POLICY: Oncology – Gonadotropin-Releasing Hormone Analogs Injectable Products

- 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.)

APPROVAL DATE: 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	• 7.5 mg every month • 22.5 mg every 3 months • 30 mg every 4 months • 45 mg every 6 months
Firmagon	Subcutaneous	• Starting dose of 240 mg given as two injections of 120 mg • First maintenance dose given 28 days after the starting dose • Maintenance dose of 80 mg as one injection given every 28 days
Trelstar	Intramuscular	• 3.75 mg every 4 weeks • 11.25 mg every 12 weeks • 22.5 mg every 24 weeks

The National Comprehensive Cancer Network Guidelines for Head and Neck Cancer (version 3.2019 – September 16, 20192.2018) recommends 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 medical benefit coverage of Eligard, Trelstar, and Firmagon. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). 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 Eligard, Trelstar, and Firmagon as well as the monitoring required for adverse events and long-term efficacy, initial 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]

Dosing. Approve one of the following doses:

A) For Eligard, approve one of the following doses:
- **i.** up to 7.5 mg subcutaneous injection once every month; OR
- **ii.** up to 22.5 mg subcutaneous injection once every 3 months; OR
- **iii.** up to 30 mg subcutaneous injection once every 4 months; OR
- **iv.** up to 45 mg subcutaneous injection once every 6 months.

B) For Firmagon, approve one of the following doses:
- **i.** For starting dose approve 240 mg administered as two subcutaneous injections of 120 mg (40 mg/mL vial); OR
- **ii.** For maintenance dose (first one is given 28 days after starting dose), approve up to 80 mg administered as one subcutaneous injection every 28 days (20 mg/mL vial).

C) For Trelstar, approve one of the following doses:
- **i.** up to 3.75 mg intramuscular injection once every 4 weeks; OR
- **ii** up to 11.25 mg intramuscular injection once every 12 weeks; OR
- **iii.** up to 22.5 mg intramuscular injection once every 24 weeks.

Duration of Therapy: Extended approvals are allowed if the patient continues to meet the criteria and dosing (see above).

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.

Dosing. Approve one of the following doses for Eligard:
- **A)** up to 7.5 mg subcutaneous injection once every month; OR
- **B)** up to 22.5 mg subcutaneous injection once every 3 months; OR
- **C)** up to 30 mg subcutaneous injection once every 4 months; OR
- **D)** up to 45 mg subcutaneous injection once every 6 months.

Duration of Therapy: Extended approvals are allowed if the patient continues to meet the criteria and dosing (see above).

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, 201923, 2018.
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.

HISTORY

Type of Revision	Summary of Changes	Reviewed Date
New Policy	--	11/28/2018
Annual revision	No criteria changes.	12/04/2019