

Clinical Policy: Triptorelin Pamoate (Trelstar, Triptodur)

Reference Number: OR.CP.PHAR.175

Effective Date: 07.01.22

Last Review Date: 11.23

Line of Business: Medicaid – Oregon Health Plan

[Coding Implications](#)
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Triptorelin pamoate (Trelstar[®], Triptodur[®]) is a gonadotropin-releasing hormone (GnRH) receptor agonist.

**Please refer to OR.CP.PHAR.1002 Gender Dysphoria for triptorelin pamoate requests for gender dysphoria use.*

FDA Approved Indication(s)

Trelstar is indicated for the palliative treatment of advanced prostate cancer.

Triptodur is indicated for the treatment of pediatric patients 2 years and older with central precocious puberty (CPP).

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 Trelstar and Triptodur are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Prostate Cancer (must meet all):

1. Diagnosis of prostate cancer;
2. Request is for Trelstar;
3. Prescribed by or in consultation with an oncologist or urologist;
4. Age \geq 18 years;
5. Request meets one of the following (a or b):*
 - a. Dose does not exceed 3.75 mg per 4 weeks, 11.25 mg per 12 weeks, or 22.5 mg per 24 weeks;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Central Precocious Puberty (must meet all):

1. Diagnosis of CPP confirmed by all of the following (a, b, and c):

- a. Elevated basal luteinizing hormone (LH) level > 0.2 - 0.3 mIU/L (dependent on type of assay used) and/or elevated leuprolide-stimulated LH level > 3.3 - 5 IU/L (dependent on type of assay used);
- b. Difference between bone age and chronological age was > 1 year (bone age-chronological age);
- c. Age at onset of secondary sex characteristics (1 or 2):
 - 1) Female: < 8 years;
 - 2) Male: < 9 years;
2. Request is for Triptodur;
3. Prescribed by or in consultation with a pediatric endocrinologist;
4. Member meets one of the following age requirements (a or b):
 - a. Female: 2 - 11 years;
 - b. Male: 2 - 12 years;
5. Dose does not exceed 22.5 mg per 24 weeks.

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1, 2, or 3):

1. Refer to OR.CP.PHAR.1002 for requests related to Gender Dysphoria.
2. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: OR.CP.PMN.1001 for Medicaid; or
3. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 or 2 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Prostate Cancer (must meet all):

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Trelstar for prostate cancer and has received this medication for at least 30 days;
2. Request is for Trelstar;
3. Member is responding positively to therapy;
4. If request is for a dose increase, request meets one of the following (a or b):*
 - a. New dose does not exceed 3.75 mg per 4 weeks, 11.25 mg per 12 weeks, or 22.5 mg per 24 weeks;
 - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Central Precocious Puberty (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. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Request is for Triptodur;
3. Member is responding positively to therapy as evidenced by, including but not limited to, improvement in any of the following parameters: decreased growth velocity, cessation of menses, softening of breast tissue or testes, arrested pubertal progression;
4. Member meets one of the following age requirement (a or b):
 - a. Female: ≤ 11 years;
 - b. Male: ≤ 12 years.
5. If request is for a dose increase, new dose does not exceed: 22.5 mg per 24 weeks.

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2):

1. Refer to OR.CP.PHAR.1002 for requests related to Gender Dysphoria
2. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: OR.CP.PMN.1001 for Medicaid; or
3. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 or 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

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 – CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CPP: central precocious puberty

DSM-5: Diagnostic and Statistical Manual of Mental Disorders, 5th edition

FDA: Food and Drug Administration

GnRH: gonadotropin-releasing hormone

LH: luteinizing hormone

NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives
 Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Hypersensitivity to triptorelin or any other component of the product, or other GnRH agonists or GnRH
 - Pregnancy (Triptodur)
- Boxed warning(s): none reported

V. Dosage and Administration

| Drug Name | Indication | Dosing Regimen | Maximum Dose |
|---------------------------------|------------------|--|--------------|
| Triptorelin pamoate (Trelstar) | Prostate cancer* | IM: 3.75 mg per 4 weeks; 11.25 mg per 12 weeks; 22.5 mg per 24 weeks | See regimen |
| Triptorelin pamoate (Triptodur) | CPP | IM: 22.5 mg IM every 24 weeks | See regimen |

**May be used in combination with therapies such as radiation therapy, antiandrogens, glucocorticoids, docetaxel.*

VI. Product Availability

| Drug Name | Availability |
|---------------------------------|---|
| Triptorelin pamoate (Trelstar) | Single-dose vial for reconstitution with Mixject system (kit): 3.75 mg, 11.25 mg, 22.5 mg |
| Triptorelin pamoate (Triptodur) | Single-dose vial for reconstitution (kit): 22.5 mg |

VII. References

1. Trelstar Prescribing Information. Wayne, PA: Verity Pharmaceuticals, Inc.; March 2023. Available at www.trelstar.com. Accessed June 30, 2023.
2. Triptodur Prescribing Information. Atlanta, GA: Arbor Pharmaceuticals, LLC; December 2022. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208956s0091bl.pdf. Accessed June 30, 2023.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Triptorelin pamoate. Available at nccn.org. Accessed July 13, 2023.
4. National Comprehensive Cancer Network. Prostate cancer (Version 1.2023). Available at https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 13, 2023.
5. Klein K, Yang J, Aisenberg J, et al. Triptorelin Efficacy and safety of triptorelin 6-month formulation in patients with central precocious puberty. *J Pediatr Endocrinol Metab*. November 2016; 29(11): 1241–1248.
6. Kaplowitz P, Bloch C. Evaluation and referral of children with signs of early puberty. *Pediatrics*. 2016; 137(1): e20153732.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|-------------|---|
| J3315 | Injection, triptorelin pamoate, 3.75 mg |
| J3316 | Injection, triptorelin, extended-release, 3.75 mg |

| Reviews, Revisions, and Approvals | Date | Plan Approval Date |
|---|----------|--------------------|
| Policy created; adapted from previously approved policy CP.PHAR.175 Triptorelin Pamoate (Trelstar, Triptodur); removed sections on off-label approval for gender dysphoria and added redirection to OR.CP.PHAR.1002 Gender Dysphoria. | 03.18.22 | 04.07.22 |
| 4Q 2022 annual review: no significant changes; references reviewed and updated. | 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 |

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.

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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.

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