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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, testosterone nasal gel, testosterone undecanoate, testosterone buccal

Estrogens: estradiol transdermal patch, estradiol valerate, estradiol cypionate, estradiol oral tablet, estradiol implant pellet, estradiol gel, estradiol TD gel, estradiol transdermal spray

Gonadotropin-Releasing Hormone Agonist: Fensolvi (leuprolide), Lupron Depot (leuprolide), Lupron Depot-Ped (leuprolide), Eligard (Leuprolide Acetate), Camcevi (leuprolide mesylate), Supprelin LA (histrelin acetate implant), Trelstar Mixject (triptorelin), Triptodur (triptorelin)

5-Alpha Reductase Inhibitor: Propecia (finasteride), Proscar (finasteride), finasteride

Aldosterone Receptor Antagonist: Aldactone (spironolactone)

Progestin: Depo-Provera (medroxyprogesterone acetate), Prometrium (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, Puberty Suppression

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

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adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. PUBERTY SUPPRESSION

1. Documentation member is an adolescent that has started puberty (Tanner stage >G2/B2, See Appendix 1)
AND
2. Member is less than 16 years of age
AND
3. A definitive diagnosis of persistent gender dysphoria has been made and documented by a qualified healthcare professional and/or mental health professional such as a licensed psychiatrist, psychologist, or psychotherapist and all of the following are present:
 - a) The adolescent has demonstrated a long lasting and intense pattern of gender dysphoria AND
 - b) 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:
 - 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

Note: All other covered, FDA labeled indications for Estrogens, 5-Alpha Reductase Inhibitors, Aldosterone Receptor Antagonists, and Progestins are covered without Prior Authorization requirement

1. Member is 16 years of age 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 health care professional and all of the following are present:
 - 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 gender-affirming medical and/or surgical treatments
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 or qualified health care professional as *defined by The Endocrine Society (2017) or World Professional Association for Transgender Health (WPATH). *Refer to 'Prescriber Requirements' section

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AND

5. Initial hormone therapy must be prescribed by a qualified health professional ('Prescriber Requirements') preceded by 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 the individual has demonstrable knowledge of the risks and benefits of hormone replacement

AND

7. REQUESTS FOR LHRH: Documentation member has not had sex confirmation surgery

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:

1. 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:

LHRH: Initial authorization: 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: Initial authorization: 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 or health care professional 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 incongruence 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

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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 (2022)

Statements of Recommendations

Adults:

5.1- We recommend health care professionals assessing transgender and gender diverse **adults** for physical treatments:

5.1.a- Are licensed by their statutory body and hold, at a minimum, a master's degree or equivalent training in a clinical field

relevant to this role and granted by a nationally accredited statutory institution.

5.1.b- For countries requiring a diagnosis for access to care, the health care professional should be competent using the latest

edition of the World Health Organization's International Classification of Diseases (ICD) for diagnosis. In countries that have not

implemented the latest ICD, other taxonomies may be used; efforts should be undertaken to utilize the latest ICD as soon as

practicable.

5.1.c- Are able to identify co-existing mental health or other psychosocial concerns and distinguish these from gender dysphoria, incongruence, and diversity.

5.1.d- Are able to assess capacity to consent for treatment.

5.1.e- Have experience or be qualified to assess clinical aspects of gender dysphoria, incongruence, and diversity.

5.1.f- Undergo continuing education in health care relating to gender dysphoria, incongruence, and diversity.

5.2- We suggest health care professionals assessing transgender and gender diverse adults seeking gender-affirming treatment

liaise with professionals from different disciplines within the field of transgender health for consultation and referral, if required.

Adolescents:

6.1- We recommend health care professionals working with gender diverse **adolescents**:

6.1.a- Are licensed by their statutory body and hold a postgraduate degree or its equivalent in a clinical field relevant to this

role granted by a nationally accredited statutory institution.

6.1.b- Receive theoretical and evidenced-based training and develop expertise in general child, adolescent, and family mental

health across the developmental spectrum.

6.1.c- Receive training and have expertise in gender identity development, gender diversity in children and adolescents, have

the ability to assess capacity to assent/consent and possess general knowledge of gender diversity across the life span.

6.1.d- Receive training and develop expertise in autism spectrum disorders and other neurodevelopmental presentations or

collaborate with a developmental disability expert when working with autistic/neurodivergent gender diverse adolescents.

6.1.e- Continue engaging in professional development in all areas relevant to gender diverse children, adolescents, and families.

6.9- We recommend health care professionals involve relevant disciplines, including mental health and medical professionals, to reach a decision about whether puberty suppression, hormone initiation, or gender-related surgery for gender diverse and transgender adolescents are appropriate and remain indicated throughout the course of treatment until the transition is made to adult care.

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AGE RESTRICTIONS:

PUBERTY SUPPRESSION: Tanner stage > G2/B2 through 16 years of age

GENDER DYSPHORIA: 16 years of age or older

QUANTITY:

Per WPATH and Endocrine Society guidelines. See Appendix 2 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.

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:

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.

State Specific Information

State Marketplace

Utah (Source: [State of Utah](#))

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For hormone therapy requests for members <18 years of age, refer to [Hormone Therapy for Gender Dysphoria MUT C24947-A](#)

For all GnRH agent requests, refer to [Gonadotropin-releasing hormone \(GnRH\) MHUT C24948-A](#)

Kentucky (Source: [State of Kentucky](#))

KY 2023 Regular Session SB 150

“A new section of KRS Chapter 311 is created to read as follows:

(1) As used in this section:

(a) "Minor" means *any person under the age of eighteen (18) years*; and

(b) "Sex" means the biological indication of male and female as evidenced by sex chromosomes, naturally occurring sex hormones, gonads, and nonambiguous internal and external genitalia present at birth.

(2) Except as provided in subsection (3) of this section, *a health care provider shall not*, for the purpose of attempting to alter the appearance of, or to validate a *minor's* perception of, the *minor's* sex, if that appearance or perception is inconsistent with the *minor's* sex, knowingly:

(a) *Prescribe or administer any drug to delay or stop normal puberty;*

(b) *Prescribe or administer testosterone, estrogen, or progesterone, in amounts greater than would normally be produced endogenously in a healthy person of the same age and sex;...*

(6) If a health care provider has initiated a course of treatment, for a minor, that includes the prescription or administration of any drug or hormone prohibited by subsection (2) of this section and if the health care provider determines and documents in the minor's medical record that immediately terminating the minor's use of the drug or hormone would cause harm to the minor, the health care provider may institute a period during which the minor's use of the drug or hormone is systematically reduced.”

MOLINA REVIEWER NOTE: Gender affirming pharmacotherapy is prohibited for members under 18 years of age. Requests for continuation of care for members under the age of 18 requires documentation from the prescriber of a taper plan and medical necessity, as described in section 6.

Mississippi (Source: [State of Mississippi](#))

MS H.B. No. 1125 Regulate Experimental Adolescent Procedures (REAP) Act (2022): "Section 2. (f) (i)

"Gender transition procedures" means any of the following medical or surgical services performed for the purpose of assisting an individual with a gender transition:

1. Prescribing or administering puberty-blocking drugs;

2. Prescribing or administering cross-sex hormones...

Section 3. (1) *A person shall not knowingly provide gender transition procedures to any person under eighteen (18) years of age*”

State Medicaid

Iowa (Source: [Iowa Legislature](#))

Senate file 538 “Section 1. NEW SECTION. 147.164 Gender transition procedure-related activities — minors — prohibitions.

1. As used in this section:

a. “Gender” means the psychological, behavioral, social, and cultural aspects of being male or female.

b. “Health care professional” means a person who is licensed, certified, or otherwise authorized or permitted by the law of this state to administer health care in the ordinary course of business or in the practice of a profession.

c. “Minor” means an unemancipated person under eighteen years of age.

d. “Sex” means the biological indication of male and female, including sex chromosomes, naturally occurring sex hormones, gonads, and nonambiguous internal and external genitalia present at birth without regard to an individual’s psychological, chosen, or subjective experience of gender.

2. a. Except as otherwise provided in paragraph “c”, a health care professional shall not knowingly engage in or cause any of the following practices to be performed on a minor if the practice is performed for the purpose of attempting to alter the appearance of, or affirm the minor’s perception of, the minor’s gender or sex, if that appearance or perception is inconsistent with the minor’s sex.

(1) Prescribing or administering gonadotropin-releasing hormone analogues or other synthetic drugs used to stop luteinizing hormone and follicle-stimulating hormone secretion, synthetic antiandrogen drugs used to block the androgen receptor, or any drug to suppress or delay normal puberty.

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(2) Prescribing or administering testosterone, estrogen, or progesterone to a minor in an amount greater than would normally be produced endogenously in a healthy individual of that individual's age and sex."

MOLINA REVIEWER NOTE: This includes all pharmacotherapy under the pharmacy benefit or medical benefit to include but not limited to:

- Androgens (testosterone cypionate, testosterone enanthate, testosterone undecanoate, Androderm, and AndroGel)
- Gonadotropin-releasing hormone (GnRH) analogs (Eligard, Lupron Depot, Lupron Depot-Ped, and Zoladex)
- Estrogen Derivatives
- Progestins
- Aldosterone Antagonists, Selective (spironolactone)
- Antiandrogen Antineoplastics (flutamide)
- Oral Contraceptives
- Gonadotropin-releasing hormone (GnRH) analogs (Eligard, Lupron Depot, Lupron Depot-Ped, and Zoladex)

Appendix 1:

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

Appendix 2:

Hormone Regimens in Transgender Persons (Endocrine Society, 2017)

Testosterone for transgender males					
Parenteral		Transdermal		Implant	
Testosterone enanthate	Testosterone cypionate	Testosterone undecanoate	Testosterone gel 1.6%	Testosterone transdermal patch	Testopel [®]
100 – 200 mg/10 - 14 days or 50 – 100 mg/week		1000 mg every 12 weeks	50 – 100 mg/day	2.5 – 7.5 mg/day	75 mg/pellet

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

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20 – 60 mg PO daily	150mg IM Q3 months	3.75 – 7.5mg SQ monthly 11.25mg SQ every 3 months	50 mg implanted Q 12 months	100 – 300 mg PO daily	1 mg PO daily
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Table 3. Gender-Affirming Hormone Regimens In Transgender And Gender Diverse Youth (Adapted from the Endocrine Society Guidelines; Hembree et al., 2017) (WPATH, 2022)

Induction of female puberty (estrogen-based regimen) with oral 17β-estradiol

Initiate at 5µg/kg/d and increase every 6 months by 5 µg/kg/d up to 20 µg/kg/d according to estradiol levels

Adult dose = 2-6mg/day

In postpubertal TGD adolescents, the dose of 17β-estradiol can be increased more rapidly: 1mg/d for 6 months followed by 2mg/d and up according to estradiol levels

Induction of female puberty (estrogen-based regimen) with transdermal 17β-estradiol

Initial dose 6.25-12.5 µg/24 h (cutting 24 g patch to ¼ then ½) Titrate up by every 6 months by 12.5 µg/24 h according to estradiol levels

Adult dose = 50-200 µg/24 hours

For alternatives once at adult dose (Table 4)

Induction of male puberty (testosterone-based regimen) with testosterone esters

25mg/m² /2 weeks (or alternatively half this dose weekly)

Increase by 25mg/m² /2 weeks every 6 months until adult dose and target testosterone levels are achieved.

See alternatives for testosterone (Table 4)

Table 4. Hormone regimens in transgender and gender diverse adults (WPATH, 2022)

Estrogen-based regimen (Transfeminine)

Estrogen

Oral or sublingual

Estradiol 2.0-6.0mg/day

Transdermal

Estradiol transdermal patch 0.025-0.2mg/day

Estradiol gel various ‡ daily to skin

Parenteral

Estradiol valerate or cypionate 5-30mg IM every 2 weeks 2-10 IM every week

Anti-Androgens

Spirolactone 100–300mg/day

Cyproterone acetate 10mg/day**

GnRH agonist 3.75–7.50mg SQ/IM monthly

GnRH agonist depot formulation 11.25/22.5mg SQ/IM 3/6 monthly

‡ Amount applied varies to formulation and strength

Testosterone-Based Regimen (Transmasculine) Transgender males

Testosterone Parenteral

Testosterone enanthate/ cypionate 50–100 IM/SQ weekly or 100–200 IM every 2 weeks

Testosterone undecanoate 1000mg IM every 12 weeks or 750mg IM every 10 weeks

Transdermal testosterone

Testosterone gel 50-100mg/day

Testosterone transdermal patch 2.5–7.5mg/day

* Doses are titrated up or down until sex steroid hormone levels are in the therapeutic range. Hormone regimens do not reflect all formulations that are available in all pharmacies throughout the world.

Hormone regimens may have to be adapted to what is available in local pharmacies.

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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

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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.

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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	Spirolactone	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

- Monitor for virilizing and adverse effects every 3 months for the first year, then every 6-12 months.
- Obtain baseline hematocrit and lipid profile and monitor every 3 months for the first year, then every 6 – 12 months.
 - Monitor weight, blood pressure, and lipids regularly during visits
- Obtain baseline bone mineral density if at risk for osteoporosis; routine screening after age 60, or earlier if sex hormone levels consistently low.
- Monitor serum estradiol during the first 6 months and thereafter until uterine bleeding has ceased.
- Monitor serum testosterone every 3 months until at, target levels, 320 – 1000 ng/dL
 - Peak levels for parenteral testosterone measured 24-48 hours after injection.
- Trough levels for parenteral measured before injection. If mastectomy was performed, conduct sub- and peri areolar annual breast examinations.
 - 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

- Monitor for feminizing and adverse effects every 3 months for the first year, then every 6-12 months.
- Obtain baseline hematocrit and lipid profile and monitor at follow up visits.
- Obtain baseline bone mineral density if at risk for osteoporosis; routine screening after age

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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 Evidence⁸⁻¹²

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

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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

HCCPS CODE	DESCRIPTION
J9217	Injection, leuprolide acetate (for depot suspension), 7.5mg
J1950	Injection, leuprolide acetate (for depot suspension), per 3.75mg
J1380	Injection, estradiol valerate, up to 10 mg
J1000	Injection, depo-estradiol cypionate, up to 5 mg
J9226	Histrelin implant (Supprelin LA), 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
J1071	Injection, testosterone cypionate, 1 mg
J1952	Leuprolide injectable, camcevi, 1 mg
J1954	Injection, leuprolide acetate for depot suspension (Cipla), 7.5 mg
J3121	Injection, testosterone enanthate, 1 mg
J3145	Injection, testosterone undecanoate, 1 mg
J9218	Leuprolide acetate, per 1 mg

AVAILABLE DOSAGE FORMS:

Aldactone TABS 25MG, 50MG, 100MG
 Alora PTTW 0.025MG/24HR, 0.05MG/24HR, 0.075MG/24HR, 0.1MG/24HR
 Androderm PT24 2MG/24HR, 4MG/24HR
 AndroGel GEL 20.25 MG/1.25GM(1.62%), 40.5 MG/2.5GM(1.62%)
 AndroGel GEL 25 MG/2.5GM(1%), 50 MG/5GM(1%)
 AndroGel Pump GEL 20.25 MG/ACT(1.62%)
 Aveed SOLN 750MG/3ML
 Camcevi PRSY 42MG
 CaroSpir SUSP 25MG/5ML
 Climara PTWK 0.025MG/24HR, 0.0375MG/24HR, 0.05MG/24HR, 0.06MG/24HR, 0.075MG/24HR, 0.1MG/24HR
 Delestrogen OIL 10MG/ML, 20MG/ML, 40MG/ML
 Depo-Estradiol OIL 5MG/ML
 Depo-Provera SUSP 150MG/ML
 Depo-Provera SUSY 150MG/ML
 Depo-SubQ Provera 104 SUSY 104MG/0.65ML
 Depo-Testosterone SOLN 100MG/ML, 200MG/ML
 Divigel GEL 0.25MG/0.25GM, 0.5MG/0.5GM, 0.75MG/0.75GM, 1MG/GM, 1.25MG/1.25GM
 Dotti PTTW 0.025MG/24HR, 0.0375MG/24HR, 0.05MG/24HR, 0.075MG/24HR, 0.1MG/24HR
 Elestrin GEL 0.52 MG/0.87 GM(0.06%)
 Eligard KIT 7.5MG, 22.5MG, 30MG, 45MG
 Estrace TABS 0.5MG, 1MG, 2MG
 Estradiol GEL 0.25MG/0.25GM, 0.5MG/0.5GM, 0.75MG/0.75GM, 1MG/GM, 1.25MG/1.25GM
 Estradiol PLLT 6MG
 Estradiol PTTW 0.025MG/24HR, 0.0375MG/24HR, 0.05MG/24HR, 0.075MG/24HR, 0.1MG/24HR
 Estradiol PTWK 0.025MG/24HR, 0.0375MG/24HR, 0.05MG/24HR, 0.06MG/24HR, 0.075MG/24HR, 0.1MG/24HR

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Estradiol TABS 0.5MG, 1MG, 2MG
Estradiol Valerate OIL 10MG/ML, 20MG/ML, 40MG/ML
EstroGel GEL 0.75 MG/1.25 GM(0.06%)
Evamist SOLN 1.53MG/SPRAY
Fensolvi (6 Month) KIT 45MG
Finasteride TABS 1MG, 5MG
Fortesta GEL 10 MG/ACT(2%)
Jatenzo CAPS 158MG, 198MG, 237MG
Kyzatrex CAPS 100MG, 150MG, 200MG
Leuprolide Acetate INJ 22.5MG
Leuprolide Acetate KIT 1MG/0.2ML
Lupron Depot (1-Month) KIT 3.75MG, 7.5MG
Lupron Depot (3-Month) KIT 11.25MG, KIT 22.5MG
Lupron Depot (4-Month) KIT 30MG
Lupron Depot (6-Month) KIT 45MG
Lupron Depot-Ped (1-Month) KIT 7.5MG, 11.25MG, KIT 15MG
Lupron Depot-Ped (3-Month) KIT 11.25MG (Ped), 30MG
Lupron Depot-Ped (6-Month) KIT 45MG
Lyllana PTTW 0.025MG/24HR, 0.0375MG/24HR, 0.05MG/24HR, 0.075MG/24HR, 0.1MG/24HR
medroxyPROGESTERone Acetate SUSP 150MG/ML
medroxyPROGESTERone Acetate SUSY 150MG/ML
Menostar PTWK 14MCG/24HR
Methitest TABS 10MG
methylTESTOSTERone CAPS 10MG
Minivelle PTTW 0.025MG/24HR, 0.0375MG/24HR, 0.05MG/24HR, 0.075MG/24HR, 0.1MG/24HR
Natesto GEL 5.5MG/ACT
Progesterone CAPS 100MG, 200MG
Prometrium CAPS 100MG, 200MG
Propecia TABS 1MG
Proscar TABS 5MG
Spironolactone TABS 25MG, 50MG, 100MG
Striant MISC 30MG
Supprelin LA KIT 50MG
Testim GEL 50 MG/5GM(1%)
Testone CIK KIT 200MG/ML
Testopel PLLT 75MG
Testosterone Cypionate SOLN 50MG/ML, 100MG/ML, 150MG/ML, 200MG/ML
Testosterone Enanthate SOLN 200MG/ML
Testosterone GEL 1.62%
Testosterone GEL 10 MG/ACT(2%)
Testosterone GEL 12.5 MG/ACT(1%)
Testosterone GEL 20.25 MG/1.25GM(1.62%), 40.5 MG/2.5GM(1.62%)
Testosterone GEL 20.25 MG/ACT(1.62%)
Testosterone GEL 25 MG/2.5GM(1%), 50 MG/5GM(1%)
Testosterone PLLT 25MG, 50MG, 100MG, 200MG
Testosterone Propionate SOLN 100MG/ML
Tlando CAPS 112.5MG
Trelstar Mixject SUSR 3.75MG, 11.25MG, 22.5MG
Triptodur SRER 22.5MG
Vivelle-Dot PTTW 0.025MG/24HR, 0.0375MG/24HR, 0.05MG/24HR, 0.075MG/24HR, 0.1MG/24HR
Vogelxo GEL 50 MG/5GM(1%)
Vogelxo Pump GEL 12.5 MG/ACT(1%)
Xyosted SOAJ 50MG/0.5ML, 75MG/0.5ML, 100MG/0.5ML

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Products Affected Diagnosis Required Medical Information Duration of Approval Prescriber Requirements Quantity Appendix Coding/Billing Information Available Dosage Forms References	Q3 2023
REVISION- Notable revisions: Products Affected Required Medical Information Quantity Place of Administration Route of Administration Coding/Billing Information Available Dosage Forms References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file