Clinical Policy: Triptorelin Pamoate (Trelstar)

Reference Number: CP.PHAR.175
Effective Date: 02/16
Last Review Date: 02/17 Revision Log

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

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® medical policy for the use of triptorelin pamoate (Trelstar®).

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® that Trelstar is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Prostate Cancer (must meet all):

1. Diagnosis of prostate cancer;
2. Meets a or b:
   a. FDA approved use:
      i. Prescribed as palliative therapy for advanced prostate cancer (stage T3 through T4 or high risk through nodal/metastatic disease);
   b. Off-label NCCN recommended use (must meet one):
      i. As adjuvant therapy (i.e., administered after radical prostatectomy [RP] if positive for pelvic lymph nodes);
      ii. As initial androgen deprivation therapy (ADT);
      iii. As ADT for biochemical failure* following RP;
      iv. As ADT for positive digital rectal examination following radiation therapy;
      v. For progressive castration-naive disease (i.e., not on ADT at time of progression) or castration-recurrent/resistant disease (i.e., no longer responsive to traditional ADT);
3. Member has no known hypersensitivity to GnRH, GnRH analogs, or any excipient in the requested product.

**Biochemical failure: 1) Failure of prostate specific antigen (PSA) to fall to undetectable levels (PSA persistence) or 2) undetectable PSA after RP with a subsequent detectable PSA that increases on 2 more determinations (PSA recurrence).*

Approval duration: 12 months

B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

A. Prostate Cancer (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy;

3. No known hypersensitivity to GnRH, GnRH analogs, or any excipient in the requested product.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:
Triptorelin is an agonist analog of GnRH and causes suppression of ovarian and testicular steroidogenesis due to decreased levels of LH and FSH with subsequent decrease in testosterone.

Formulations:
Trelstar (triptorelin pamoate): Reconstituted suspension for intramuscular administration:
- Trelstar vials: 3.75 mg; 11.25 mg
- Trelstar vials with Mixject system (kit): 3.75 mg; 11.25 mg; 22.5 mg

FDA Approved Indications:
Trelstar is a GnRH agonist/injectable suspension indicated for the palliative treatment of advanced prostate cancer.

Appendices

Appendix A: Abbreviation Key
ADT: Androgen deprivation therapy
GnRH: Gonadotropin-releasing hormone
PSA: Prostate specific antigen
RP: Radical prostatectomy

Reviews, Revisions, and Approvals	Date	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

References

1. Trelstar prescribing information. Irvine, CA: Allergan USA, Inc.; August 2016. Available at www.trelstar.com. Accessed December 28, 2016.
2. Triptorelin pamoate. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed December 29, 2016.

3. Prostate cancer (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed December 29, 2016.

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.

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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.