Clinical Policy: Triptorelin Pamoate (Trelstar, Triptodur)

Reference Number: CP.PHAR.175
Effective Date: 10.01.16
Last Review Date: 11.25
Line of Business: Commercial, HIM, Medicaid

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.

FDA Approved Indication(s)

Trelstar is indicated for the 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 health plans affiliated with Centene Corporation® 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 ≥ 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:
HIM/Medicaid – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

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/mL (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:
HIM/Medicaid – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

C. Gender Dysphoria, Gender Transition (off-label) (must meet all)**:**
1. Diagnosis of gender dysphoria or request is for gender transition;
2. Prescribed by or in consultation with both of the following (a and b):
a. An endocrinologist;
b. A provider with expertise in gender dysphoria and transgender medicine based on a certified training program or affiliation with local transgender health services (e.g., mental health professional such as psychologist, psychiatrist, see *Appendix D*);
3. Age and pubertal development – meets one of the following (a or b):
a. Member is < 18 years of age and has reached or passed through Tanner Stage 2*;
**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;
4. Member demonstrates understanding of expected GnRH analogue treatment outcomes and has given consent for such treatment;
5. If member has a psychiatric comorbidity, member is followed by mental health provider;
6. Psychosocial support will be provided during treatment;
7. Provider attestation of understanding current State regulations regarding transgender-related health care and such care is coverable under the State regulations (see *Appendix D*);
8. Dose is within FDA maximum limit for any FDA-approved indication (see Section V) or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:
HIM/Medicaid – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

D. Breast Cancer (off-label) (must meet all)**:**
1. Diagnosis of breast cancer;

2. Request is for Trelstar;
3. Prescribed by or in consultation with an oncologist;
4. Disease is hormone receptor positive;
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:
HIM/Medicaid – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

E. Salivary Gland Tumors (off-label) (must meet all)**:**
1. Diagnosis of salivary gland tumors;
2. Request is for Trelstar;
3. Disease is androgen receptor positive and recurrent, unresectable, or metastatic;
4. Prescribed by or in consultation with an oncologist;
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:
HIM/Medicaid – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

F. Uterine Sarcoma (off-label) (must meet all)**:**
1. Diagnosis of uterine sarcoma;
2. Request is for Trelstar;
3. Prescribed by or in consultation with an oncologist;
4. Member has endometrial stromal sarcoma or adenosarcoma without sarcomatous overgrowth;
5. Member is premenopausal;
6. Prescribed in combination with anastrozole, letrozole or exemestane;
7. 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:
HIM/Medicaid – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

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

1. 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 formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. 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 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and 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:
HIM/Medicaid – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

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:
HIM/Medicaid – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

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

Approval duration:
HIM/Medicaid – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

D. Breast Cancer, Salivary Gland Tumors, Uterine Sarcoma (off-label) (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Trelstar for breast cancer, salivary gland tumors, or uterine sarcoma 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:
HIM/Medicaid – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

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

1. 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 formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. 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 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and 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.CPA.09 for commercial, 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

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
WPATH: World Professional Association for Transgender Health

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

Appendix D: General Information

- World Professional Association for Transgender Health (WPATH) offers their Global Education Institute (GEI) Certified Training Courses: Best Practices in Transgender Medical and Mental Health Care. Additionally, the following link provides a search tool to locate WPATH member providers: https://app.wpath.org/provider/search

- Transgender Care Therapy Certification Training is also offered by the International Transgender Certification Association (ITCA). Professionals with expertise in transgender care can be located using the following search tool: https://transgendercertification.com/locate-a-professional/
- The WPATH Standards of Care Version 8 recommend that adolescents are managed by a multidisciplinary care team that involves both medical and mental health professionals. The list of key disciplines includes but is not limited to: adolescent medicine/primary care, endocrinology, psychology, psychiatry, speech/language pathology, fertility, social work, support staff, and the surgical team. The need to include a healthcare professional with some expertise in mental health does not dictate the inclusion of a psychologist, psychiatrist or social work in every assessment. Instead, a general medical practitioner, nurse or other qualified health care professional could also fulfill this requirement if they have sufficient expertise to diagnose gender incongruence, recognize mental health concerns, distinguish between these concerns and gender dysphoria, incongruence, and diversity, assist a transgender person in care planning and preparing for gender affirmative medical and surgical treatments, and refer to a mental health professional if needed.
- The Movement Advancement Project can be referenced to confirm transgender-related health care is coverable under the State regulations. This can be accessed at: https://www.lgbtmap.org/equality-maps/healthcare/youth_medical_care_bans

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 2025. Available at www.trelstar.com. Accessed July 10, 2025.
2. Triptodur Prescribing Information. Atlanta, GA: Arbor Pharmaceuticals, LLC; December 2022. Available at www.triptodur.com. Accessed July 10, 2025.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Triptorelin pamoate. Available at nccn.org. Accessed July 22, 2025.

4. National Comprehensive Cancer Network. Prostate cancer (Version 2.2025). Available at https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 22, 2025.
5. National Comprehensive Cancer Network. Uterine Neoplasms (Version 3.2025). Available at https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed July 17, 2025.
6. National Comprehensive Cancer Network. Head and Neck Cancers (Version 4.2025). Available at https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf . Accessed July 17, 2025.
7. National Comprehensive Cancer Network. Breast cancer (Version 4.2025). Available at https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed July 17, 2025, 2025.
8. 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.
9. Kaplowitz P, Bloch C. Evaluation and referral of children with signs of early puberty. Pediatrics. 2016; 137(1): e20153732.

Gender Dysphoria

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11. 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, November 2017, 102(11):3869–3903.
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13. 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.
14. Standards of care for the health of transsexual, transgender, and gender nonconforming people. WPATH: World Professional Association for Transgender Health. 7th version; 2001. Available at www.wpath.org.
15. 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.
16. Emmanual M, Bokor BR. Tanner Stages. Treasure Island, FL: StatPearls Publishing; 2019 Jan. Available at https://www.ncbi.nlm.nih.gov/books/NBK470280/. Last update: December 11, 2022. Accessed July 10, 2025.
17. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 13, 2024.
18. WPATH: World Professional Association for Transgender Health Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Available at: https://www.wpath.org/soc8. Accessed July 10, 2025.

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	P&T Approval Date
4Q 2021 annual review: added gender transition to gender dysphoria criteria set; references to HIM.PHAR.21 revised to HIM.PA.154; retire WCG.CP.PHAR.175; modified Commercial approval duration to 6 months or to member's renewal date, whichever is longer; references reviewed and updated.	07.14.21	11.21
For gender dysphoria or request is for gender transition modified prescriber requirements to allow experts in transgender medicine based on a certified training program or affiliation with local transgender health services; added general information Appendix D with resources for transgender provider search tools and examples of training programs.	12.14.21	02.22
4Q 2022 annual review: no significant changes; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.	07.26.22	11.22
4Q 2023 annual review: no significant changes; for gender dysphoria continuation of therapy added example of positive response to therapy; references reviewed and updated.	06.30.23	11.23
Corrected units for basal luteinizing hormone level to mIU/mL.	02.08.24	
4Q 2024 annual review: no significant changes; references reviewed and updated.	07.10.24	11.24
For gender dysphoria and gender transition, added requirement for provider attestation of understanding current State regulations regarding transgender-related health care and such care is coverable under the State regulations, added to Appendix D link and notation that the Movement Advancement Project can be referenced to confirm transgender-related health care is coverable under the State regulations.	02.12.25	
4Q 2025 annual review: for Trelstar added NCCN compendium supported off-label uses in breast cancer, salivary gland tumors, and uterine sarcoma; references reviewed and updated.	07.10.25	11.25

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.

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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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