Clinical Policy: Gender Affirming Treatments

Reference Number: WA.PHAR.142
Effective Date: 09.01.24
Last Review Date: 08.24, 02.25
Line of Business: HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Gender-affirming treatment is a service or product that a health care provider prescribes to an individual to treat any condition related to the individual's gender identity and is prescribed in accordance with generally accepted standards of care. Examples of gender-affirming pharmaceutical treatments may include, but are not limited to: finasteride (Propecia®), eflornithine (Vaniqa®), botulinumtoxin, and hyaluronic acid injections.

For gender-affirming hormone therapy, refer to WA.PHAR.104 for Medicaid only

For non-pharmaceutical, medical procedures, refer to WA.CP.MP.95.

FDA Approved Indication(s)

Not Applicable.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that gender-affirming treatment is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Gender Affirming Treatment (must meet all)**:**

1. Diagnosis of gender incongruence, gender dysphoria, or request is for gender-transition;
2. Requested agent is an FDA-approved product that is prescribed in accordance with generally accepted standards of care (e.g., WPATH guidelines);
3. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months or duration of request, whichever is less

II. Continued Therapy

A. Gender Affirming Treatment (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;

2. Member is responding positively to therapy (e.g., member continues to meet their individual goals of therapy for gender affirming therapy);
3. If request is for a dose increase, new dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months or duration of request, whichever is less

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not Applicable.

Appendix C: Contraindications/Boxed Warnings
Not Applicable.

V. Dosage and Administration

Not Applicable.

VI. Product Availability

Not Applicable.

VII. References

1. Coleman E, Radix AE, Bouman WP, et al. Standards of care for the health of transgender and gender diverse people, version 8. International Journal of Transgender Health. 2022; 23(S1):S1-S259. https://doi.org/10.1080/26895269.2022.2100644.
2. Washington State Legislature RCW Title 48 Chapter 43 Section 0128. Available at: https://app.leg.wa.gov/rcw/default.aspx?cite=48.43.0128. Accessed July 26,2024.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07.10.24	08.24
Added clarification to the policy that the WA.PHAR.104 Hormone Therapy for Gender Dysphoria policy is applicable for Medicaid only	01.24.25	02.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.