Washington State Health Care Authority

Hormone Therapy for Gender Dysphoria

Medical policy no. 24.00.00-1 Effective Date: March 1, 2021

Related medical policies:

- **23.10.00: Androgenic Agents- Testosterone Replacement Therapy (TRT)**

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

The intent of this policy is to describe how hormone replacement therapy (HRT) and puberty suppression therapy are covered in relation to Transgender Health.

Background:

Gender dysphoria is the conflict between a person's gender assigned at birth and the gender with which he/she/they identify. Individuals with gender dysphoria may often experience significant distress and problems functioning as they deal with the conflict between their expressed gender and the gender assigned at birth. Treatment of individuals with gender dysphoria varies, with some treatments involving a change in gender expression or body modifications. Hormone replacement therapy is a process common among patients with gender dysphoria to transform either male or female biological characteristics to ones similar to their expressed gender. Masculinizing hormone therapy includes medications that increase testosterone levels in the body causing masculinizing changes to occur. Feminizing hormone therapy includes medications that reduce testosterone levels while providing estrogen to allow feminizing changes to occur. Treatment of gender dysphoria should be specific to the patient and involve a multidisciplinary team with clinicians from different specialties such as psychology, social work, endocrinology, urology, and surgery.

Medical necessity

Drug	Medical Necessity
Testosterone therapy Testosterone cypionate IM Testosterone enanthate (**Xyosted**) Testosterone transdermal gel 1%, 1.62%, 2% Testosterone transdermal patch (**AndroDerm**) Testosterone undecanoate (**Aveed**)	Testosterone therapy may be considered medically necessary for the following indications related to Transgender Health: • Gender dysphoria Gonadotropin-releasing Hormone (GnRH) Agonist therapy may be considered medically necessary for the following indications related to Transgender Health: • Puberty suppression in adolescents diagnosed with gender dysphoria • Gender dysphoria

Gonadotropin-releasing Hormone (GnRH) Agonist therapy Goserlin (**Zoladex**) Histrelin implant (**Supprelin, Vantas**) Leuprolide (**Eligard, Fensolvi, Lupron Depot, Lupron-Depot-Ped**) Triptorelin (**Triptodur**)	Non-preferred products require a trial of preferred products as indicated on the Apple Health Preferred Drug List. Requests for brand-name medications with a generic equivalent available must also meet the criteria described in the Brands with Generic Equivalents policy (Non-Clinical Policy No. 0001).

Clinical guidelines:

Clinical Criteria	
Gender dysphoria - Testosterone Testosterone cypionate IM Testosterone enanthate (**Xyosted**) Testosterone transdermal gel 1%, 1.62%, 2% Testosterone transdermal patch (**AndroDerm**) Testosterone undecanoate (**Aveed**)	Testosterone therapy may be considered medically necessary for the treatment of **gender dysphoria** if the following criteria are met: 1. Diagnosis of gender dysphoria as defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) 2. If patient is 17 years of age or younger: a. A pediatric endocrinologist or other clinician experienced in pubertal assessment has determined hormone treatment to be appropriate **If ALL criteria are met, claims may be processed with expedited authorization (EA).** • Testosterone therapy: The pharmacy may submit the claim with EA 85000000102. ○ If the diagnosis is provided to the pharmacy telephonically documentation must include diagnosis, who provided verification of the criteria, and the date the verification was provided. • If the pharmacy is unable to verify if the patient meets all criteria, the request will be subject to prior authorization. ○ If all criteria are met, the request may be approved for 12 months. ○ If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to 12 months.
	NOTE: Expedited authorization will not override non-preferred status or prior authorization for brand products with generic equivalents.
Gender Dysphoria/Puberty Suppresion- GnRH Agonists	GnRH agonist therapy may be considered medically necessary for the treatment of **gender dysphoria or puberty suppression** if the following criteria are met:

Goserlin (**Zoladex**) Histrelin implant (**Supprelin, Vantas**) Leuprolide (**Eligard, Fensolvi, Lupron Depot, Lupron-Depot-Ped**) Triptorelin (**Triptodur**)	1. Diagnosis of gender dysphoria or puberty suppression as defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) 2. If patient is 17 years of age or younger: a. A pediatric endocrinologist or other clinician experienced in pubertal assessment has determined hormone treatment to be appropriate **If ALL criteria are met, claims may be processed with expedited authorization (EA).** • GnRH therapy for Puberty Suppression: The pharmacy may submit the claim with EA 85000000103. • GnRH therapy for Gender Dysphoria: The pharmacy may submit the claim with EA 85000000104. ○ If the diagnosis is provided to the pharmacy telephonically documentation must include diagnosis, who provided verification of the criteria, and the date the verification was provided. • If the pharmacy is unable to verify if the patient meets all criteria, the request will be subject to prior authorization. ○ If all criteria are met, the request may be approved for 12 months. ○ If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to 12 months.
	NOTE: Expedited authorization will not override non-preferred status or prior authorization for brand products with generic equivalents.

Coding:

HCPCS Code	Description
C9023	Injection, testosterone undecanoate, 1 mg
J1000	Injection, depo-estradiol cypionate, up to 5 mg

References

1. Fuld K, Chi C, Neely E. A Randomized Trial of 1- and 3-Month Depot Leuprolide Doses in the Treatment of Central Precocious Puberty. *J Pediatr*. 2011;159(6):982-987.e1. doi:10.1016/j.jpeds.2011.05.036
2. Hembree WC, Cohen-Kettenis PT, Gooren L, et al: Endocrine treatment of gender-dysphoric/gender-incongruent persons: an Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab 2017; 102(11):3869-3903.

3. Mericq V, Lammoglia J, Unanue N et al. Comparison of three doses of leuprolide acetate in the treatment of central precocious puberty: preliminary results. *Clin Endocrinol (Oxf)*. 2009;71(5):686-690. doi:10.1111/j.1365-2265.2009.03584.x
4. Tangpircha V, Safer JD. Transgender women: Evaluation and management. In: Martin K, ed. *UpToDate*. Waltham, MA.: UpToDate; 2019. www.uptodate.com. Accessed May 11, 2020
5. The World Professional Association for Transgender Health (WPATH), Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, 7th Version.
6. What Is Gender Dysphoria? https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-gender-dysphoria. Accessed May 18, 2020.

History

Date	Action and Summary of Changes
05/15/2020	New Policy
08/19/2020	Approved by DUR Board
01/27/2021	Updated criteria for testosterone, estrogen, and GnRH agonists to include diagnosis of gender dysphoria/puberty suppression and specialist requirement for patients 17 years of age and younger
02/25/2021	Removed Testosterone implant pellets (**Testopel**) from policy
03/04/2021	Added Testosterone 1% and 2% gel to policy. Corrected testosterone 1.62% strength.