VENTURA COUNTY
HEALTH CARE PLAN

# UTILIZATION MANAGEMENT MEDICAL POLICY

**POLICY:** Oncology (Injectable) – Gonadotropin-Releasing Hormone Analogs Utilization Management Medical 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

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## OVERVIEW

Camcevi, Eligard, Leuprolide Depot (formerly Lutrate Depot), Trelstar, and Firmagon 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. Table 1 has the approved doses for the four agents.

**Table 1. Recommended FDA-Approved Dosages.[1-4, 8]**

| Drug | Route of Administration | Dose and Frequency |
|---|---|---|
| Camcevi | Subcutaneous | • 42 mg every 6 months |
| Eligard | Subcutaneous | • 7.5 mg every month<br>• 22.5 mg every 3 months<br>• 30 mg every 4 months<br>• 45 mg every 6 months |
| Leuprolide Depot (formerly Lutrate Depot) | Intramuscular | • 22.5 mg every 3 months |
| Firmagon | Subcutaneous | • Starting dose of 240 mg given as two injections of 120 mg<br>• Maintenance dose of 80 mg as one injection given every 28 days (first maintenance dose is given 28 days after the starting dose) |
| Trelstar | Intramuscular | • 3.75 mg every 4 weeks<br>• 11.25 mg every 12 weeks<br>• 22.5 mg every 24 weeks |

## Guidelines

The GnRH analogs have been addressed in National Comprehensive Cancer Network Guidelines:

- **Head and Neck Cancers:** 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:** 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 medical benefit coverage of Camcevi, Eligard, Leuprolide Depot, Trelstar, and Firmagon. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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, Trelstar, and Firmagon as well as the monitoring required for adverse events and long-term efficacy, approval requires Camcevi, Eligard, Leuprolide Depot, Trelstar, and Firmagon 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:

### FDA-Approved Indication

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**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.

**Dosing.** Approve one of the following doses (A, B, C, D, or E):

**A)** For Camcevi, approve the following dose (administered as a subcutaneous injection): 42 mg injection not more frequently than once every 6 months.

**B)** For Eligard, approve one of the following doses (administered as a subcutaneous injection) [i, ii, iii, or iv]:
- **i.** 7.5 mg injection not more frequently than once every month; OR
- **ii.** 22.5 mg injection not more frequently than once every 3 months; OR
- **iii.** 30 mg injection not more frequently than once every 4 months; OR
- **iv.** 45 mg injection not more frequently than once every 6 months.

**C)** For Firmagon, approve one of the following doses (i or ii):
- **i.** For starting dose, approve 240 mg administered as two subcutaneous injections of 120 mg; OR
- **ii.** For maintenance dose (first one is given 28 days after starting dose), approve up to 80 mg administered as one subcutaneous injection not more frequently than once every 28 days.

**D)** For Trelstar, approve one of the following doses (administered as an intramuscular injection) [i, ii, or iii]:
- **i.** 3.75 mg injection not more frequently than once every 4 weeks; OR
- **ii.** 11.25 mg injection not more frequently than once every 12 weeks; OR
- **iii.** 22.5 mg injection not more frequently than once every 24 weeks.

**E)** For Leuprolide Depot, approve the following dose (administered as an intramuscular injection): 22.5 mg injection not more frequently than once every 3 months.

**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.

**Dosing.** Approve one of the following doses (A or B):
- **A)** For Camcevi, approve the following dose (administered as a subcutaneous injection): 42 mg injection not more frequently than once every 6 months.
- **B)** For Eligard, approve one of the following doses (administered as a subcutaneous injection) [i, ii, iii, or iv]:
  - **i.** 7.5 mg injection not more frequently than once every month; OR
  - **ii.** 22.5 mg injection not more frequently than once every 3 months; OR
  - **iii.** 30 mg injection not more frequently than once every 4 months; OR
  - **iv.** 45 mg injection not more frequently than once every 6 months.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Camcevi, Eligard, Leuprolide Depot, Trelstar, and 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.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | **Head and Neck Cancer – Salivary Gland Tumors:** "Patient has distant metastases" was reworded to "Patient has recurrent, unresectable, or metastatic disease." | 01/11/2023 |
| Selected Revision | Leuprolide Depot (formerly Lutrate Depot) was added to the policy.<br>**Prostate Cancer:** Criteria and dosing for Leuprolide Depot was added. | 04/26/2023 |
| Annual Revision | No criteria changes. | 01/17/2024 |