Washington State Health Care Authority

# Hormone Therapy for Gender Dysphoria

## Medical policy no. 24.00.00-1 Effective Date: TBD

**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.*

*The intent of this policy is to describe an existing medical benefit of Transgender Health where hormone replacement therapy (HRT) and puberty suppression therapy are covered. Pharmacists may process claims for hormone therapy as an expedited authorization (EA) when prescribed in accordance with the criteria outline in this policy.*



### 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 |
|---|---|
| **Preferred**<br>Testosterone cypionate IM<br>Testosterone transdermal gel 1.6%<br>Testosterone transdermal patch (**AndroDerm**)<br><br>**Non-Preferred**<br>Testosterone undecanoate (**Aveed**)<br>Testosterone enanthate (**Xyosted**) | **Testosterone therapy** may be approved for the following indications related to Transgender Health:<br>• **Gender dysphoria** |
| **Preferred**<br>Estradiol (**Estrace**) | **Estrogen therapy** may be approved for the following indications related to Transgender Health: |

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| Estradiol Transdermal Patch (**Dotti, generics**)<br>Estradiol valerate IM<br>Estradiol cypionate IM (**Depo-Estradiol)**<br><br>**Non-Preferred**<br>Estradiol valerate IM (**Delestrogen**)<br>Estradiol Transdermal Patch (**Minivelle, Vivelle Dot, Alora, Menostar, Climara**) | • **Gender dysphoria** |
| **Preferred**<br>Histrelin implant **(Supprelin, Vantas)**<br>Leuprolide **(Lupron Depot-Ped, Lupron Depot)**<br>Triptorelin **(Triptodur)**<br>Goserelin **(Zoladex)** | **Gonadotropin-releasing Hormone (GnRH) Agonist Therapy** may be approved for the following indications related to Transgender Health:<br><br>• **Puberty suppression in adolescents diagnosed with gender dysphoria**<br>• **Gender dysphoria when used in combination with estrogen** |

## Clinical policy:

| Clinical Criteria | |
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| **Gender dysphoria** - Testosterone<br><br>**Preferred**<br>Testosterone cypionate IM **(generic)**<br>Testosterone transdermal gel 1.6% **(generic packet and pump)**<br>Testosterone transdermal patch (**AndroDerm**)<br><br>**Non-Preferred**<br>Testosterone undecanoate (**Aveed**)<br>Testosterone enanthate (**Xyosted**)<br>Testosterone implant Pellets **(Testopel, generic)** | Testosterone may be used for the treatment of gender dysphoria if the following criteria are met:<br><br>1. A diagnosis of gender dysphoria as defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5); **AND**<br>2. Patient identifies as a female-to-male (FTM) or non-binary; **AND**<br>3. Patient has been informed of irreversible effects, including potential loss of fertility; **AND**<br>4. Documented informed consent is given for the treatment of gender dysphoria; **AND**<br>5. If patient is less than 17 years of age:<br>a. Informed consent was given by the parents or other legal guardians, as applicable; **AND**<br>b. A pediatric endocrinologist or other clinician experienced in pubertal assessment has determined hormone treatment to be appropriate; **AND**<br>6. Patient is not pregnant or breastfeeding; **AND**<br>7. Patient's risk has been evaluated and treated (if necessary) for the following prior to initiation of testosterone therapy<br>a. Breast cancer<br>b. Elevated hematocrit (>50%)<br>c. Untreated severe obstructive sleep apnea<br>d. Uncontrolled or poorly-controlled heart failure |

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| | e. Experienced a major cardiovascular event (such as an MI, stroke, acute coronary syndrome) in the past six months<br>f. Unstable coronary artery disease (CAD)<br><br>If ALL criteria are met, the request may be **approved for 12 months.** |
| | **Criteria (Reauthorization)** |
| | Testosterone may be reauthorized with documentation of appropriate use (defined by criteria 1-7 above), and positive clinical response.<br><br>If ALL criteria are met, the request may be approved for 12 months. |
| **Gender Dysphoria**- Estrogens<br><br>**Preferred**<br>Estradiol (**Estrace**)<br>Estradiol Transdermal Patch (**Dotti, generic**)<br>Estradiol valerate IM **(generic)**<br>Estradiol cypionate IM (**Depo-Estradiol)**<br><br>**Non-Preferred**<br>Estradiol valerate IM (**Delestrogen**)<br>Estradiol Transdermal Patch (**Minivelle, Vivelle Dot, Alora, Menostar, Climara**)<br>Estradiol gel (**Elestrin, Divigel)** | Estrogen therapy may be considered medically necessary for treatment of **gender dysphoria** if the following criteria are met:<br>**1.** Diagnosis of gender dysphoria as defined by the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5); **AND**<br>**2.** Patient identifies as male-to-female (MTF) or non-binary; **AND**<br>3. Patient has been informed of irreversible effects, including potential loss of fertility; **AND**<br>4. Informed consent is given for the treatment of gender dysphoria; **AND**<br>5. If patient is less than 17 years of age:<br>a. Informed consent was given by the parents or other legal guardians, as applicable; **AND**<br>b. A clinician experienced in pubertal assessment has determined hormone treatment to be appropriate; **AND**<br>6. Patient's risk has been evaluated and treated (if necessary) for the following prior to initiation of estrogen therapy:<br>a. History of breast cancer<br>b. Venous thromboembolism<br>c. Cardiovascular disease<br>d. Cerebrovascular disease<br>e. Severe liver dysfunction<br>f. History of migraines<br>g. Prolactinoma<br><br>If ALL criteria are met, the request may be **approved for 12 months.** |
| | **Criteria (Reauthorization)** |
| | Estrogen products may be reauthorized with documentation of appropriate use (defined by criteria 1-7 above) and positive clinical response<br><br>If ALL criteria are met, the request may be **approved for 12 months.** |
| **Gender dysphoria/Puberty Suppression –** Gonadotropin-releasing Hormone (GnRH) Agonist Therapy | **Gonadotropin-releasing Hormone (GnRH) Agonist Therapy** may be approved for **puberty suppression in the context of gender dysphoria** when the following criteria are met:<br><br>1. A diagnosis of gender dysphoria by a qualified health professional as defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5); **AND** |

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| Histrelin implant **(Supprelin, Vantas)**<br>Leuprolide **(Lupron Depot-Ped, Lupron Depot)**<br>Triptorelin **(Triptodur)**<br>Goserlin **(Zoladex)** | 2. Client is an adolescent (less than 17 years old) with documentation that the first physical changes of puberty have arrived (Tanner stage 2); **AND**<br>3. Documentation that puberty is ongoing and has not completed (Tanner stage 5); **AND**<br>4. Confirmation from a mental health professional that **ALL** of the following are true:<br>a. Coexisting social, medical, or psychological problems have been managed to allow successful initiation of treatment; **AND**<br>b. Client has sufficient mental capacity to make fully informed decisions; **AND**<br>c. Behavioral health provider specializes in the treatment of gender dysphoria in adolescents<br>5. Client has been educated about possible adverse effects, including potential loss of fertility; **AND**<br>6. Informed consent was given by the patient **AND** the parents or other legal guardians, if applicable.<br><br>**Gonadotropin-releasing Hormone (GnRH) Agonist Therapy** may be approved for **the treatment of gender dysphoria** as gender affirming hormone therapy when the following criteria are met:<br><br>1. A diagnosis of gender dysphoria as defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5); **AND**<br>2. Patient identifies as a male-to-female (MTF) or non-binary; **AND**<br>3. Patient meets the criteria for appropriate estrogen therapy (see estrogen criteria).<br><br>If ALL criteria are met, the request may be **approved for 12 months.** |
| | **Criteria (Reauthorization)** |
| | GnRH agonist therapy may be reauthorized when the following criteria are met:<br><br>1. Documentation of positive clinical response; **AND**<br>2. If used for puberty suppression, documentation of ongoing need, including appropriate consent for continued treatment<br><br>If ALL criteria are met, the request may be **approved for 12 months** |

## Dosage and quantity limits

| Drug Class | Product | Usual dose regimen | Quantity Limits |
|---|---|---|---|
| **Testosterone** - | Testosterone cypionate | **Adult:** 100 to 200 mg IM every 2 weeks<br>**Adolescent (Induction of puberty):** 25 $mg/m^2$ titrated up to 100 $mg/m^2$ IM every 2 weeks<br>**Adolescent (Post-puberty):** 75 mg titrated to 125 mg IM every 2 weeks | **100mg/mL:** 400mg per 28 days<br>**200mg/mL**: 400 mg per 28 days |

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| | Testosterone enanthate | **Adult:** 100 to 200 mg IM every 2 weeks or 50% subQ every week<br>**Adolescent (Induction of puberty):** 25 mg/m$^2$ titrated up to 100 mg/m$^2$ IM or subQ every 2 weeks<br>**Adolescent (Post-puberty):** 75 mg titrated to 125 mg IM or subQ every 2 weeks | **50mg/0.5mL:** 200 mg per 28 days<br>**75mg/0.5mL:** 300 mg per 28 days<br>**100mg/0.5mL:** 400 mg per 28 days |
| | Testosterone undecanoate | **Adult:** 1000 mg IM at 0 and 6 weeks, then every 12 weeks | **250mg/mL:** 750 mg per 30 days |
| | Testosterone transdermal gel 1.62% | **Adult:** 50 to 100 mg topically daily | **Gel packet (20.25mg/1.25g):** 90 packets (112.5g) per 30 days<br>**Gel packet (40.5mg/2.5g):** 90 packets (225 g) per 30 days<br>**Gel pump (20.25mg/1.25g):** 3 containers (225 g) |
| | Testosterone transdermal patch | **Adult:** 2.5 to 7.5 mg transdermal daily | **2 mg patch:** 60 per 30 days<br>**4 mg patch:** 60 per 30 days |
| | Testosterone pellets (implant) | **Adult:** 150 mg to 450 mg subcutaneously every 3 to 6 months | |
| **Estrogen** | Estradiol (Estrace) | **Adult:** 2 to 8mg orally daily<br>**Adolescent (Induction of puberty):** 5mcg/kg/day orally. Increase by 5mcg/kg/day every 6 months until adult dose achieved<br>**Adolescent (Post-puberty):** 1mg orally daily. Increase to 2 mg daily after 6 months | **0.5 mg tab:** 90 tabs per 30 days<br>**1 mg tab:** 90 tabs per 30 days<br>**2 mg tab:** 120 tabs per 30 days |
| | Estradiol transdermal patch | **Adult:** 25 to 200 mcg/24 hour patch applied topically every 3 to 5 days<br>**Adolescent (Induction of puberty):** 6.25 to 12.6 mcg/day patch applied every 3.5 days; increase dosage by 12.5 mcg/24 hours every 6 months to adult dosage | |
| | Estradiol valerate injection (Depo-Estradiol) | **Adult:** 5 to 30 mg IM every 2 weeks | |
| | Estradiol cypionate injection (Delestrogen) | **Adult:** 2 to 10 mg IM every week | |
| **Gonadotropin-releasing Hormone (GnRH) Agonist Therapy** | Histrelin implant **(Supprelin, Vantas)** | **Adolescent:** 50 mg implant every 12 months | 1 implant/ 12 months |

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| | Leuprolide (Eligard, Lupron Depot) | **Adult:** 3.75 mg subQ or IM monthly or 11.25 mg every 3 months in combination with estrogen<br>**Adolescent:** Dose tailored to achieve puberty suppression | **Lupron Depot**<br>3.75 mg/syringe (1 month): 1 per 30 days<br>11.25 mg/syringe (3 month): 1 per 90 days<br>**22.5 mg/syringe (3 month): 1 per 90 days**<br>**Lupron Depot - PED**<br>7.5mg/syringe (1 month): 1 per 30 days<br>11.25mg /syringe (1 month): 1 per 30 days<br>15mg/syringe (1 month): 1 per 30 days<br>11.25 mg/syringe (3 month): 1 per 90 days<br>30mg/syringe (3 month): 1 per 90 days |
| | Triptorelin **(Triptodur)** | **Adolescent:** 22.5 mg IM every 6 months | 22.5 mg per 180 days |
| | Goserelin **(Zoladex)** | **Adult:** 3.8 mg subQ implant every 4 weeks in combination with estradiol valerate | **Implant:** 3.8 mg per 28 days |

## Coding:

| HCPCS Code | *Description* |
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| C9023 | Injection, testosterone undecanoate, 1 mg |
| J1000 | Injection, depo-estradiol cypionate, up to 5 mg |
| J1380 | Injection, estradiol valerate, up to 10 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 |

Washington State Health Care Authority

# Request For Additional Clinical Information

**PLEASE FAX RESPONSE TO: 1-866-668-1214**

DRUG UTILIZATION REVIEW TEAM

*Assuring the highest quality of care by guiding the appropriate use for Medicaid client*

| DATE OF REQUEST | REFERENCE NUMBER | MAS |
|---|---|---|
| | | |

**PLEASE PRINT.** Please provide the information below, **PRINT** your answer, **attach supporting documentation**, sign, date and return to our office as soon as possible to expedite this request. **Without this information the request may be denied in seven (7) working days.**

| PATIENT | DATE OF BIRTH | PROVIDERONE CLIENT ID |
|---|---|---|
| | | |

| PHARMACY NAME | PHARMACY NPI | TELEPHONE NUMBER | FAX NUMBER |
|---|---|---|---|
| | | | |

| PRESCRIBER | TELEPHONE NUMBER | FAX NUMBER |
|---|---|---|
| | | |

| DRUG/STRENGTH | DIRECTIONS FOR USE | QUANTITY / DAYS SUPPLY |
|---|---|---|
| | | |

1. What is the diagnosis and date of diagnosis for which this drug has been prescribed?

2. What alternatives have been tried?

   What were the outcomes?

   Length of trial?

3. Is there another prescriber/specialist involved with this patient's care for the same or related condition?
   ☐ Yes ☐ No
   If so, please send relevant reports and recommendations.

4. **BRAND vs. GENERIC**: In order to consider a request for a brand name drug for approval, the patient MUST have had a trial of the generic and there must be supporting clinical documentation of observed adverse reactions. Please attach and fax documentation, or write below.

5. Please justify use of drug if prescribed for other than FDA approved indications. Please attach supporting refereed medical journal citations.

6. Other

| PRESCRIBER SIGNATURE | PRESCRIBER SPECIALTY | DATE |
|---|---|---|
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Washington State Health Care Authority

COVER SHEET REQUIRED

# Instructions on how to obtain and create the barcode cover sheet for Pharmacy Prior Authorization (PA) Supporting Documents

To link your supporting documentation to an existing authorization, you must include the cover sheet for Pharmacy PA Supporting Documents as the first page of your fax.

**Step 1:** Go to Document Submission Cover Sheets
http://www.hca.wa.gov/billers-providers/claims-and-billing/document-submission-cover-sheets

**Step 2:** Click on Prior authorization request.

**Step 3:** Click on Pharmacy prior authorization (PA) supporting documents

**Step 4:** Manually key the Pharmacy RX Auth Reference # on the cover sheet.

**Step 5:** Press **Enter** to configure the barcode to your reference number.

**Step 6:** Choose **Print Cover Sheet** on the cover sheet.

**Step 7:** Place any supporting documentation behind the Pharmacy PA Supporting Documents cover sheet and fax to:

**1-866-668-1214**
Drug Utilization Team

Please follow these steps so we can promptly process your request. **We must return the fax to you for correction if you do not accurately prepare it.** We appreciate your assistance in expediting requests for authorization.

**What are Pharmacy PA Supporting Documents cover sheets?**

Cover sheets are used when submitting the supporting documentation for the PA request that is being held for additional information.

- They help the Health Care Authority quickly match your response to requests submitted by pharmacies for the authorization of specific medications.
- They are needed when you fax your response to a request for more information or submit other back-up documentation to support the medical necessity of an authorization request.