

PreferredOne[®]

ATION POLICY

POLICY: Oncology (Injectable) – Gonadotropin-Releasing Hormone Analogs

- Eligard[®] (leuprolide acetate for subcutaneous injection – Tolmar Pharmaceuticals Inc.)
- Firmagon[®] (degarelix for subcutaneous injection – Ferring Pharmaceuticals Inc.)
- Trelstar[®] (triptorelin pamoate for intramuscular injection – Allergan Inc.)

DATE REVIEWED: 12/04/2019

OVERVIEW

Eligard, Trelstar, and Firmagon are all indicated for the treatment of advanced prostate cancer.¹⁻³ Eligard and Trelstar are gonadotropin-releasing hormone (GnRH) agonists, whereas Firmagon is a GnRH antagonist. Table 1 has the approved doses for the three agents.

Table 1. Recommended FDA-Approved Dosages.¹⁻³

Drug	Route of Administration	Dose and Frequency
Eligard	Subcutaneous	<ul style="list-style-type: none">• 7.5 mg every month• 22.5 mg every 3 months• 30 mg every 4 months• 45 mg every 6 months
Firmagon	Subcutaneous	<ul style="list-style-type: none">• Starting dose of 240 mg given as two injections of 120 mg• First maintenance dose (80 mg) given 28 days after the starting dose• Maintenance dose of 80 mg as one injection given every 28 days
Trelstar	Intramuscular	<ul style="list-style-type: none">• 3.75 mg every 4 weeks• 11.25 mg every 12 weeks• 22.5 mg every 24 weeks

The National Comprehensive Cancer Network (NCCN) Guidelines for Head and Neck Cancer (version 3.2019 – September 16, 2019) recommend the use of androgen receptor therapy (i.e., leuprolide, bicalutamide) for androgen receptor (AR)-positive, recurrent salivary gland tumors with distant metastases.^{4,5}

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Eligard, Trelstar, and Firmagon. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Eligard, Trelstar, and Firmagon 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 Eligard, Firmagon, or Trelstar is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Prostate Cancer.** Approve Eligard, Firmagon, or Trelstar for 1 year if prescribed by, or in consultation with, an oncologist.^{1-3,5}

Other Uses with Supportive Evidence

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

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Eligard, Trelstar, or Firmagon have not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

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 Pharmaceuticals Inc.; April 2019.
2. Firmagon[®] Subcutaneous Injection [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; May 2017.
3. Trelstar[®] Intramuscular Injection [prescribing information]. Madison, NJ: Allergan; January 2018.
4. The NCCN Head and Neck Cancer Clinical Practice Guidelines in Oncology (Version 3.2019 – September 16, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed November 29, 2019.
5. The NCCN Drugs and Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on November 29, 2019. Search terms: leuprolide acetate, degarelix, triptorelin pamoate.

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Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

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ဟ်သ့ဟ်သး- နမၤကတိၤ ကသီၤ ကျိၣ်အယိၤ, နမၤန့ၣ် ကျိၣ်အတၢ်မၤစၢၤလၢ တလၢၣ်ဘျဉ်လၢၣ်စၢၤ နီၣ်တမံၤဘၣ်သ့န့ၣ်လီၤ. ကိး 1.800.940.5049 (TTY: 763.847.4013).

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Fax: 763.847.4010
customerservice@preferredone.com

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
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