

## PREFERRED SPECIALTY MANAGEMENT POLICY

- POLICY:** Oncology (Injectable) – Gonadotropin-Releasing Hormone Analogs Preferred Specialty Management Policy
- Eligard® (leuprolide acetate for injectable suspension – Tolmar Pharmaceuticals)
  - Firmagon® (degarelix for injection – Ferring Pharmaceuticals Inc.)
  - Leuprolide acetate injection – Sandoz, various
  - Lupron Depot® (leuprolide acetate for depot suspension – AbbVie)
  - Trelstar® (triptorelin pamoate for injectable suspension – Verity Pharmaceuticals, Inc.)

**REVIEW DATE:** 12/09/2020

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### OVERVIEW

Eligard, leuprolide acetate injection, Lupron Depot, and Trelstar are gonadotropin-releasing hormone (GnRH) agonists and Firmagon is a GnRH receptor antagonist.<sup>1-4</sup> 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.<sup>5-7</sup> In addition to the approved indications, Lupron Depot may be used for other conditions.

There are Prior Authorization criteria for 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 (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.<sup>8</sup> Many different drugs can be used as androgen deprivation therapy, including leuprolide acetate, Firmagon, and Trelstar.

### POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of Preferred Products. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The program also directs the patient to try one 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.

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:** Firmagon, Leuprolide acetate injection, Lupron Depot, Trelstar

**Recommended Exception Criteria**

Non-Preferred Product	Exception Criteria
Leuprolide Acetate Injection	<p><b>1. <u>Prostate Cancer.</u></b> The patient must meet one of the following (A <u>or</u> B):</p> <p>A) The patient has tried Eligard; OR</p> <p>B) If the patient has not tried the preferred product (Eligard) for prostate cancer: approve Eligard.</p> <p><b>2. <u>Other Conditions.</u></b> Approve.</p>
Firmagon Trelstar	<p><b>1. <u>Prostate Cancer.</u></b> The patient must meet one of the following (A, B, <u>or</u> C):</p> <p>A) Approve if the patient meets the following criteria (i <u>and</u> ii):</p> <p>i. The patient meets the Firmagon or Trelstar criteria in the ESI Standard <i>Oncology (Injectable) – Gonadotropin-Releasing Hormone Analogs Prior Authorization Policy</i> for prostate cancer; AND</p> <p>ii. The patient has tried Eligard; OR</p> <p>B) If the patient has already been started on Firmagon or Trelstar: approve; OR</p> <p>C) If the patient has not tried the preferred product (Eligard) for prostate cancer: approve Eligard.</p>
Lupron Depot	<p><b>1. <u>Prostate Cancer.</u></b> The patient must meet one of the following (A <u>or</u> B):</p> <p>A) Approve if the patient meets the following criteria (i <u>and</u> ii):</p> <p>i. The patient meets the Lupron Depot criteria in the ESI Standard <i>Gonadotropin-Releasing Hormone Agonists – Injectable Long-Acting Products Prior Authorization Policy</i> for prostate cancer; AND</p> <p>ii. The patient has tried Eligard; OR</p> <p>B) If the patient has not tried the preferred product (Eligard) for prostate cancer: approve Eligard.</p> <p><b>2. <u>Other Conditions.</u></b> For conditions other than prostate cancer, refer to the Lupron Depot criteria in the ESI Standard <i>Gonadotropin-Releasing Hormone Agonists – Injectable Long-Acting Products Prior Authorization Policy</i>.</p>

**REFERENCES**

1. Eligard [prescribing information]. Fort Collins, CO: Tolmar Pharmaceuticals Inc.; April 2019.
2. Leuprolide acetate injection [prescribing information]. Princeton, NJ: Sandoz Inc.; January 2019.
3. Trelstar [prescribing information]. Wayne, PA: Verity Pharmaceuticals, Inc; May 2020.
4. Firmagon [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals, Inc.; 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 Inc.; March 2019.
6. Lupron Depot® – 3 Month 11.25 mg [prescribing information]. North Chicago, IL: AbbVie Inc.; April 2018.
7. Lupron Depot® – 3.75 mg [prescribing information]. North Chicago, IL: AbbVie Inc.; October 2013.
8. 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.