

PRIOR AUTHORIZATION POLICY

- POLICY:** Oncology (Injectable) – Gonadotropin-Releasing Hormone Analogs Prior Authorization Policy
- Camcevi™ (leuprolide subcutaneous injection – Accord BioPharma)
 - Eligard® (leuprolide acetate subcutaneous injection – Tolmar)
 - Firmagon® (degarelix subcutaneous injection – Ferring)
 - Leuprolide Depot (leuprolide acetate 22.5 mg for depot suspension [formerly Lutrate Depot] – Cipla USA)
 - Trelstar® (triptorelin pamoate intramuscular injection – Verity)

REVIEW DATE: 01/17/2024

OVERVIEW

Camcevi, Eligard, Leuprolide Depot (formerly Lutrate Depot), Firmagon, and Trelstar are all indicated for the treatment of advanced **prostate cancer**.^{1-4,8} Camcevi, Eligard, Leuprolide Depot, and Trelstar are gonadotropin-releasing hormone (GnRH) agonists, whereas Firmagon is a GnRH antagonist.

Guidelines

The GnRH analogs have been addressed in National Comprehensive Cancer Network (NCCN) guidelines:

- **Head and Neck Cancer:** NCCN guidelines (version 2.2024 – December 8, 2023) recommend androgen receptor therapy (e.g., leuprolide and bicalutamide) for patients with recurrent, unresectable, or metastatic androgen receptor positive salivary gland tumors.^{5,6}
- **Prostate Cancer:** NCCN guidelines (version 4.2023 – September 7, 2023) note androgen deprivation therapy as primary systemic therapy for regional or advanced disease and as neoadjuvant/concomitant/adjuvant therapy in combination with radiation in localized or locally advanced prostate cancers. Many drugs can be used as androgen deprivation therapy, including Camcevi, Eligard, Firmagon, and Trelstar.⁷

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Camcevi, Eligard, Leuprolide Depot, 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 Camcevi, Eligard, Leuprolide Depot, 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 Camcevi, Eligard, Leuprolide Depot, Firmagon, or Trelstar is recommended in those who meet one of the following criteria:

01/17/2024

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FDA-Approved Indication

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

Other Uses with Supportive Evidence

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

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Camcevi, Eligard, Leuprolide Depot, 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; July 2023.
2. Firmagon® subcutaneous injection [prescribing information]. Parsippany, NJ: Ferring; February 2020.
3. Trelstar® intramuscular injection [prescribing information]. Wayne, PA: Verity; November 2023.
4. Camcevi subcutaneous injection [prescribing information]. Durham, NC: Accord BioPharma; May 2021.
5. The NCCN Head and Neck Cancer Clinical Practice Guidelines in Oncology (version 2.2024 – December 08, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 12, 2024.
6. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 11, 2024. Search terms: leuprolide acetate, degarelix, triptorelin pamoate, leuprolide mesylate.
7. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 4.2023 – September 7, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 12, 2024.
8. Lutrate Depot intramuscular injection [prescribing information]. Warren, NJ: Cipla USA; February 2023.