PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Oncology (Injectable) – Gonadotropin-Releasing Hormone Analogs Preferred Specialty Management Policy

- Camcevi™ (leuprolide subcutaneous injection – Accord)
- Eligard® (leuprolide acetate subcutaneous injection – Tolmar)
- Firmagon® (degarelix subcutaneous injection – Ferring)
- Leuprolide acetate subcutaneous injection – generic only
- Lupron Depot® (leuprolide acetate for depot intramuscular injection – AbbVie)
- Trelstar® (triptorelin pamoate intramuscular injection – Verity)

REVIEW DATE: 01/11/2023

OVERVIEW

Camcevi, Eligard, leuprolide acetate injection, Lupron Depot, and Trelstar are gonadotropin-releasing hormone (GnRH) agonists and Firmagon is a GnRH receptor antagonist.[1-4] All of these agents are indicated for the treatment of **advanced prostate cancer**. Lupron Depot is available in different strengths; some strengths are indicated for the treatment of advanced prostate cancer and some strengths are indicated for the management of endometriosis and uterine leiomyomata.[5-7] In addition to the approved indications, Lupron Depot may be used for other conditions.

There are Prior Authorization criteria for Camcevi, Eligard, Firmagon, Lupron Depot, and Trelstar; for more information on criteria for these agents, refer to the respective *Prior Authorization Policies*. There is no Prior Authorization criteria for leuprolide acetate injection.

Guidelines

The National Comprehensive Cancer Network Guidelines for Prostate Cancer (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.[9] Many different drugs can be used as androgen deprivation therapy, including Camcevi, leuprolide acetate, Firmagon, and Trelstar.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Oncology (Injectable) – Gonadotropin-Releasing Hormone Analogs Prior Authorization Policy* or *Gonadotropin-Releasing Hormone Agonists – Injectable Long-Acting Products Prior Authorization Policy* criteria. This program also directs the patient to try the Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for the duration noted below. If the patient meets the respective *Oncology (Injectable) – Gonadotropin-Releasing Hormone Analogs Prior Authorization Policy* or *Gonadotropin-Releasing Hormone Agonists – Injectable Long-Acting Products Prior Authorization Policy* criteria but has not tried a Preferred Product, approval for the Preferred Products will be authorized.
Note: Leuprolide acetate injection is not managed by a *Prior Authorization Policy*. This Preferred Specialty Management Policy will approve leuprolide acetate injection when it is prescribed for conditions other than prostate cancer. If leuprolide acetate injection is prescribed for infertility use, it will only be approved if the patient has infertility coverage.

Automation: None.

Preferred Product: Eligard
Non-Preferred Products: Camcevi, Firmagon, leuprolide acetate injection, Lupron Depot, Trelstar

Recommended Exception Criteria

Non-Preferred Product	Exception Criteria
Camcevi	**1. Prostate Cancer.** Approve for 1 year if the patient meets the following criteria (A or B): **A)** Patients meets both of the following (i and ii): **i.** Patient meets the Camcevi criteria in the standard *Oncology (Injectable) – Gonadotropin-Releasing Hormone Analogs Prior Authorization (PA) Policy*; AND **ii.** Patient has tried Eligard; OR **B)** If the patient has met the standard *Oncology (Injectable) – Gonadotropin-Releasing Hormone Analogs PA Policy* criteria (Ai), but has not met exception criteria (Aii) above for brand Camcevi: approve Eligard. **2. Other Conditions.** For conditions other than prostate cancer, refer to the Camcevi criteria in the standard *Oncology (Injectable) – Gonadotropin-Releasing Hormone Analogs PA Policy*.
Leuprolide Acetate Injection	**1. Prostate Cancer.** Approve for 1 year if the patient meets one of the following (A or B): **A)** Patient has tried Eligard; OR **B)** If the patient has not tried the preferred product (Eligard) for prostate cancer: approve Eligard. **2. Other Conditions.** Approve.
Firmagon Trelstar	**1. Prostate Cancer.** Approve for 1 year if the patient meets the following (A or B): **A)** Patient meets both of the following (i and ii): **i.** Patient meets the Firmagon or Trelstar criteria in the standard *Oncology (Injectable) – Gonadotropin-Releasing Hormone Analogs Prior Authorization (PA) Policy*; AND **ii.** Patient meets one of the following criteria (a or b): **a)** Patient has tried Eligard; OR **b)** Patient has already been started on Firmagon or Trelstar and is continuing therapy. **B)** If the patient has met the standard *Oncology (Injectable) – Gonadotropin-Releasing Hormone Analogs PA Policy* criteria (Ai), but has not met exception criteria (Aii) above for brand Firmagon or Trelstar: approve Eligard.
Lupron Depot	**1. Prostate Cancer**. Approve for 1 year if the patient meets the following (A or B): **A)** Patient meets both of the following (i and ii): **i.** Patient meets the Lupron Depot criteria in the standard *Gonadotropin-Releasing Hormone Agonists – Injectable Long-Acting Products Prior Authorization (PA) Policy*; AND **ii.** Patient has tried Eligard. **B)** If the patient has met the standard *Gonadotropin-Releasing Hormone Agonists – Injectable Long-Acting Products PA Policy* criteria (Ai), but has

	not met exception criteria (Aii) above for brand Lupron Depot: approve Eligard. **2. <u>Other Conditions</u>.** For conditions other than prostate cancer, refer to the Lupron Depot criteria in the standard *Gonadotropin-Releasing Hormone Agonists – Injectable Long-Acting Products Prior Authorization Policy*.

REFERENCES

1. Eligard [prescribing information]. Fort Collins, CO: Tolmar Pharmaceuticals; April 2019.
2. Leuprolide acetate injection [prescribing information]. Princeton, NJ: Sandoz; January 2019.
3. Trelstar [prescribing information]. Wayne, PA: Verity Pharmaceuticals; May 2020.
4. Firmagon [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals; February 2020.
5. Lupron Depot - 7.5 mg for 1 month, 22.5 mg for 3 month; 30 mg for 4-month, and 45 mg for 6-month administration [prescribing information]. North Chicago, IL: AbbVie; March 2019.
6. Lupron Depot® – 3 Month 11.25 mg [prescribing information]. North Chicago, IL: AbbVie; March 2020.
7. Lupron Depot® – 3.75 mg [prescribing information]. North Chicago, IL: AbbVie; February 2021.
8. Camcevi subcutaneous injection [prescribing information]. Durham, NC: Accord BioPharma; May 2021.
9. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – September 16, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 9, 2023.