Clinical Policy: Gender Dysphoria

Reference Number: OR.CP.PHAR.1002
Effective Date: 10.1.21
Last Review Date: 09.24
Line of Business: Medicaid – Trillium Oregon Health Plan Revision Log

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

Description
This policy applies to all medication requests used for the treatment of gender dysphoria. Including, but not exclusive to hormone treatment with GnRH analogues for delaying the onset of puberty and/or continued pubertal development and gender-affirming cosmetic agents and hormonal therapy for the treatment of gender dysphoria.

All requests for continued coverage of an agent used for the treatment of gender dysphoria are subject to the requirements in section II.A. of this clinical policy. This includes requests for members who received the agent prior to Trillium Community Health plan coverage.

Preferred Agents:
- GnRH Analogue:
  - Leuprolide acetate: 3.75mg; 11.25mg Intramuscular Powder for Suspension
- Gender-Affirming Hormonal Therapy:
  - Male-Affirming Hormonal Therapy:
    - Testosterone cypionate: 100mg/ml; 200mg/ml Intramuscular Oil
    - Testosterone enanthate: 200mg/ml Intramuscular Oil
    - Testosterone TD gel: 1% and 1.62% gel
  - Female-Affirming Hormonal Therapy:
    - Estradiol: 0.5mg; 1mg; 2mg Tablets
    - Estradiol TD patch:
      - 0.025mg/24HR; 0.05mg/24HR; 0.0375mg/24HR; 0.075mg/24HR; 0.1mg/24HR biweekly patch
      - 0.025mg/24HR; 0.0375mg/24HR; 0.05mg/24HR; 0.06mg/24HR; 0.075mg/24HR, 0.1mg/24HR weekly patch
    - Estradiol Valerate: 20mg/ml; 40mg/ml Intramuscular Oil

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 Trillium Community Health Plan that pharmaceutic treatment of gender dysphoria is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria
A. GnRH Analogue Therapy (must meet all):

1. Member has a diagnosis of a gender identity disorder (ICD 10: F64.0-F64.9; Z87.890) made by a health professional with experience in gender dysphoria;
2. Member has completed a comprehensive mental health evaluation;
3. Submitted documentation supports member's eligibility and readiness for initiation of puberty suppression therapy;
4. Member meets one of the following (a or b):
   a. Member has reached or passed through Tanner Stage 2* and is <18 years of age;
      **Age ranges approximating Tanner Stage 2 pubertal development extend from 8 to 13 years of age in girls and 9 to 14 years of age in boys.*
   b. Member is ≥18 years of age and has failed to achieve physiologic hormone levels with gender-affirming hormonal therapy (e.g., estrogen, testosterone) unless contraindicated or clinically significant adverse effects are experienced;
5. Request is for a preferred GnRH analogue agent listed above or all of the following is met for coverage of a non-preferred agent (a, b, and c);
   a. Failure of at least two preferred agents within the same therapeutic class that are FDA-approved for the same indication and/or drugs that are considered the standard of care for the indication, when such agents exist, at up to maximally indicated doses, each used for the appropriate duration of treatment or for ≥ 30 days for diseases requiring maintenance treatment, unless clinically significant adverse effects are experienced or all are contraindicated;
   b. Trial and failure of preferred agents is supported by one of the following (I, ii, iii, or iv):
      i. Presence of claims in pharmacy claims history supporting failure of preferred agents as described in criteria 2 above;
      ii. Documented contraindication(s) or clinically significant adverse effects to **all** preferred agents within the same therapeutic class or preferred drugs that are recognized as standards of care for the treatment of member's diagnosis;
      iii. Drug sample logs which include all of the following: medication name, dose/strength, lot number, expiration date, quantity dispensed, date sample was provided, and initials/title of the dispenser;
      iv. Documentation in provider chart notes which include all of the following: medication name, dose/strength, and start/end dates of therapy;
   c. For combination product or alternative dosage form or strength of existing drugs, medical justification* supports inability to use the individual drug products concurrently or alternative dosage forms or strengths (e.g., contraindications to the excipients of all alternative products);
      **Use of a copay card or discount card does not constitute medical necessity*
6. 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: up to 12 months

***Guideline Note 127 of the Prioritized List is considered to be met if initial approval criteria is met.**

B. Gender-Affirming Hormonal Therapy (must meet all)**:**

1. Member has a diagnosis of a gender identity disorder (ICD 10: F64.0-F64.9; Z87.890);
2. If patient <18 years of age, the prescriber is a pediatric endocrinologist;
3. Request is for a preferred gender-affirming hormonal therapy agent listed above or all of the following is met for coverage of a non-preferred agent (a, b, and c);
   a. Failure of at least two preferred agents within the same therapeutic class that are FDA-approved for the same indication and/or drugs that are considered the standard of care for the indication, when such agents exist, at up to maximally indicated doses, each used for the appropriate duration of treatment or for ≥ 30 days for diseases requiring maintenance treatment, unless clinically significant adverse effects are experienced or all are contraindicated;
   b. Trial and failure of preferred agents is supported by one of the following (I, ii, iii, or iv):
      i. Presence of claims in pharmacy claims history supporting failure of preferred agents as described in criteria 2 above;
      ii. Documented contraindication(s) or clinically significant adverse effects to **all** preferred agents within the same therapeutic class or preferred drugs that are recognized as standards of care for the treatment of member's diagnosis;
      iii. Drug sample logs which include all of the following: medication name, dose/strength, lot number, expiration date, quantity dispensed, date sample was provided, and initials/title of the dispenser;
      iv. Documentation in provider chart notes which include all of the following: medication name, dose/strength, and start/end dates of therapy;
   c. For combination product or alternative dosage form or strength of existing drugs, medical justification* supports inability to use the individual drug products concurrently or alternative dosage forms or strengths (e.g., contraindications to the excipients of all alternative products);
      **Use of a copay card or discount card does not constitute medical necessity*
4. 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: up to 12 months

***Guideline Note 127 of the Prioritized List is considered to be met if initial approval criteria is met.**

C. Other Drugs/Therapeutics Prescribed as Part of the Treatment of Gender Dysphoria (must meet all)**:**

1. Member has a diagnosis of a gender identity disorder (ICD 10: F64.0-F64.9; Z87.890);
2. Requested agent is prescribed as part, or in support of member's gender dysphoria treatment;
3. The requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized);
4. If request is for a non-preferred agent, all the following must be met (a, b, and c):
   a. Failure of at least two preferred agents within the same therapeutic class that are FDA-approved for the same indication and/or drugs that are considered the

standard of care for the indication, when such agents exist, at up to maximally indicated doses, each used for the appropriate duration of treatment or for ≥ 30 days for diseases requiring maintenance treatment, unless clinically significant adverse effects are experienced or all are contraindicated;

b. Trial and failure of preferred agents is supported by one of the following (I, ii, iii, or iv):
   i. Presence of claims in pharmacy claims history supporting failure of preferred agents as described in criteria 2 above;
   ii. Documented contraindication(s) or clinically significant adverse effects to **all** preferred agents within the same therapeutic class or preferred drugs that are recognized as standards of care for the treatment of member's diagnosis;
   iii. Drug sample logs which include all of the following: medication name, dose/strength, lot number, expiration date, quantity dispensed, date sample was provided, and initials/title of the dispenser;
   iv. Documentation in provider chart notes which include all of the following: medication name, dose/strength, and start/end dates of therapy;

c. For combination product or alternative dosage form or strength of existing drugs, medical justification* supports inability to use the individual drug products concurrently or alternative dosage forms or strengths (e.g., contraindications to the excipients of all alternative products);
   **Use of a copay card or discount card does not constitute medical necessity*

5. Request meets one of the following (a or b):
   a. Dose does not exceed the FDA approved maximum recommended dose for the relevant indication and health plan approved daily quantity limit;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: up to 12 months.
***Guideline Note 127 of the Prioritized List is considered to be met if initial approval criteria is met.**

II. Continued Therapy

A. All Medications for Treatment of Gender Dysphoria (must meet all):

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Documentation supports that member is currently receiving medication or has previously been on medication for treatment of gender dysphoria;
2. 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: up to 12 months
***Guideline Note 127 of the Prioritized List is considered to be met if initial approval criteria is met.**

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

A. Services considered experimental or investigational, that deviates from acceptable and customary standards of medical practice or for which there is insufficient outcome data to indicate efficacy.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
GnRH: gonadotropin-releasing hormone
WPATH: World Professional Association for Transgender Health

Appendix B: Definitions

Gender Dysphoria: Discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics).

Tanner Stages: Sexual maturity staging system consisting of systematized descriptions of the development of secondary sexual characteristics, consisting of breast changes in females, genital changes in males, and pubic hair changes in both males and females. Five stages, with stage 1 representing prepuberty and stage 5 representing adult development.

Tanner Stages of Secondary Sexual Characteristics
Boys – Development of external genitalia
Stage 1: Prepubertal
Stage 2: Enlargement of testes and scrotum; scrotal skin reddens and changes in texture
Stage 3: Enlargement of penis (length at first); further growth of testes
Stage 4: Increased size of penis with growth in breadth and development of glans; testes and scrotum larger, scrotal skin darker
Stage 5: Adult genitalia
Girls – Breast development
Stage 1: Prepubertal
Stage 2: Breast bud stage with elevation of breast and papilla; enlargement of areola
Stage 3: Further enlargement of breast and areola; no separation of their contour
Stage 4: Areola and papilla form a secondary mound above level of breast
Stage 5: Mature stage: Projection of papilla only, related to recession of areola
Boys and girls – Pubic hair
Stage 1: Prepubertal (the pubic area may have vellus hair, similar to that of forearms)
Stage 2: Sparse growth of long, slightly pigmented hair, straight or curled, at base of penis or along labia
Stage 3: Darker, coarser, and more curled hair, spreading sparsely over junction of pubes
Stage 4: Hair adult in type, but covering smaller area than in adult; no spread to medial surface of thighs
Stage 5: Adult in type and quantity, with horizontal upper border

V. References

1. Prioritized List of Health Services Guideline Note 127, Gender Dysphoria. OHA: Oregon Health Authority. Available at www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx. Last update: February 1, 2023. Accessed August 29, 2024.
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5. Rafferty J. Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents. Policy statement. American Academy of Pediatrics. Pediatrics; 142(4), October 2018:e20182162.
6. Deutsch MB. Guidelines for the primary and gender-affirming care of transgender and gender nonbinary people. Center of Excellence for Transgender Health. Department of Family & Community Medicine, University of California, San Francisco; 2nd Ed, published June 17, 2016.
7. Coleman E, Bockting W, Botzer M, et al. Standards of care for the health of transsexual, transgender, and gender nonconforming people. WPATH: World Professional Association for Transgender Health. 7th version; 2012. Available at www.wpath.org.
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9. Wylie KR, Fung R, Boshier C, Rotchell M. Recommendations of endocrine treatment for patients with gender dysphoria. Sexual and Relationship Therapy Vol. 24, No. 2, May 2009, 175–187.
10. Biro FM, ChanY. Normal Puberty. Hoppin AG (Ed.), *UpToDate.* Available at www.uptodate.com/contents/normal-puberty. Last update February 2, 2023. Accessed August 29, 2024.

Reviews, Revisions, and Approvals	Date	Plan Approval Date
Policy created: adapted from previously approved policy TCHP.PHAR.1907 Gender Dysphoria. Removed requirement that all initial approvals are sent to MD for determination. Added that diagnosis of gender dysphoria should be made by a health professional with experience in gender dysphoria in I.A.1. and I.B.1. Removed requirement in I.A. for persistent well documented gender dysphoria, medical/mental health concerns are well controlled, and that compressive mental health evaluation is provided in accordance to version 7 of the WPATH standards of care. In I.B. added that gender-affirming hormonal therapy is to be prescribed by a pediatric endocrinologist if <18 years of age and that medical/mental health concerns may also be referred for further evaluation and/or	07.13.21	07.15.21

treatment, removed that compressive mental health evaluation is provided in accordance to version 7 of the WPATH standards of care, changed "eligibility and readiness" to "capacity to make fully informed decisions and give consent".		
Added clarification that if initial approval criteria is met then Guideline Note 127 of the Prioritized List is met. Updated policy ID for non-preferred agent review.	10.06.21	10.25.21
Added testosterone gel to preferred agent list.	01.14.22	02.07.22
Added progesterone TD patches to preferred agent list. Edited I.B. coverage guidelines for gender-affirming hormone treatment to no longer require proof of mental health evaluation; removed requirement for medical & mental health concerns to be well controlled or referred for treatment; removed requirement to submit proof that member is able to make fully informed decisions. Edited II.A. to no longer to require proof that member is responding positively to therapy.	03.17.22	04.07.22
Added estradiol valerate IM oil to list of preferred agents to reflect current available formulary options.	09.16.22	10.06.22
4Q 2023 annual review: no significant changes; template changes applied to other diagnoses/indications and continued therapy section; references reviewed and updated.	09.19.23	11.21.23
Expanded scope of clinical policy to cover requests of all agents used for the treatment of gender dysphoria; edited Section III to only exclude coverage of experimental/investigational services; clarified that all continued coverage requests are to be reviewed under Section II.A regardless of party that provided prior coverage; references reviewed and updated.	08.30.24	09.17.24

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.