SmartHealth Ascension

Leuprolide Acetate

(Eligard®) J9217 (7.5 mg)

Covered with prior authorization

Leuprolide Acetate (Eligard®) may be authorized when the following criteria are met:

- **Individual is using for the treatment of salivary gland tumors; AND**
  - Individual has androgen receptor positive recurrent disease with distant metastases

OR

- **Individual is using for the treatment of prostate cancer and ANY of the following are met:**
  - Used as androgen deprivation therapy as a single agent or in combination with an antiandrogen; **OR**
  - Used for clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, or prostate specific antigen (PSA) value of 10-20 ng/mL) or higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery; **OR**
  - Used for progressive castration-naïve disease; **OR**
  - Used for castration-recurrent disease; **OR**
  - Other advanced, recurrent, or metastatic disease.

OR

- **Individual is using in the preservation of fertility in pre-menopausal women; AND**
  - Individual currently has a cancer diagnosis; **AND**
  - Individual meets one of the following:
    - Individual will receive chemotherapy for cancer with a curative intent; **OR**
    - Individual will receive radiation therapy for cancer with a curative intent.

OR

- **Individual is using for treatment of Malignant Sex Cord-Stromal Tumors**

Exclusion criteria:

Requests for Leuprolide Acetate (Eligard®) may not be approved for the following:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial authorization is up to 12 months.

Reauthorization Criteria:

Leuprolide Acetate is considered medically necessary for continued use when initial criteria are met **AND** the patient has experienced clinical benefit to therapy **AND** has not experienced an unacceptable toxicity.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:

This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Eligard® is a gonadotropin releasing hormone (GnRH) agonist indicated for the palliative treatment of advanced prostate cancer

References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website.
2. Elgindy EA, El-Haieg DO, Khorshid OM, et al. Gonadatrophin suppression to prevent chemotherapy-induced ovarian damage: a randomized controlled trial. Obstet Gynecol. 2013; 121(1):78-86.
3. Eligard® [Prescribing Information]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc., 2019
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp

Date	Summary of Changes
January 2023	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
February 2023	Criteria for use summary approved by the Ascension Hematology/Oncology Expert Review Panel.
March 2023	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.