Clinical Policy: Triptorelin Pamoate (Trelstar, Triptodur)

Reference Number: CP.PHAR.175
Effective Date: 10.01.16
Last Review Date: 11.17
Line of Business: Medicaid

Revision Log

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

Description

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

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 (which may include office chart notes and lab results) 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. Request is for Trelstar;
2. Diagnosis of prostate cancer;
3. Age ≥ 18 years;
4. Meets (a or b):
   a. FDA approved use:
      i. Palliative treatment of advanced prostate cancer;
   b. NCCN recommended use (any of the following):
      i. Adjuvant androgen deprivation therapy (ADT) as a single agent or in combination with an antiandrogen if positive lymph nodes found during pelvic lymph node dissection;
      ii. Initial ADT as a single agent or in combination with an antiandrogen (a, b or c):
         a) With radiation therapy for (1, 2 or 3):
            1) Intermediate risk disease;
            2) High or very high risk disease +/- docetaxel;
            3) Regional disease (any T, N1, M0);
         b) For very high risk disease if not a candidate for definitive therapy;
         c) For regional disease (any T, N1, M0) or metastatic disease (M1);

iii. ADT as a single agent or in combination with an antiandrogen (a or b):
  a) For biochemical failure following radical prostatectomy (1 or 2):
    1) With radiation therapy if no distant metastases;
    2) +/- radiation therapy if distant metastases;
  b) For positive digital rectal examination following radiation therapy (1 or 2):
    1) If biopsy is negative and there are no distant metastases;
    2) If not a candidate for local therapy;
iv. For progressive castration-naive disease (a, b or c):
  a) As a single agent;
  b) With an antiandrogen;
  c) With docetaxel +/- prednisone +/- an antiandrogen for metastatic (M1) disease;
v. For castration-recurrent disease to maintain castrate levels of serum testosterone as a single agent or with an antiandrogen;

5. Request meets one of the following:
  a. Dose does not exceed Trelstar (IM): 3.75 mg/4 weeks, 11.25 mg/12 weeks, 22.5 mg/24 weeks;
  b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Central Precocious Puberty (must meet all):
1. Request is for Triptodur;
2. Diagnosis of central precocious puberty confirmed by (a through 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/I (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 is < 8 years if female, or < 9 years if male;
3. Member meets the following age requirements:
  a. Female: 2 - 11 years;
  b. Male: 2 - 12 years;
4. Prescribed by or in consultation with a pediatric endocrinologist;
5. At the time of request, member is not pregnant;
6. Dose does not exceed Triptodur (IM): 22.5 mg/24 weeks.

Approval duration: 12 months

C. Other diagnoses/indications
1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Prostate Cancer (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Request is for Trelstar;
3. Member is responding positively to therapy (e.g., improved quality of life; no unacceptable toxicity);
4. If request is for a dose increase, request meets one of the following:
   a. New dose does not exceed Trelstar (IM): 3.75 mg/4 weeks, 11.25 mg/12 weeks, 22.5 mg/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*).

Approval duration: 12 months

B. Central Precocious Puberty (must meet all):
1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Request is for Triptodur;
3. Member is responding positively to therapy (e.g., decreased growth velocity, cessation of menses, softening of breast tissue or testes, arrested pubertal progression);
4. Member meets the following age requirement:
   a. Female: ≤ 11 years;
   b. Male: ≤ 12 years.
5. If request is for a dose increase, new dose does not exceed Triptodur (IM): 22.5 mg/24 weeks.

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2):
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CPP: central precocious puberty
FDA: Food and Drug Administration
GnRH: gonadotropin-releasing hormone
IM: intramuscular
NCCN: National Comprehensive Cancer Network

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Triptorelin pamoate (Treslstar [IM])	Prostate cancer*	3.75 mg/4 weeks; 11.25 mg/12 weeks; 22.5 mg/24 weeks	See regimen
Triptorelin pamoate Triptodur [IM])	CPP	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	Availability
Triptorelin pamoate (Treslstar)	Single-dose vial for reconstitution: 3.75 mg; 11.25 mg
	Single-dose vial for reconsitution with Mixject system (kit): 3.75 mg; 11.25 mg; 22.5 mg
Triptorelin pamoate (Treslstar)	Single-dose vial for reconstitution: 22.5 mg

VII. References

1. Trelstar Prescribing Information. Irvine, CA: Allergan USA, Inc.; August 2016. Available at https://www.allergan.com/assets/pdf/trelstar_pi. Accessed July 26, 2017.
2. Triptodur Prescribing Information. Atlanta, GA: Arbor Pharmaceuticals, LLC; June 2017. Available at https://www.accessdata.fda.gov/scripts/cder/daf/. Accessed July 26, 2017.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Triptorelin pamoate. Available at nccn.org. Accessed July 26, 2017.
4. National Comprehensive Cancer Network. Prostate cancer (Version 2.2017). Available at nccn.org. Accessed July 26, 2017.
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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PHAR.118.GnRH Analogs. Max dose added; removed preferencing; staging of advanced prostate cancer restated as stage T3 through T4 or high risk through nodal/metastatic disease per guidelines; approval period extended to 12 months	02.16	02.16
Age removed. Formulations added. NCCN recommended uses added (prostate cancer; doses removed).	01.17	02.17
Age and dosing added for prostate cancer; positive therapeutic response examples added. Prostate cancer	09.17	11.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
FDA/NCCN (categories 1 and 2A) indications listed separately. New drug/indication added: Triptodur/CPP. Safety information removed (hypersensitivity).		

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.