

PRIOR AUTHORIZATION POLICY

- POLICY:** Oncology (Injectable) – Gonadotropin-Releasing Hormone Analogs Prior Authorization Policy
- Eligard® (leuprolide acetate for subcutaneous injection – Tolmar Pharmaceuticals Inc.)
 - Firmagon® (degarelix for subcutaneous injection – Ferring Pharmaceuticals Inc.)
 - Trelstar® (triptorelin pamoate for intramuscular injection – Verity Pharmaceuticals Inc.)

REVIEW DATE: 12/09/2020

OVERVIEW

Eligard, Trelstar, and Firmagon are all indicated for the treatment of advanced prostate cancer.¹⁻³ Eligard and Trelstar are gonadotropin-releasing hormone (GnRH) agonists, whereas Firmagon is a GnRH antagonist. Both Eligard and Firmagon are as a subcutaneous injection and Trelstar is administered as an intramuscular injection.

Guidelines

The National Comprehensive Cancer Network (NCCN) Guidelines for Head and Neck Cancer (version 1.2021 – November 9, 2020) recommend the use of androgen receptor therapy (i.e., leuprolide, bicalutamide) for androgen receptor (AR)-positive, recurrent salivary gland tumors with distant metastases.^{4,5}

The NCCN Guidelines for Prostate Cancer (version 3.2020 – November 17, 2020) note androgen deprivation therapy as primary systemic therapy for regional or advanced prostate cancer and as neoadjuvant/concomitant/adjuvant therapy in combination with radiation in localized or locally advanced prostate cancer.⁶ Many different drugs can be used as androgen deprivation therapy, including Eligard, Firmagon, and Trelstar.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Eligard, Firmagon, and Trelstar. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Eligard, Firmagon, and Trelstar as well as the monitoring required for adverse events and long-term efficacy, approval requires these agents to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Eligard, Firmagon, or Trelstar is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Prostate Cancer.** Approve Eligard, Firmagon, or Trelstar for 1 year if prescribed by or in consultation with an oncologist.

Other Uses with Supportive Evidence

- 2. Head and Neck Cancer – Salivary Gland Tumors.** Approve Eligard for 1 year if the patient meets the following criteria (A, B, and C):
 - A)** Patient has recurrent disease with distant metastases; AND
 - B)** Patient has androgen receptor (AR)-positive disease; AND
 - C)** The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Eligard, Trelstar, or Firmagon is not recommended in the following situations:

- 1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Eligard[®] Subcutaneous Injection [prescribing information]. Fort Collins, CO: Tolmar Pharmaceuticals Inc.; April 2019.
2. Firmagon[®] Subcutaneous Injection [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; February 2020.
3. Trelstar[®] Intramuscular Injection [prescribing information]. Wayne, PA: Verity Pharmaceuticals, Inc; May 2020.
4. The NCCN Head and Neck Cancer Clinical Practice Guidelines in Oncology (Version 1.2021 – November 9, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed November 24, 2020.
5. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on November 24, 2020. Search terms: leuprolide acetate, degarelix, triptorelin pamoate.
6. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (Version 3.2020 – November 17, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on November 24, 2020.