

## PHARMACY POLICY STATEMENT

### Marketplace

|                         |  |
|-------------------------|--|
| <b>DRUG NAME</b>        | <b>Gender Identity Hormone Therapy</b> |
| BILLING CODE            | Must use valid NDC or J code           |
| BENEFIT TYPE            | Medical or Pharmacy                    |
| SITE OF SERVICE ALLOWED | Home/Office                            |
| STATUS                  | Prior Authorization Required           |

Gender dysphoria is a condition of feeling one’s emotional and psychological identity as male or female to be incongruent to one’s assigned sex at birth. Gender-affirming hormone therapy can be used to allow different degrees of masculinization or feminization tailored to the patient’s needs. For example, masculinizing hormone therapy includes medications that will increase testosterone levels to cause masculinizing changes to occur. In contrast, feminizing hormone therapy includes medications that reduce testosterone levels while raising estrogen level to allow feminizing changes to occur. Patients may also identify as non-binary and require flexible interventions. As a result, hormone therapy must be individualized based on a patient’s goals, the risk/benefit ratio of medications, the presence of other medical conditions, and consideration of social and economic issues. Hormone treatment is not recommended for prepubertal gender-dysphoric individuals. Gonadotropin-releasing hormone (GnRH) agonists may be prescribed to suppress puberty in qualifying adolescents.

Gender identity hormone therapy will be considered for coverage when the following criteria are met:

#### GnRH Agonists

For **initial** authorization:

1. Member has started puberty as evidenced by Tanner stage 2 or greater; AND
2. Medication must be prescribed by or in consultation with a pediatric endocrinologist or other clinician experienced in pubertal assessment; AND
3. Member has a diagnosis of persistent gender dysphoria present for at least 6 months duration associated with clinically significant distress or functional impairment; AND
4. If medication requires a step therapy, must have a trial and failure of, or contraindication to the preferred product; AND
5. Provider attests the member has sufficient mental capacity to make a fully informed decision and to consent to treatment; AND
6. If coexisting medical or mental health concerns are present, they must be reasonably well controlled before commencing treatment.
7. **Dosage allowed/Quantity limit:** See Table 1 for dosing suggestions.

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes must show the member is experiencing clinical benefit from the use of GnRH agonist therapy.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

## Gender-Affirming Hormones

For **initial** authorization:

1. Member is at least 16 years of age; AND
2. Medication must be prescribed by or in consultation with a pediatric endocrinologist or other clinician experienced in pubertal induction (or can be by a mental health provider in adults); AND
3. Member has a diagnosis of persistent gender dysphoria present for at least 6 months duration and associated with clinically significant distress or functional impairment; AND
4. If medication requires a step therapy, must have a trial and failure of, or contraindication to the preferred step therapy product; AND
5. Provider attests the member has sufficient mental capacity to make a fully informed decision and to consent to treatment; AND
6. If significant medical or mental health concerns are present, they must be reasonably well controlled before starting gender-affirming therapy.
7. **Dosage allowed/Quantity limit:** See Table 1 for dosing suggestions.

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes must show the member is experiencing clinical benefit from the use of gender-affirming therapy.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

**CareSource considers gender identity hormones not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

| DATE       | ACTION/DESCRIPTION  |
|------------|---|
| 04/24/2021 | New policy for Gender-Affirming Therapy created.  |
| 03/18/2022 | Changed policy title to 'Gender Identity Hormone Therapy.' Separated policy into 2 sections, gender affirming hormones and GnRH agonists (added new section). Added sentence to intro. Edited specialist wording. Added significant distress and present at least 6 mo specified as persistent gender dysphoria (per guidelines). Removed Tanner stage from gender affirming section as that is more applicable to the GnRH section. In Table 1, clarified that these doses are what is recommended for trans adults. |

### References:

1. 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.
2. Unger CA. Hormone therapy for transgender patients. *Transl Androl Urol.* 2016;5(6):877-884. doi:10.21037/tau.2016.09.04.
3. UCSF Transgender Care, Department of Family and Community Medicine, University of California San Francisco. Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People; 2nd edition. Deutsch MB, ed. June 2016. Available at [transcare.ucsf.edu/guidelines](http://transcare.ucsf.edu/guidelines).
4. Hashemi L, Weinreb J, Weimer AK, Weiss RL. Transgender Care in the Primary Care Setting: A Review of Guidelines and Literature. *Fed Pract.* 2018;35(7):30-37.
5. World Professional Association for Transgender Health. (2012). Standards of Care for the Health of Transsexual, Transgender, and Gender-Conforming People [7th Version].

### **Table 1**

Please note that this is not a comprehensive list of all available gender hormone therapy options. The dosing regimens listed below are generally accepted dosing regimens for **transgender adults** in current guidelines. Actual dosing of medications may vary for certain patients to achieve hormonal goal levels.

| Hormone  | Dosing Regimen  |
|--|---|
| <b>Testosterone Therapy</b>                                    |   |
| Testosterone transdermal gel 1%, 1.62%, 2%                     | 50 – 100 mg/day   |
| Testosterone transdermal patch (AndroDerm)                     | 2.5 - 7.5 mg/day  |
| Testosterone enanthate or cypionate                            | 100 – 200 mg every 2 weeks OR<br>50 – 100 mg every week |
| Testosterone undecanoate (Aveed)                               | 1000 mg every 12 weeks                                  |
| <b>Estrogen/Progesterone Therapy</b>                           |   |
| Estradiol oral   | 2 - 6 mg daily  |
| Estradiol transdermal patch                                    | 0.025 – 0.2 mg patch twice weekly                       |
| Estradiol valerate (Delestrogen)                               | 5 – 30 mg every 2 weeks                                 |
| Estradiol cypionate (Depo-Estradiol)                           | 2 – 10 mg every week                                    |
| Progesterone   | 20 - 60 mg daily  |
| Medroxyprogesterone acetate (Depo-Provera)                     | 150 mg every 3 months                                   |
| <b>GnRH Agonist</b>  |   |
| Leuprolide (Lupron Depot, Lupron Depot-PED, Eligard, Fensolvi) | 3.75 - 7.5 mg monthly OR<br>11.25 mg every 3 months     |
| Goserelin (Zoladex) implant                                    | 3.6 mg monthly  |
| <b>Anti-androgens</b>  |   |
| Spironolactone   | 100 - 300 mg daily                                      |

Effective date: 10/01/2022

Revised date: 03/18/2022