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)
- Trelstar[®] (triptorelin pamoate intramuscular injection Verity)

REVIEW DATE: 01/11/2023

OVERVIEW

Camcevi, Eligard, Firmagon, and Trelstar are all indicated for the treatment of advanced **prostate cancer**.¹⁻ Camcevi, Eligard, 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 1.2023 December 20, 2022) 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 1.2023 September 16, 2022) 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, 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, 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, Firmagon, or Trelstar is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Prostate Cancer.** Approve <u>Camcevi, Eligard, Firmagon, or Trelstar</u> for 1 year if prescribed by or in consultation with an oncologist or urologist.

Other Uses with Supportive Evidence

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- 2. Head and Neck Cancer Salivary Gland Tumors. Approve <u>Camcevi or Eligard</u> for 1 year if the patient meets the following criteria (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, 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; April 2019.
- 2. Firmagon[®] subcutaneous injection [prescribing information]. Parsippany, NJ: Ferring; February 2020.
- 3. Trelstar[®] intramuscular injection [prescribing information]. Wayne, PA: Verity; May 2020.
- 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 1.2023 December 20, 2022). © 2022 National Comprehensive Cancer Network. Available at: <u>http://www.nccn.org</u>. Accessed on January 9, 2023.
- 6. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: <u>http://www.nccn.org</u>. Accessed on January 9, 2023. Search terms: leuprolide acetate, degarelix, triptorelin pamoate.
- 7. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2023 September 16, 2022). © 2022 National Comprehensive Cancer Network. Available at: <u>http://www.nccn.org</u>. Accessed on January 9, 2023.