CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Gender–Affirming Hormone Therapy
BILLING CODE	Must use valid NDC or J code
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
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. Patient's 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.

Gender-affirming therapy will be considered for coverage when the following criteria are met:

Gender Dysphoria

For **initial** authorization:

1. Member is at least 16 years of age; AND
2. Medication must be prescribed by or in consultation with a mental health provider or a pediatric endocrinologist who has experience in providing gender-affirming therapy; AND
3. Member has a diagnosis of gender dysphoria with all of the following:
   a) Persistent, well-documented gender dysphoria;
   b) If member is under 18 years of age, puberty has started (Tanner stage 2 or greater); 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 that member has sufficient mental capacity to make a fully informed decision and to consent for 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 that 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-Affirming Therapy 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.

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.
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-affirming therapy options. The dosing regimens listed below are generally accepted dosing regimens in current guidelines. Actual dosing of medications might vary for certain patients to achieve hormonal goal levels.

Gender-Affirming Therapy	Dosing Regimen
Testosterone Therapy	
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 50 – 100 mg every week
Testosterone undecanoate (Aveed)	1000 mg every 12 weeks
Estrogen/Progesterone Therapy	
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
GnRH Agonist	
Leuprolide (Lupron Depot, Lupron Depot-PED, Eligard, Fensolvi)	3.75 - 7.5 mg monthly OR 11.25 mg every 3 months
Goserelin (Zoladex) implant	3.6 mg monthly
Anti-androgens	
Spironolactone	100 - 300 mg daily

Effective date: 10/01/2021
Revised date: 04/24/2021