a previously diagnosed illness or condition that requires additional services. The determination of whether a screening service outside of the periodicity schedule is necessary may be made by the child's physician or dentist, or by a health, developmental, or educational professional who comes into contact with a child outside of the formal health care system. This includes, for example, personnel working for state early intervention or special education programs, Head Start, and the Special Supplemental Nutrition Program for Women, Infants, and Children. A state may not limit the number of medically necessary screenings a child receives and may not require prior authorization for either periodic or "interperiodic" screenings.

Example of Screenings Beyond Those Required by the Periodicity Schedule

A child receives a regularly scheduled periodic vision screening at age 5 at which no problem is detected. According to the state's periodicity schedule, his next vision screening is due at age 7. At age 6, the school nurse recommends to the child's parent that the child see an optometrist because a teacher suspects a vision problem. Even though the next scheduled vision screening is not due until the age of 7, the child would be entitled to receive a timely "interperiodic" screening to determine if there is a vision problem for which treatment is needed. The screening should not be delayed if there is a concern the child may have a vision problem.

Source: NPRM, 58 Fed. Reg. 51288, 51290, 51291 (Oct. 1, 1993)

Screening services provide the crucial link to necessary covered treatment, as EPSDT requires states to "arrang[e] for . . . corrective treatment," either directly or through referral to appropriate providers or licensed practitioners, for any illness or condition detected by a screening.[8] The affirmative obligation to connect children with necessary treatment makes EPSDT different from Medicaid for adults.[9] It is a crucial component of a quality child health benefit.

[8] Section 1902(a)(43)(C) of the Social Security Act.
[9] CMS, State Medicaid Manual § 5124.B.

The affirmative obligation to connect children with necessary treatment makes EPSDT different from Medicaid for adults.

Any qualified provider operating within the scope of his or her practice, as defined by state law, can provide a screening service. The screening *need not be* conducted by a Medicaid provider in order to trigger EPSDT coverage for follow up diagnostic services and medically necessary treatment by a qualified Medicaid provider. A screening service provided before a child enrolls in Medicaid is sufficient to trigger EPSDT coverage, after enrollment, for follow-up diagnostic services and necessary treatment. The family or beneficiary need not formally request an EPSDT screening in order to receive the benefits of EPSDT. Rather, any visit or contact with a qualified medical professional is sufficient to satisfy EPSDT's screening requirement, and states should consider a beneficiary who is receiving services to be participating in EPSDT, whether the beneficiary requested screening services directly from the state or the health care provider.[10]

Any qualified provider operating within the scope of his or her practice, as defined by state law, can provide a screening service.

States establish their own fee schedules for screening services and should be using Health Insurance Portability and Accountability Act (HIPAA) compliant billing codes. States may develop a bundled payment rate to pay for the physical health screening components under one billing code. States may also recognize each component of the EPSDT screening separately. For example, one state pays for the visit itself with one code and pays separately for each individual screening service delivered during the visit. This payment methodology not only encourages providers to perform every component of an EPSDT well-child visit, it also provides the state, through claims, information as to whether the physician actually met the elements of the EPSDT guidelines set out in the periodicity

[10] CMS, State Medicaid Manual § 5310; HCFA, Title XIX State Agency Letter No. 91-33 (April 3, 1991).

schedules. States may encourage providers to perform all five components of the EPSDT screening but may not exclude providers who perform only partial screenings from being reimbursed for the parts they do provide.

Professional guidelines (e.g., Bright Futures) recommend that physicians include an oral health screening as part of the well-child visit at specified ages. In addition, states are permitted to include dental or oral health screening as a separately covered EPSDT service. These screening services, which may be performed by dental professionals or by medical professionals according to state scope of practice rules, can take place in community or group settings as well as in clinics or medical and dental offices. Such screenings can be helpful in identifying children with unmet dental care needs so they can be referred to a dental professional for treatment. Two new procedure codes were added to the Code on Dental Procedures and Nomenclature (CDT) in 2012 to facilitate payment for oral health screenings and assessments: CDT 0190 and CDT 0191.

In 2012, two new procedure codes were added to facilitate payment for oral health screenings and assessments: CDT 0190 and 0191.

Vision and hearing screening services must also be provided. States should consult with ophthalmologists and optometrists to determine what procedures should be used during a vision screening and to establish the criteria for referral for a diagnostic examination. For hearing screenings, appropriate procedures for screening and methods of administering them can be obtained from audiologists or from state health or education departments.[11]

[11] CMS, State Medicaid Manual § 5123.2.F.

III. DIAGNOSTIC SERVICES

EPSDT covers medically necessary diagnostic services. When a screening examination indicates the need for further evaluation of a child's health, the child should be appropriately referred for diagnosis without delay.

A child's diagnosis may be performed by a physician, dentist or other practitioner qualified to evaluate and diagnose health problems at locations, including practitioners' offices, maternal and child health (MCH) facilities, community health centers, rehabilitation centers, and hospital outpatient departments. Diagnosis can generally be made on an outpatient basis. However, inpatient services are covered when necessary to complete a diagnosis.

When a screening examination indicates the need for further evaluation of a child's health, the child should be referred for diagnosis without delay.

IV. THE SCOPE OF EPSDT TREATMENT SERVICES

A. Scope of Services

The Act provides for coverage of all medically necessary services that are included within the categories of mandatory and optional services listed in section 1905(a), regardless of whether such services are covered under the State Plan. These include physician and hospital services, private duty nursing, personal care services, home health and medical equipment and supplies, rehabilitative services, and vision, hearing, and dental services. Covered EPSDT services also include "any other medical care, and any other type of remedial care recognized under State law, specified by the Secretary."[12] The role of states is to make sure the full range of EPSDT services is available as well as to assure that families of enrolled children are aware of and have access to those services so as to meet the individual child's needs. The broad scope of services enables states to design a child health benefit to meet the individual needs of the children served by its Medicaid program—a benefit design that has the potential to result in better care and healthier children at a lower overall cost. As discussed in the next section: while children enrolled in Medicaid are entitled to a broad scope of treatment services, no such service is covered under Medicaid unless medically necessary for that particular child.

The Act provides for coverage of all medically necessary services that are included within the categories of mandatory and optional services listed in section 1905(a), regardless of whether such services are covered under the State Plan.

[12] Section 1905(a)(29) of the Social Security Act.

If a service, supply or equipment that has been determined to be medically necessary for a child is not listed as covered (for adults) in a State Medicaid Plan, the state will nonetheless need to provide it to the child as long as the service or supply could be covered under the State Plan, that is, as long as it is included within the categories of mandatory and optional services listed in section 1905(a). In such circumstances, the state would need to develop a payment methodology for the service, supply or equipment, including the possibility that payment may need to be made using a single-service agreement with an in-state provider or an out-of-state provider who will accept Medicaid payment.

A service need not cure a condition in order to be covered under EPSDT. Services that maintain or improve the child's current health condition are also covered in EPSDT because they "ameliorate" a condition. Maintenance services are defined as services that sustain or support rather than those that cure or improve health problems. Services are covered when they prevent a condition from worsening or prevent development of additional health problems. The common definition of "ameliorate" is to "make more tolerable." Thus, services such as physical and occupational therapy are covered when they have an ameliorative, maintenance purpose. This is particularly important for children with disabilities, because such services can prevent conditions from worsening, reduce pain, and avert the development of more costly illnesses and conditions. Other, less common examples include items of durable medical equipment, such as decubitus cushions, bed rails and augmentative communication devices. Such services are a crucial component of a good, comprehensive child-focused health benefit.

B. Covering a Range of Treatment Services to Meet a Child's Needs

As noted above, EPSDT covers physical and mental health and substance use disorder services, regardless of whether these services are provided under the State Plan and regardless of any restrictions that states may impose on coverage for adult services, as long as those services *could* be covered under the State Plan. This section provides some examples of EPSDT's broad scope of services, focusing on mental health and substance use services, personal care services, oral health and dental services, and vision and hearing services.

a. Mental Health and Substance Use Services

Treatment for mental health and substance use issues and conditions is available under a number of Medicaid service categories, including hospital and clinic services, physician services, and services provided by a licensed professional such as a psychologist. States should also make use of rehabilitative services. While rehabilitative services can meet a range of children's treatment needs, they

can be particularly critical for children with mental health and substance use issues. Rehabilitative services are defined to include:

> *any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts within the scope of their practice under State law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level.*[13]

Like other services covered under EPSDT, rehabilitative services need not actually cure a disability or completely restore an individual to a previous functional level. Rather, such services are covered when they ameliorate a physical or mental disability, as discussed above. Moreover, determinations of whether a service is rehabilitative must take into consideration that a child may not have attained the ability to perform certain functions. That is, a child's rehabilitative services plan of care should reflect goals appropriate for the child's developmental stage.

Rehabilitative services are particularly critical for children with mental health and substance use issues.

Depending on the interventions that the individual child needs, services that can be covered as rehabilitative services include:

- ✓ Community-based crisis services, such as mobile crisis teams, and intensive outpatient services;
- ✓ Individualized mental health and substance use treatment services, including in non-traditional settings such as a school, a workplace or at home;
- ✓ Medication management;
- ✓ Counseling and therapy, including to eliminate psychological barriers that would impede development of community living skills; and
- ✓ Rehabilitative equipment, for instance daily living aids.

With respect to the provision of rehabilitative services, including those noted above, CMS requires more specificity of providers and services due to the wide spectrum of rehabilitative services coverable under the broad definition. CMS

[13] Section 1905(a)(13) of the Social Security Act; 42 C.F.R. § 440.130(d).

would expect a state to include in their State Plan the services, and providers with their qualifications, as well as a reimbursement methodology for each service it provides. CMS is available to provide technical assistance to states that are covering a service for children that has not otherwise been identified in their State Plan.

A number of home and community-based services, including those that can be provided through EPSDT, have proven to significantly enhance positive outcomes for children and youth. These include intensive care coordination ("wraparound"), intensive in-home services, and mobile crisis response and stabilization.

CMS has issued detailed guidance encouraging states to include screening, assessments, and treatments focusing on children who have been victims of complex trauma. EPSDT can be a crucial tool in addressing the profound needs of this population, including children who are involved in the child welfare system.

b. Personal Care Services

EPSDT requires coverage of medically necessary personal care services, which:

> *are furnished to an individual who is not an inpatient or resident of a hospital, nursing facility, intermediate care facility . . . or institution for mental disease, that are (A) authorized for the individual by a physician in accordance with a plan of treatment or (at the option of the State), otherwise authorized for the individual in accordance with a service plan approved by the State; (B) provided by an individual who is qualified to provide such services and is not a member of the individual's family; and (C) furnished in a home or . . . in other location.*[14]

Personal care services provide a range of assistance with performing activities of daily living, such as dressing, eating, bathing, transferring, and toileting; and instrumental activities of daily living, such as preparing meals and managing medications.[15] While it is optional for states to provide personal care services for adults in locations other than the home, this is not the case for a child. Under EPSDT, personal care services are to be provided, for example, in a school or group home if necessary to "correct or ameliorate" a condition.

The determination of whether a child needs personal care services must be based upon the child's individual needs and provided in accordance with a plan of treatment or service plan. Under regular State Plan Medicaid, no Medicaid payments are available for personal care services provided by the child's legally

[14] Section 1905(a)(24) of the Social Security Act; 42 C.F.R. § 440.167.
[15] CMS, State Medicaid Manual § 4480.

responsible relatives.[16] In addition, the determination of whether a child needs personal care services must be based upon the child's individual needs and a consideration of family resources that are actually—not hypothetically—available.

c. Oral Health and Dental Services

Dental services required in the EPSDT benefit include:[17]

- ✓ Dental care needed for relief of pain, infection, restoration of teeth, and maintenance of dental health (provided at as early an age as necessary); and
- ✓ Emergency, preventive, and therapeutic services for dental disease that, if left untreated, may become acute dental problems or cause irreversible damage to the teeth or supporting structures.18

In addition, medically necessary oral health and dental services,[19] including those identified during an oral screening or a dental exam, are covered for children. States must provide orthodontic services to EPSDT-eligible children to the extent necessary to prevent disease and promote oral health, and restore oral structures to health and function.[20] Orthodontic services for cosmetic purposes are not covered.

Once a child reaches the age specified by the state in its pediatric dental periodicity schedule, typically age one, a direct dental referral is required.[21] The referral must be for an encounter with a dentist or with another dental professional, such as a dental hygienist, working under the supervision of a dentist.[22] Dental supervision includes the entire range, for example, direct, indirect, general, public health and collaborative practice arrangements.

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[16] 42 C.F.R. § 440.167.

[17] Information on CMS efforts working with states to improve access to oral health services for children enrolled in Medicaid and CHIP can be found in CMS, *Improving Access to and Utilization of Oral Health Services for Children in Medicaid and CHIP Programs: CMS Oral Health Strategy* (April 11, 2011). Approaches states can use to improve the delivery of dental and oral health services to children in Medicaid and CHIP can be found in *Keep Kids Smiling: Promoting Oral Health Through the Medicaid Benefit for Children and Adolescents* and in *Improving Oral Health Care Delivery in Medicaid and CHIP: A Toolkit for States*. All of these documents are available at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Dental-Care.html.

[18] CMS, State Medicaid Manual § 5124.B.2.b.

[19] CMS, State Medicaid Manual § 2700.4 (Form 416 Instructions, Note for Line 12 Data). Dental services are those performed by or under the supervision of a dentist. Oral health services are those performed by other licensed providers not working under the supervision of a dentist, for example, a physician or nurse, or by a dental professional operating without a supervisory relationship to a dentist (e.g., an independent practice dental hygienist).

[20] CMS, State Medicaid Manual § 5124.B.2.b

[21] 42 C.F.R. § 441.56(b)(vi).

[22] CMS, State Medicaid Manual § 5123.2.G.

Current clinical guidelines recommend that a child have a first dental visit when the first tooth erupts or by age one.

Dental care must be provided at intervals indicated in the pediatric dental periodicity schedule adopted by the state after consultation with a recognized dental organization involved in child health care.[23] Current clinical guidelines recommend that a child have a first dental visit when the first tooth erupts or by age one, whichever occurs first. Dental care that is deemed medically necessary for an individual child is covered even when the frequency is greater than specified in the periodicity schedule.[24] For example, a child determined by a qualified provider to be at moderate or high risk for developing early childhood caries could be covered to receive dental exams and preventive treatments more frequently than the twice-yearly periodicity schedule recommended by the AAPD.

As determined by dental practice acts in individual states, there is a wide range of dental professionals who can work under the supervision of a dentist, for example, dental hygienists, dental therapists, dental health aide therapists, dental hygienists in advanced practice, advanced practice dental therapists, dental assistants, and community dental health coordinators. Some state practice acts permit specified dental professionals to work without dentist supervision in certain circumstances. Such provisions can help ensure access to dental care as well as promote an integrated health care delivery system. As with medical care, any qualified provider operating within the scope of his or her practice, as defined by state law, can provide a dental or oral health service to a Medicaid enrollee. To qualify for federal matching funds, State Plans must list all provider types that will be permitted to bill for dental or oral health services. However, rendering providers (providers who actually serve the patient) need not be separately enumerated in the State Plan.

Better integration of primary medical care with dental care can help identify children at risk for tooth decay at the youngest age possible, offer evidence-based preventive care, such as fluoride varnish and oral health education, and refer children to a dental professional for a complete check-up and any needed treatment. Three oral health risk assessment CDT billing codes can support this

[23] Section 1905(r)(3) of the Social Security Act; CMS, State Medicaid Manual § 5110.
[24] CMS, State Medicaid Manual § 5110.

approach, potentially preventing the need for costly treatment, such as that provided in an operating room.

State Medicaid and CHIP programs can use risk assessment codes to help children access services based on their individual levels of risk, instead of assuming that all children need the same level of intervention. AAPD guidelines encourage providers to customize care plans based on an assessment of each child's individual risk for developing dental disease. Risk assessment resources are available for providers, including an assessment tool from AAPD that includes a caries-risk assessment form, clinical guidelines and treatment protocols.

In addition to dental providers, states may reimburse primary care medical providers for conducting oral health risk assessments, providing oral health education to parents and children, applying preventive measures such as fluoride varnish, and making referrals to dental professionals. The CMCS oral health strategy guide, *Keep Kids Smiling: Promoting Oral Health Through the Medicaid Benefit for Children & Adolescents,* provides additional information on oral health and EPSDT.

d. Vision and Hearing Services

Vision and hearing services are an essential component of the EPSDT benefit. Hearing impairments can lead to other problems, including interference with normal language development in young children. They can also delay a child's social, emotional, and academic development. Vision problems can be evidence of serious, degenerative conditions, and can also lead to delays in learning and social development.

EPSDT requires that vision and hearing services be provided at intervals that meet reasonable standards as determined in consultation with medical experts, and at other intervals, as medically necessary, to determine the existence of a suspected illness or condition. At a minimum, vision services must include diagnosis and treatment for defects in vision, including eyeglasses. Glasses to replace those that are lost, broken, or stolen also must be covered. Hearing services must include, at a minimum, diagnosis and treatment for defects in hearing, including hearing aids.[25]

In addition, if hearing and vision problems are detected through screening, medically necessary services that are coverable under section 1905(a) must be covered. This includes not only physician and clinic services, but services from licensed professionals such as ophthalmologists, and equipment such as augmentative communication devices and cochlear implants.

[25] Sections 1905(r)(2) and (4) of the Social Security Act.

e. *Other Services*

Examples of other services covered for children under Medicaid when medically necessary (and for which a federal match is available) include, but are not limited to, case management services (including targeted case management);[26] incontinence supplies; organ transplants and any related services; a specially adapted car seat that is needed by a child because of a medical problem or condition; and nutritional supplements.

Physicians and other providers use medical terminology, not Medicaid terms or legal terms, when recommending or prescribing medical services and treatments. If a requested service or treatment is not listed by name in Medicaid's list of services, it should nonetheless be provided if the service or item is determined to be medically necessary and coverable under the list of services at section 1905(a). In general, states are encouraged to include in their State Plans a range of provider types and settings likely to be sufficient to meet the needs of enrollees. Nonetheless, there may be cases in which the type of provider that is needed is not already participating in Medicaid. In such an instance, the state could meet the EPSDT requirement by, for example, entering into a single-service agreement with the needed provider.

When providers use medical terminology instead of Medicaid or legal terms to recommend medically necessary services, the recommended services should be covered if coverable under section 1905(a).

C. Enabling Services

a. *Transportation Services*

In order to promote access to needed preventive, diagnostic and treatment services, states must offer appointment scheduling assistance and are required to assure necessary transportation, to and from medical appointments, for children

[26] Section 1905(a)(19) of the Social Security Act; 42 C.F.R. §§ 440.169, 441.18.

enrolled in Medicaid.[27] This includes covering the costs of an ambulance, taxi, bus, or other carrier. It can also include reimbursing for mileage. As with other services covered through EPSDT, states may cover the least expensive means of transportation if it is actually available, accessible, and appropriate. For example, public transportation can be covered instead of a taxi if the public transportation is physically accessible for a particular beneficiary and takes a reasonable amount of time. In addition, "related travel expenses" are covered if medically necessary, including meals and lodging for a child and necessary attendant.[28]

Some states have addressed the transportation requirement by offering non-emergency transportation through brokers who coordinate transportation services, or through administrative managers who act as gatekeepers for transportation services. Transportation may also be included in managed care contracts. If a state chooses not to include transportation services in their managed care contracts, or otherwise to contract out administration of the service, the state must administer the service itself. No matter the type of arrangement, it is important to remember that the state has ultimate responsibility for ensuring the provision of transportation services.

b. Language Access and Culturally Appropriate Services

Many Medicaid-enrolled children live in families where English is not spoken at home. State Medicaid agencies and their contractors should inform eligible individuals about the EPSDT benefit with a combination of written and oral methods "using clear and nontechnical language" and "effectively informing those individuals who . . . cannot read or understand the English language."[29] State Medicaid agencies and Medicaid managed care plans, as recipients of federal funds, also have responsibilities to assure that covered services are delivered to children without a language barrier. They are required take "reasonable steps" to assure that individuals who are limited English proficient have meaningful access to Medicaid services.[30] This may include providing interpreter services, including at medical appointments, depending on factors such as the number of limited English proficient individuals served by the program.[31]

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[27] Section 1905(a)(29) of the Social Security Act; 42 C.F.R. §§ 440.170, 441.62.
[28] 42 C.F.R. § 440.170(a).
[29] 42 C.F.R. § 441.56(a); CMS, State Medicaid Manual §§ 5121.A, 5121.C.
[30] 42 U.S.C. § 2000d (Title VI of the Civil Rights Act); Affordable Care Act § 1557; CMS Dear State Medicaid Director (Aug. 31, 2000).
[31] Department of Health & Human Services, Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 Fed. Reg. 47311 (August 8, 2003).

Though interpreter services are not classified as mandatory 1905(a) services, all providers who receive federal funds from HHS for the provision of Medicaid services are obligated, under Title VI of the Civil Rights Act, to make language services available to those with limited English proficiency.

Though interpreters are not Medicaid qualified providers, their services may be reimbursed when billed by a qualified provider rendering a Medicaid covered service.

States are not required to (but may) reimburse providers for the cost of language services. States may consider the cost of language services to be included in the regular rate of reimbursement for the underlying direct service. In those cases, Medicaid providers are obligated to provide language services to those with limited English proficiency and to bear the costs for doing so. Alternatively, states may allow providers to bill specifically for interpreter services. States have the option to claim for the cost of interpretation services, either as medical-assistance related expenditures or as administration.[32]

Claiming Federal Matching Funds for Interpreter Services. Interpreters are not Medicaid qualified providers. However, their services may be reimbursed when billed by a qualified provider rendering a Medicaid covered service. Interpreters may not be paid separately. As of February 2009, oral interpreter services can be claimed using billing code T-1013 along with the CPT code used for the medical encounter. States can also raise reimbursement rates to recognize additional service costs, including interpreter costs, but must do so for services rendered by all providers in the class. With the enactment of the Children's Health Insurance Program Reauthorization Act in 2009, states were given the option to claim a higher federal matching rate (75% under Medicaid) for translation and interpretation services that are claimed as administration and are related to the enrollment, retention and use of services under Medicaid and CHIP by children of families for whom English is not their primary language.[33] Otherwise, longstanding CMS policy permits reimbursement at the standard 50% federal

[32] CMS, Dear State Medicaid Director (July 1, 2010); CMS, CMCS Informational Bulletin: *Recent Developments in Medicaid* (April 26, 2011).
[33] Section 1903(a)(2)(E) of the Social Security Act.

matching rate for translation and interpretation activities that are claimed as an administrative expense, so long as they are not included and paid for as part of the reimbursement rate for direct services.[34]

State Medicaid programs, managed care entities, and Medicaid-participating health care providers should all be culturally competent.

The HHS Office for Civil Rights and the Department of Justice have provided guidance for recipients of federal funds on expectations of how to provide language services.[35]

State Medicaid programs, managed care entities, and Medicaid-participating health care providers should all be culturally competent. This means they need to recognize and understand the cultural beliefs and health practices of the families and children they serve, and use that knowledge to implement policies and inform practices that support quality interventions and good health outcomes for children. Given changing demographics, this process is ongoing. The DHHS Office of Minority Health offers numerous resources, including:

- ✓ Center for Linguistic and Cultural Competence in Health Care;
- ✓ Think Cultural Health;
- ✓ A Physician's Practical Guide to Culturally Competent Care;
- ✓ The National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards); and
- ✓ The National CLAS Standards' implementation guide, A Blueprint for Advancing and Sustaining CLAS Policy and Practice.

D. Settings and Locations for Services

a. Services Provided Out of State

States may need to rely upon out-of-state services if necessary covered services are not available locally, or if a Medicaid beneficiary is out of state at the time a need for medical services arises. States are required to pay for services provided

[34] CMS, Dear State Medicaid Director (August 31, 2000).
[35] *Id*; U.S. Department of Justice, Executive Order 13166.

in another state to the same extent services furnished in-state would be paid for if:

- ✓ The out-of-state services are required because of an emergency;
- ✓ The child's health would be endangered if she or he were required to travel to their home state;
- ✓ The state determines that the needed services are more readily available in the other state; or
- ✓ It is a general practice of the locality to use the services of an out-of-state provider, for example, in areas that border another state.[36]

Including out-of-state providers gives states the opportunity to expand the range and accessibility of Medicaid services that are available to their enrollees.[37]

b. Services Provided in Schools

Services provided in schools can play an important role in the health care of adolescents and children. Whether implemented for children with special needs under the Individuals with Disabilities Education Act (IDEA) or through school-based or linked health clinics, school-centered programs may be able to provide medical and dental care efficiently and effectively while avoiding extended absences from school.

In order for Medicaid to reimburse for health services provided in the schools, the services must be included among those listed in section 1905(a) of the Act and included in the State Plan, or be available under the EPSDT benefit. There is no benefit category in the Medicaid statute titled "school health services" or "early intervention services." Therefore a state must describe its school health services in terms of the specific section 1905(a) services which will be provided. In addition, there must be a provider agreement in place between the state Medicaid agency and the provider billing for the service; and the school must agree to comply with Medicaid-specific requirements regarding service documentation and claims submission.[38] States are encouraged to promote relationships between school-based providers and managed care plans.

Services provided in schools can play an important role in the health care of adolescents and children.

[36] Section 1902(a)(16) of the Social Security Act; 42 C.F.R. § 431.52.
[37] HCFA, Dear State Medicaid Director (July 25, 2000).
[38] 42 C.F.R. § 431.107.

Schools are particularly appropriate places to provide medical, vision, and hearing screenings; vaccinations; some dental care; and behavioral health services. The Individuals with Disabilities Education Act (IDEA) requires that every child with a disability have available a free appropriate public education that includes special education and related services. Part B of IDEA requires the development and implementation of an individualized education program (IEP) that addresses the unique needs of each child with a disability ages 3 through 21.[39] A child's IEP identifies the special education and related services needed by that child. Medicaid covered services included in the IEP may be provided in, and reimbursed to, schools. Part C of IDEA covers early intervention services, which are developmental services designed to meet a child's developmental needs in physical, cognitive, communication, adaptive, and social and emotional development, for children from birth to age 3. These services are provided pursuant to an Individualized Family Service Plan (IFSP).

Examples of IDEA services that can be covered by Medicaid for a Medicaid eligible child include physical therapy, occupational therapy, personal care, and services for children with speech, hearing and language disorders.[40]

c. *Most Integrated Setting Appropriate*

Title II of the Americans with Disabilities Act (ADA) prohibits discrimination on the basis of disability in public programs, including Medicaid. In *Olmstead v. L.C.,* the Supreme Court held that unjustified institutionalization of Medicaid beneficiaries violates the ADA. Accordingly, states must cover services in the community, rather than in an institution, when the need for community services can be reasonably accommodated and providing services in the community will not fundamentally alter the state's Medicaid program.

Community-based care is a best practice for supporting children with disabilities and chronic conditions.

CMS has long encouraged states to provide services in home and community settings, particularly for children, not only because of *Olmstead,* but because community-based care is considered a best practice for supporting children with

[39] While EPSDT covers children only through age 20 (up to the 21st birthday), the IDEA covers children through age 21 (up to the 22nd birthday).
[40] Additional information about Medicaid-covered services provided in schools can be found in the CMS, *Medicaid School Based Administrative Claiming Guide* (2003).

disabilities and chronic conditions. In addition, it is generally more cost-effective.[41]

EPSDT provides states with many options for covering physical and mental health services in the community. The EPSDT benefit requires coverage of medically necessary personal care, private duty nursing, physical, occupational and speech-language therapy. And, as discussed below, optional services provided through home and community based services waivers can further advance the state's efforts to provide services in the community.

[41] HCFA, Dear State Medicaid Director, Olmstead Update Nos. 2 and 3 (July 25, 2000), No. 5 (January 10, 2001); CMS, Dear State Medicaid Director (May 20, 2010); CMS, Joint CMCS and SAMHSA Informational Bulletin: *Coverage of Behavioral Health Services for Children, Youth, and Young Adults with Significant Mental Health Conditions* (May 7, 2013).

V. PERMISSIBLE LIMITATIONS ON COVERAGE OF EPSDT SERVICES

A. Individual Medical Necessity

Services that fit within the scope of coverage under EPSDT must be provided to a child only if necessary to correct or ameliorate the individual child's physical or mental condition, i.e., only if "medically necessary." The determination of whether a service is medically necessary for an individual child must be made on a case-by-case basis, taking into account the particular needs of the child. The state (or the managed care entity as delegated by the state) should consider the child's long-term needs, not just what is required to address the immediate situation. The state should also consider all aspects of a child's needs, including nutritional, social development, and mental health and substance use disorders. States are permitted (but not required) to set parameters that apply to the determination of medical necessity in individual cases, but those parameters may not contradict or be more restrictive than the federal statutory requirement. As discussed above, services such as physical and occupational therapy are covered when they have an ameliorative, maintenance purpose.

Determination of whether a service is medically necessary must be made on a case-by-case basis, taking into account a particular child's needs.

Because medical necessity decisions are individualized, flat limits or hard limits based on a monetary cap or budgetary constraints are not consistent with EPSDT requirements.[42] States may adopt a definition of medical necessity that places tentative limits on services pending an individualized determination by the state, or that limits a treating provider's discretion, as a utilization control, but additional services must be provided if determined to be medically necessary for

[42] HCFA, *Regional Transmittal Notice* (Region IV) (Sept. 18, 1990); Memorandum from Rozann Abato, Acting Director, HCFA, to Associate Regional Administrator, Atlanta (Sept. 5, 1990); Memorandum from Christine Nye, HCFA Medicaid Director, to Regional Administrator Region VIII (FME-42) (1991).

an individual child.[43] For example, while a state may place in its State Plan a limit of a certain number of physical therapy visits per year for individuals age 21 and older, such a "hard" limit could not be applied to children. A state could impose a "soft" limit of a certain number of physical therapy visits annually for children, but if it were to be determined in an individual child's case, upon review, that additional physical therapy services were medically necessary to correct or ameliorate a diagnosed condition, those services would have to be covered.

While the treating health care provider has a responsibility for determining or recommending that a particular covered service is needed to correct or ameliorate the child's condition,[44] both the state and a child's treating provider play a role in determining whether a service is medically necessary. If there is a disagreement between the treating provider and the state's expert as to whether a service is medically necessary for a particular child, the state is responsible for making a decision, for the individual child, based on the evidence. That decision may be appealed by the child (or the child's family) under the state's Medicaid fair hearing procedures, as described in Section VIII below.

B. Prior Authorization

States may impose utilization controls to safeguard against unnecessary use of care and services. For example, a state may establish tentative limits on the amount of a treatment service a child can receive and require prior authorization for coverage of medically necessary services above those limits.[45] Prior authorization must be conducted on a case-by-case basis, evaluating each child's needs individually. Importantly, prior authorization procedures may not delay delivery of needed treatment services and must be consistent with the "preventive thrust" of EPSDT.[46] As such, prior authorization may not be required for any EPSDT screening services. In addition, medical management techniques used for mental health and substance use disorders should comply with the Mental Health Parity and Addiction Equity Act.

C. Experimental Treatments

EPSDT does not require coverage of treatments, services, or items that are experimental or investigational. Such services and items may, however, be covered at the state's discretion if it is determined that the treatment or item would be effective to address the child's condition.[47] Neither the Federal Medicaid statute nor the regulations define what constitutes an experimental

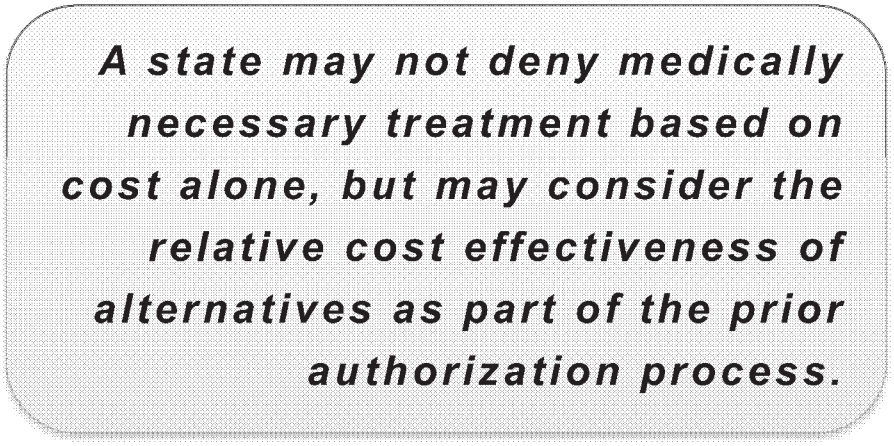
[43] 42 C.F.R. §§ 440.230(c), (d); HCFA Dear State Medicaid Director (May 26, 1993).
[44] Sections 1905(a) and (r) of the Social Security Act.
[45] *Id.*
[46] H.R. Rep. No. 101-247 at 399, *reprinted in* U.S.C.C.A.N. 1906, 2125.
[47] CMS, State Medicaid Manual §§ 4385.C.1, 5122.F.

treatment. The state's determination of whether a service is experimental must be reasonable and should be based on the latest scientific information available.[48]

Medicare guidance on whether a service is experimental or investigational is not determinative of the issue and may not be relevant to the pediatric population.[49]

D. Cost-Effective Alternatives

A state may not deny medically necessary treatment to a child based on cost alone, but may consider the relative cost effectiveness of alternatives as part of the prior authorization process. Also, a state need not make services available in every possible setting as long as the services are reasonably available through the settings where the service is actually offered. States may cover services in the most cost effective mode as long as the less expensive service is equally effective and actually available.[50] The child's quality of life must also be considered.[51] In addition, the ADA and the *Olmstead* decision require states to provide services in the most integrated setting appropriate to a child's needs, as long as doing so does not fundamentally alter the state's program. See above, Section IV.D. Thus, if an institutional setting is less costly than providing services in a home or community, the ADA's integration mandate may nevertheless require that the services be provided in the community.[52]



[48] Memorandum from S. Richardson to State Medicaid Directors (April 17, 1995).
[49] Memorandum from S. Richardson to State Medicaid Directors (April 17, 1995).
[50] CMS, Dear State Medicaid Director, Olmstead Update No. 4 (January 10, 2001); Letter from Rozann Abato, Acting Director, Medicaid Bureau, to State Medicaid Directors (May 26, 1993).
[51] *Id.*
[52] 28 C.F.R. § 35.130(d); CMS, Dear State Medicaid Director, Olmstead Update No. 4 (January 10, 2001); DOJ, Statement of the Department of Justice on Enforcement of the Integration Mandate of Title II of the ADA and *Olmstead v. L.C.* (June 22, 2011).

VI. SERVICES AVAILABLE UNDER OTHER FEDERAL AUTHORITIES

A. Home and Community Based Services Waivers

A state Medicaid program may offer services through home and community based services (HCBS) waiver programs. Such programs allow states to provide HCBS to individuals who would otherwise need long-term care in a nursing facility, intermediate care facility, or hospital. Waiver programs provide for coverage of services that are not otherwise available through the Medicaid program (including EPSDT) because they do not fit into one of the categories listed in section 1905(a). This includes habilitative services, respite services, or other services approved by CMS that can help prevent institutionalization. These programs are sometimes called 1915(c) waivers after the section of the Social Security Act that authorizes them.[53]

Children under age 21 who are enrolled in an HCBS waiver program are also entitled to all EPSDT screening, diagnostic, and treatment services. Because HCBS waivers can provide services not otherwise covered under Medicaid, waivers and EPSDT can be used together to provide a comprehensive benefit for children with disabilities who would otherwise need the level of care provided in an institutional setting. This enables those children to remain in their homes and communities while receiving medically necessary services and supports. The HCBS waiver services essentially "wrap-around" the EPSDT benefit. If a child enrolled in Medicaid is on a waiting list for HCBS waiver services, EPSDT requirements apply and necessary services that fit into the categories listed in 1905(a) must be covered.[54]

Children who are enrolled in an HCBS waiver program are also entitled to all EPSDT services.

States may also choose to offer services to children under section 1915(j) (self-directed personal assistance services), section 1915(k) (home and community-based attendant services and support) and section 1945 (coordinated care in

[53] Section 1915(c) of the Social Security Act.
[54] CMS, Dear State Medicaid Director, Olmstead Update No. 4, Att. 4-B (Jan. 10, 2001).

health homes for individuals with chronic conditions). Like services provided pursuant to a 1915(c) waiver, these services are not subject to EPSDT coverage provisions, but are instead available to supplement EPSDT services.

B. Alternative Benefit Plans

States must assure access to services available under the EPSDT benefit for all EPSDT-eligible children under age 21 enrolled in Alternative Benefit Plans (formerly known as benchmark plans and benchmark-equivalent plans).[55]

C. Role of Maternal and Child Health Services

Federal rules require state Medicaid agencies and Title V Maternal and Child Health (MCH) agencies and grantees to collaborate to assure better access to and receipt of the full range of screening, diagnostic, and treatment services covered under EPSDT.[56] Title V is administered by the Health Resources and Services Administration. Many state Medicaid agencies have entered into written agreements with their sister MCH programs and collaborate on improving access to EPSDT services in order to improve child health status. Among other things, cooperating MCH agencies can provide outreach, screening, diagnostic or treatment services, health education and counseling, case management and other assistance in achieving a comprehensive and effective child health benefit. MCH programs can also help Medicaid programs to enlist providers who can help deliver a broad array of services. In addition, they can inform potential and actual Medicaid recipients about EPSDT and refer them to necessary services.[57] CMS encourages such collaborations as MCH programs are crucial partners in the creation and delivery of a high quality, well-integrated child health benefit.

Many state Medicaid agencies have written agreements with their states' MCH programs and collaborate to improve access to EPSDT services.

[55] 42 C.F.R. § 440.345.
[56] 42 U.S.C. §§ 705(a)(5)(F), 709(a)(2); 42 C.F.R. § 441.61(c).
[57] CMS, State Medicaid Manual § 5230.

VII. ACCESS TO SERVICES

A. Access to Providers

Access to covered services is of course a critical component of delivering an appropriate health benefit to children. Accordingly, a number of Medicaid and EPSDT provisions are intended to assure that children have access to an adequate number and range of pediatric providers. For example, states are required to "make available a variety of individual and group providers qualified and willing to provide" services to children.[58] States must also "take advantage of all resources available" to provide a "broad base" of providers who treat children."[59] Some states may find it necessary to recruit new providers to meet children's needs.[60] In the event a child needs a treatment that is not coverable under the categories listed in section 1905(a), states are to provide referral assistance that includes giving the family or beneficiary the names, addresses, and telephone numbers of providers who have expressed a willingness to furnish uncovered services at little or no expense to the family.[61]

States are required to make available a variety of providers who are qualified and willing to treat EPSDT children.

A child is entitled to receive Medicaid services from any provider qualified to provide the service and willing to furnish it, unless CMS has decided that this "freedom of choice" requirement will not apply.[62] Most states have received permission from CMS to provide some services to some children through managed care arrangements that restrict the free choice of provider.

An appropriate level of reimbursement can be critical to ensuring adequate access to providers.[63] While the statute provides states with broad authority to set provider payment rates, it requires that payments to providers must be consistent with efficiency, economy, and quality care and be sufficient to enlist enough

[58] 42 C.F.R. § 441.61.
[59] CMS, State Medicaid Manual § 5220.
[60] *Id.*
[61] 42 C.F.R. § 441.61(a).
[62] Sections 1902(a)(23) and 1932(a) of the Social Security Act; 42 C.F.R. § 431.51(b).
[63] HCFA, Dear State Medicaid Director (Jan 18, 2001).

providers that care and services are available to Medicaid beneficiaries at least to the extent that they are available to the general population in the geographic area.[64]

Federal regulations provide that a Medicaid provider must agree to accept, as payment in full, the Medicaid payment for a covered service or item.[65] This means that a provider *may not* bill a Medicaid beneficiary for the difference between the provider's charge and the Medicaid payment (called "balance billing"). The payment in full requirement also prohibits Medicaid providers from billing beneficiaries for missed appointments. States may need to monitor compliance with this requirement.

Section 1905(a) lists coverable Medicaid services and some provider types. There are at least two means by which a state may cover a service by a provider type that is not specified in section 1905(a). Section 1905(a)(6) permits states to cover "medical care, or any other type of remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice as defined by State law." Thus, a state may cover services performed by a class of providers (such as licensed dieticians) when the service they provide is not specified in section 1905(a) as long as the service is determined medically necessary for a child. Alternatively, a provider's services can be covered as a component of a section 1905(a) service. For example, in the case of a licensed social worker, the services could be provided through a federally qualified health center or a clinic, both of which are recognized providers under section 1905(a). The process for covering a provider for a service not specified in section 1905(a) varies depending on how the state intends to provide the service.

B. Managed Care

EPSDT benefits must be available to all children covered by Medicaid. As such, children enrolled in managed care plans, prepaid inpatient health plans, prepaid ambulatory health plans, primary care case management systems (collectively referred to as managed care entities) are entitled to the same EPSDT benefits they would have in a fee for service Medicaid delivery system. Properly implemented, managed care can enhance and promote EPSDT's goals of ensuring that care is provided in a coordinated way and with an emphasis on prevention.

States are responsible for assuring that the full EPSDT benefit is available to all Medicaid children in the state, even if the state contracts with a managed care entity to deliver some or all of the services available under EPSDT. The state's

[64] Section 1902(a)(30)(A) of the Social Security Act; Medicaid Program: Methods for Assuring Access to Covered Medicaid Services, 76 Fed. Reg. 26,342 (May 11, 2011) (proposed regulations).
[65] 42 C.F.R. § 447.15.

contracts with managed care entities should be drafted with sufficient precision so that the entity's responsibilities with respect to children are clearly delineated. A contract can provide that the managed care entities will be responsible for providing services under the EPSDT benefit to the same degree that the services are covered by the state. Or, if certain responsibilities are carved out of the managed care contract, those carve-outs must be explicit, and the state will retain the responsibility for ensuring that those carved-out services are provided to enrolled children. For example, the state may 'carve out' dental services from the managed care contract; nonetheless, the state must assure that children receive those services (through either fee for service or a specialized dental plan).

Managed care entities may not use a definition of medical necessity for children that is more restrictive than the state's definition.

Managed care entities may not use a definition of medical necessity for children that is more restrictive than the state's definition. One way to ensure this is for the state to include its definition of medical necessity in the entity's contract. States should review managed care entities' medical necessity definitions and criteria to ascertain whether they meet this requirement. As a further step to provide for consistency across the delivery system and proper implementation of the children's benefit package, it is the state's responsibility to educate its contracted managed care entities about EPSDT requirements, as well as to verify that managed care providers are informed about EPSDT requirements through trainings and provider manuals. Further, states are responsible for ensuring that managed care entities fulfill their contractual responsibilities to inform all families of the services available under EPSDT and how to access them.[66] Information made available to enrollees, usually included in a member handbook, should clearly explain which EPSDT services the managed care entity will provide and how any EPSDT services not within the scope of the contract can be accessed by enrollees. Managed care entities must make available to all enrolled children the entire scope of services included in the EPSDT benefit that is within their contract with the state.[67]

[66] Sections 1902(a)(5) and (a)(43) of the Social Security Act.
[67] 42 C.F.R. § 438.210(a)(4).

Managed care entities must demonstrate to the state that they have adequate provider capacity in the plan to serve enrolled children, including an appropriate range of pediatric and specialty services; access to primary and preventive care; and a sufficient number, mix and geographic distribution of providers.[68]

Monitoring managed care entities' compliance with EPSDT requirements is essential; a strong oversight framework ensures that states are meeting their responsibilities to children as well as Federal monitoring requirements.[69] There are several methods of exercising effective oversight in managed care systems.

First, states contracting with managed care organizations (MCOs) or prepaid inpatient health plans (PIHPs) are statutorily required to draft, implement, and maintain a managed care quality strategy.[70] The quality strategy is intended to provide a blueprint for states in assessing and improving the quality of care provided to managed care enrollees.[71] By means of this strategy, states can monitor and evaluate managed care entities' compliance with quality initiatives, track their performance on specified performance measures, and require them to design, implement and report the results of performance improvement projects.

Second, states are also required to ensure that external quality review of MCOs and PHIPs are performed by unbiased, external entities.[72] In this way, states can determine whether managed care entities are reporting accurate performance outcomes data and whether they are in compliance with state contract provisions.

Third, states can engage in an ongoing review of grievances and appeals related to children's services, as well as monitoring complaints filed with the state's enrollee and provider hotlines (if the state operates such hotlines). States could also require reports and perform data analysis of managed care entities' encounter data to detect underutilization of services by children.

In addition, all states are required to complete and file the Form 416 each year.[73] This reports the number of children receiving health screening services, dental and oral health services, and referrals for corrective treatment, as well as the state's rates of meeting EPSDT participation goals.

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[68] 42 C.F.R. § 438.206.
[69] 42 C.F.R. § 438.240.
[70] Section 1932(c)(1) of the Social Security Act; 42 C.F.R. §§ 438.202, 438.204.
[71] 42 C.F.R. § 438.202.
[72] Section 1932(c)(2) of the Social Security Act; 42 C.F.R. § 438.350.
[73] Section 1902(a)(43)(D) of the Social Security Act.

C. Timeliness

Services under the EPSDT benefit, like all Medicaid services, must be provided with "reasonable promptness."[74] The state must set standards to ensure that EPSDT services are provided consistent with reasonable standards of medical and dental practice. The state must also ensure that services are initiated within a reasonable period of time. What is reasonable depends on the nature of the service and the needs of the individual child. Because states have the obligation to "arrang[e] for . . . corrective treatment" either directly or through referral to appropriate providers, a lack of providers does not automatically relieve a state of its obligation to ensure that services are provided in a timely manner. For example, as noted above, it may be necessary to cover services provided out of state.

Services under the EPSDT benefit, like all Medicaid services, must be provided with reasonable promptness.

[74] Section 1902(a)(8) of the Social Security Act.

VIII. NOTICE AND HEARING REQUIREMENTS

Children under age 21, like all other people enrolled in Medicaid, have the right to notice and an opportunity for a hearing. If a state or managed care entity takes an "action" – to deny, terminate, suspend, or reduce a requested treatment or service, it must give the beneficiary written notice of the action and of their right to a hearing (a pre-termination hearing, in instances where services are reduced or terminated), including instructions on how to request a hearing.[75] When services are being terminated or reduced, the notice must be sent at least ten days before the effective date of the action.[76] Under exceptional circumstances, the notice must be mailed no later than the day of the action, such as when the beneficiary's physician prescribes a change in treatment or the beneficiary has been admitted to an institution and is no longer eligible.[77] The notice must contain a statement of the intended action, the specific reasons and legal support for the action, and an explanation of the individual's hearing rights, rights to representation and to continued benefits.[78]

If a state or managed care entity takes an action to deny, terminate, suspend, or reduce a requested treatment or service, it must give the beneficiary written notice of the action and of their right to a hearing.

The beneficiary is entitled to a hearing before the state Medicaid agency, or, if a state's hearing process provides for it, an evidentiary hearing at the local level (for example at a county department of social services) with a right of appeal to the state agency.[79] The hearing must be conducted at a reasonable time, date, and place by an impartial hearing official. A beneficiary must be allowed to present his or her case to an impartial decision maker and present evidence and

[75] Section 1902(a)(3) of the Social Security Act; *Goldberg v. Kelly*, 397 U.S. 254 (1970).
[76] 42 C.F.R. § 431.211.
[77] 42 C.F.R. § 431.213.
[78] 42 C.F.R. §§ 431.206, 431.210.
[79] 42 C.F.R. § 431.205(b).

witnesses.[80] The beneficiary is also entitled to have representation, including legal counsel, a relative, or a friend.[81] Before the hearing, beneficiaries must have the right to examine the case file and all documents that will be used at the hearing.[82]

When a service is terminated or reduced, if the beneficiary requests a hearing within ten days of receiving notice of the termination or reduction, the beneficiary has the right to continued coverage of services pending a hearing decision.[83] This is sometimes called "aid paid pending." Once the agency issues a final decision, the beneficiary generally has the right to appeal that decision to state court.

Managed care enrollees must have access to in-plan grievance and appeal processes, in addition to the state fair hearing system.[84] Managed care plans must provide enrollees written notices that explain the action, the reason for the action, and the procedures for using the in-plan grievance and state fair hearing processes, including rights to continued benefits. Managed care plans must resolve complaints in a timely manner, including within three working days when the enrollee or provider indicates that delay could seriously jeopardize the enrollee's life, health or ability to attain, maintain, or retain maximum function.[85] The state can require enrollees to exhaust the plan's internal grievance process before obtaining a state fair hearing.

The state agency must issue and publicize its hearing decisions.[86] In addition, the public must have access to all fair hearing decisions, subject to regulatory requirements providing for safeguarding of confidential personal and health information.[87]

[80] 42 C.F.R. §§ 431.240, 431.242.
[81] 42 C.F.R. § 431.206(b)(3).
[82] 42 C.F.R. § 431.242.
[83] 42 C.F.R. § 431.230.
[84] 42 C.F.R. § 438.402.
[85] 42 C.F.R. § 438.408.
[86] 42 C.F.R. § 431.206(a).
[87] 42 C.F.R. § 431.244(g).

IX. CONCLUSION

The goal of EPSDT is to assure that all Medicaid-enrolled children under age 21 receive the health care they need. EPSDT covers not only medically necessary treatment to correct or ameliorate identified conditions, but also preventive, and maintenance services. In addition, EPSDT covers age-appropriate medical, dental, vision and hearing screening services at specified times, and when health problems arise or are suspected.

The broad scope of EPSDT provides states with the tools necessary to offer a comprehensive, high-quality health benefit. To fully realize EPSDT's potential, however, attention is needed on issues affecting access to services, including supply of providers, the presence of managed care, linguistic and disability access, and transportation. CMS is available to help states address these issues to ensure that EPSDT coverage meets the needs of children under age 21 who depend on Medicaid for their health care.

X. WHAT YOU NEED TO KNOW ABOUT EPSDT

EARLY: Assessing and identifying problems early

Children covered by Medicaid are more likely to be born with low birth weights, have poor health, have developmental delays or learning disorders, or have medical conditions (e.g., asthma) requiring ongoing use of prescription drugs. Medicaid helps these children and adolescents receive quality health care.

EPSDT is a key part of Medicaid for children and adolescents. EPSDT emphasizes preventive and comprehensive care. Prevention can help ensure the early identification, diagnosis, and treatment of conditions before they become more complex and costly to treat. It is important that children and adolescents enrolled in Medicaid receive all recommended preventive services and any medical treatment needed to promote healthy growth and development.

PERIODIC: Checking children's health at age-appropriate intervals

As they grow, infants, children and adolescents should see their health care providers regularly. Each state develops its own "periodicity schedule" showing the check-ups recommended at each age. These are often based on the American Academy of Pediatrics' Bright Futures guidelines: Recommendations for Preventive Pediatric Health Care. Bright Futures helps doctors and families understand the types of care that infants, children and adolescents should get and when they should get it. The goal of Bright Futures is to help health care providers offer prevention-based, family-focused, and developmentally-oriented care for all children and adolescents. Children and adolescents are also entitled to receive additional check-ups when a condition or problem is suspected.

SCREENING: Providing physical, mental, developmental, dental, hearing, vision and other screening tests to detect potential problems

All infants, children and adolescents should receive regular well-child check-ups of their physical and mental health, growth, development, and nutritional status. A well-child check-up includes:

- A comprehensive health and developmental history, including both physical and mental health development assessments;
- Physical exam;
- Age-appropriate immunizations;
- Vision and hearing tests;
- Dental exam;
- Laboratory tests, including blood lead level assessments at certain ages; and
- Health education, including anticipatory guidance.

DIAGNOSTIC: Performing diagnostic tests to follow up when a health risk is identified

When a well-child check-up or other visit to a health care professional shows that a child or adolescent might have a health problem, follow up diagnostic testing and evaluations must be provided under EPSDT. Diagnosis of mental health, substance use, vision, hearing and dental problems is included. Also included are any necessary referrals so that the child or adolescent receives all needed treatment.

TREATMENT: Correct, reduce or control health problems found

EPSDT covers health care, treatment and other measures necessary to correct or ameliorate the child or adolescent's physical or mental conditions found by a screening or a diagnostic procedure. In general, States must ensure the provision of, and pay for, any treatment that is considered "medically necessary" for the child or adolescent. This includes treatment for any vision and hearing problems, including eyeglasses and hearing aids. For children's oral health, coverage includes regular preventive dental care and treatment to relieve pain and infections, restore teeth, and maintain dental health. Some orthodontia is also covered.

XI. RESOURCES

CMS Resources

- CMS, *State Medicaid Manual §§ 2700.4 and 5010-5360*
- CMS, *Early and Periodic Screening Diagnostic and Treatment Resources*

Adolescent Health

- CMS, *Paving the Road to Good Health: Strategies for Increasing Medicaid Adolescent Well-Care Visits (Feb. 2014)*

Oral Health

- CMS, *Keep Kids Smiling: Promoting Oral Health Through the Medicaid Benefit for Children and Adolescents* (September 2013)
- CMS, *Improving Access to and Utilization of Oral Health Services for Children in Medicaid and CHIP Programs*, CMS Oral Health Strategy (April 11, 2011)
- CMS, *CMCS Informational Bulletin, CMS Oral Health Initiative and Other Dental Related Issues* (April 18, 2013)
- *Improving Oral Health Care Delivery in Medicaid and CHIP: A Toolkit for States* (February 2014)

Mental Health

- CMS, *CMCS Informational Bulletin, Prevention and Early Identification of Mental Health and Substance Use Conditions* (March 27, 2013)
- CMS, *Joint CMCS and SAMHSA Informational Bulletin, Coverage of Behavioral Health Services for Children, Youth, and Young Adults with Significant Mental Health Conditions* (May 7, 2013)

Screening Services

- CMS, *Guide for States Interested in Transitioning to Targeted Blood Lead Screening for Medicaid-eligible Children* (May 2012)

Accessibility

- CMS, *CMCS Informational Bulletin* (April 26, 2011) (federal funding for interpretation and translation services)
- CMS, *Dear State Medicaid Director* (Aug. 31, 2000) (Limited English Proficiency)
- CMS, *Dear State Medicaid Director, Olmstead Update No. 4*, Att. 4-B EPSDT (Jan. 10, 2001)
- CMS, *Medicaid School-Based Administrative Claiming Guide* (May 2003)

Other Federal Resources

- CDC, Vaccine Recommendations of the ACIP
- HRSA, *EPSDT & Title V Collaboration to Improve Child Health*
- Health Resources and Services Administration EPSDT website
- HHS Office of Minority Health's *Think Cultural Health: Advancing Health Equity at Every Point of Contact*
- HHS Office of Minority Health's *A Physician's Practical Guide to Culturally Competent Care*
- HHS Office of Minority Health's *Culturally Competent Nursing Care: A Cornerstone of Caring*
- HHS Office of Minority Health's *Cultural Competency Curriculum for Disaster Preparedness and Crisis Response*
- HHS Office of Minority Health's *Cultural Competency Program for Oral Health Professionals*
- HHS Office of Minority Health's *National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards)*
- HHS Office of Minority Health's *A Blueprint for Advancing and Sustaining CLAS Policy and Practice (The Blueprint)*

Other Resources

- American Academy of Pediatrics, *Bright Futures* (2014)
- American Academy of Pediatrics, *Bright Futures Recommendations for Pediatric Preventive Care* (2014)
- American Academy of Pediatric Dentistry, *Guideline on Periodicity of Examination, Preventive Dental Services, Anticipatory Guidance/Counseling, and Oral Treatment for Infants, Children, and Adolescents* (2013)
- Association of Maternal and Child Health Programs, *Standards for Systems of Care for Children and Youth with Special Health Care Needs* (March 2014)
- George Washington University, Health Information & The Law, *Understanding the Interaction Between EPSDT and Federal Health Information Privacy and Confidentiality Laws* (2013)
- National Academy of State Health Policy, Managing the "T" in EPSDT Services (2010)
- National Academy of State Health Policy, Resources to Improve Medicaid for Children and Adolescents
- National Health Law Program, Toward a Healthy Future: Medicaid EPSDT Services for Poor Children and Youth
- National Health Law Program, Annotated Federal Documents