Eligard (leuprolide acetate)

Line(s) of Business:
HMO; PPO; QUEST Integration

Original Effective Date:
10/01/2015
Current Effective Date:
05/01/2018

POLICY

A. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

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

Compendial Uses

- Prostate Cancer:
  - Adjuvant androgen deprivation therapy (ADT) (single agent or with anti-androgen) with or without external beam radiation therapy (EBRT) if positive lymph nodes found during lymph node dissection
- Initial androgen deprivation therapy as a single agent or in combination with an antiandrogen for
  - 4-6 months in combination with external beam radiation therapy (EBRT) with or without brachytherapy for patients in the intermediate risk group
  - 2-3 years in combination with EBRT with or without brachytherapy for patients in the high or very high risk group
  - 2-3 years in combination with EBRT and docetaxel for patients in the high or very high risk group
  - 2-3 years in combination with EBRT for regional disease (any T, N1, M0)
  - patients in the very high risk group who are not candidates for definitive therapy
  - regional or metastatic disease
- Androgen deprivation therapy as a single agent or in combination with an antiandrogen for biochemical failure
  - following radical prostatectomy in combination with external beam radiation therapy (EBRT) for disease without distant metastases
  - following radical prostatectomy in combination with or without EBRT for distant metastatic disease
  - or positive digital rectal examination (DRE) following radiation therapy if biopsy negative and no distant metastases

- or positive DRE following radiation therapy in patients who are not candidates for local therapy (especially if bone scan positive)
- Used for progressive castration-naive disease
  - as a single agent
  - in combination with an antiandrogen
  - in combination with docetaxel with or without prednisone for M1 disease
- In patients with M1 disease who are at risk of developing symptoms associated with the flare in testosterone levels with luteinizing hormone-releasing hormone (LHRH) agonist therapy alone, LHRH agonist should be given in combination with an antiandrogen for at least 7 days
- Used for castration-recurrent disease to maintain castrate levels of serum testosterone as a single agent or in combination with an antiandrogen

B. INITIAL CRITERIA FOR APPROVAL

Prostate cancer

Initial authorization of 12 months may be granted for members when either 1, 2, or 3 below are met:

1. Adjuvant androgen deprivation therapy if positive pelvic lymph nodes are found on pelvic lymph node dissection
2. Member has a diagnosis of clinically localized prostate cancer and
   a. Eligard is being used in combination with external beam radiation therapy (EBRT) for intermediate or high risk stratification groups
   b. Members risk stratification group is very high risk

   Note: Androgen deprivation therapy (ADT) with Eligard may also include an anti-androgen medication.

3. Member has locally advanced disease, recurrent disease, biochemical failure from previous therapy, progressive castration-naïve disease, castration-recurrent disease, or regional/metastatic disease.

C. CONTINUATION OF THERAPY

Prostate cancer

1. No previous authorization/precertification:
   All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section B.
2. Reauthorization:
   - Authorization of 12 months may be granted for members requesting authorization for continuation of therapy who were previously authorized by HMSA/CVS, who show no progression of the cancer being treated, and who provide appropriate documentation.

   -For members with prostate cancer who have evidence of disease progression (eg, increase in serum prostate-specific antigen [PSA], new metastases, progression of existing metastases) while being managed with androgen deprivation therapy (ADT) , authorization for 12 months can be granted if ADT is to be used with any following agents: abiraterone, enzalutamide, taxane chemotherapy, sipuleucel-t, radium-223.

D. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

E. ADMINISTRATIVE GUIDELINES

Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

F. IMPORTANT REMINDER

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA's determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

G. REFERENCES

1. Eligard [package insert]. Fort Collins, CO: TOLMAR Pharmaceuticals Inc.; January 2017.
2. The NCCN Drugs & Biologics Compendium™. © 2017 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 17, 2017.

Document History

10/01/2015	Original effective date
09/2016	Annual review
05/2017	Annual review
05/01/2018	Revision effective date