

PHARMACY POLICY STATEMENT

Ohio Medicaid

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| DRUG NAME | Gender Identity Hormone Therapy |
| BENEFIT TYPE | Medical |
| 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 and Gender-Affirming Hormones

For initial authorization:

1. CareSource complies with state and federal regulations for the coverage of medically necessary services. Medically necessary services are health care services needed to diagnose or treat that meet the accepted standards of medicine. 42 C.F.R. § 440.230. All requests are reviewed on a case-by-case basis, including any applicable requests under the Early Periodic Screening, Diagnosis and Treatment (EPSDT) program; AND
2. For any member under the age of 18, Ohio Revised Code § 3129.06 prohibits coverage of gender transition services, subject to certain exceptions as follows:
 - a) Mental health services provided for a gender-related condition
 - b) Treatment, including surgery or prescribing drugs or hormones, to a minor who
 - i) Was born with a medically verifiable disorder of sex development
 - ii) Received a diagnosis of a disorder of sexual development
 - iii) Needs treatment for any infection, injury, disease, or disorder that has been caused or exacerbated by the performance of gender transition services; OR
3. Any member between the ages of 18 years and 21 age 18 to 20 years, as per 42 CFR § 441.56 and 42 U.S.C. § 1396d(r), will be reviewed for medical necessity as required by the EPSDT program (ie, Ohio Healthchek). CareSource will cover medically necessary care if deemed essential by a healthcare provider, including gender-related care; OR
4. For any member 21 years of age or older, gender transition services are not covered services; AND
5. All behavioral health services for gender dysphoria will be subject to the same utilization management and cost-sharing requirements as other behavioral and medical benefits in compliance with Mental Health Parity and Addiction Equity Act. 42 U.S.C. § 300gg-26; 45C.F.R. Part 146; AND

6. If medication requires a step therapy, must have a trial and failure of, or contraindication to the preferred product; AND
7. Provider attests the member has sufficient mental capacity to make a fully informed decision and to consent to treatment; AND
8. If coexisting medical or mental health concerns are present, they must be reasonably well controlled before commencing treatment.
9. **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 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. |
| 10/6/2022 | Updated to medical benefit and removed pharmacy benefit drugs from policy due to OH single PBM. |
| 10/29/2024 | Annual review. No updates. Approved by ODM 11/28/2024. |
| 06/24/2025 | Updated references; combined gender affirming hormones and GnRH agonists indication sections; removed age limit; added criteria 1,2,3,4 and 5 to align with medical policy and revised law; removed diagnosis confirmation; added definitions |
| <u>11/4/2025</u> | <u>Clarified age per 42 CFR § 441.56 and 42 U.S.C. § 1396d(r)</u> |

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. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. *Int J Transgend Health.* 2022;23(Suppl 1):S1-S259. Published 2022 Sep 6. doi:10.1080/26895269.2022.2100644

6. House Bill 68. 135th General Assembly. Ohio Legislature. Accessed June 24, 2025. <https://www.legislature.ohio.gov/legislation/135/hb68>.
7. Ohio Administrative Code. (2022, February 23). 5160-1-01 (C) Medicaid medical necessity: definitions and principles. Retrieved February 22 2023 from codes.ohio.gov.
8. Ohio Administrative Code. (2022, July 18). 5160-26-03 Managed care: covered services. Retrieved February 22, 2023 from codes.ohio.gov.
9. Ohio Administrative Code. (2020, January 1). 5160-9-03 Pharmacy services: covered drugs and associated limitations. Retrieved February 22, 2023 from codes.ohio.gov.

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 |
|--|---|
| Testosterone Therapy | |
| 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 valerate (Delestrogen) | 5 – 30 mg every 2 weeks |
| Estradiol cypionate (Depo-Estradiol) | 2 – 10 mg every week |
| 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 |

Definitions:

- A. **Cross-Sex Hormone** – Testosterone, estrogen, or progesterone given to a minor individual in an amount greater than would normally be produced endogenously in a healthy individual of the minor individual's age and sex.
- B. **Gender Transition Services** – Any medical or surgical service (including physician services, inpatient and outpatient hospital services, or prescription drugs or hormones) provided for the purpose of assisting an individual with gender transition that seeks to alter or remove physical or anatomical characteristics or features that are typical for the individual's biological sex, or to instill or create physiological or anatomical characteristics that resemble a sex different from the individual's birth sex, including medical services that provide puberty blocking drugs, cross-sex hormones, or other mechanisms to promote the development of feminizing or masculinizing features in the opposite sex, or genital or non-genital gender reassignment surgery.
- C. **Minor** – Any member under the age of 18. Ohio Rev. Code § 3129.01(I).
- D. **Puberty-Blocking Drugs** - Gonadotropin-releasing hormone analogs 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 delay or suppress normal puberty.

Effective date: TBD01/01/2026

Revised date: 07/16/11/04/2025

OH-MED-P-366685



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3. Any member age 18 to 20 years, as per 42 CFR § 441.56 and 42 U.S.C. § 1396d(r), will be reviewed for medical necessity as required by the EPSDT program (ie, Ohio Healthchek). CareSource will cover medically necessary care if deemed essential by a healthcare provider, including gender-related care; OR
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Effective date: 01/01/2026

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