Reference number(s)
2084-A

SPECIALTY GUIDELINE MANAGEMENT

ELIGARD (leuprolide acetate)

POLICY

I. 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.

A. FDA-Approved Indication
Palliative treatment of advanced prostate cancer

B. Compendial Uses
1. Prostate cancer
2. Recurrent androgen receptor positive salivary gland tumors

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Prostate cancer
Authorization of 12 months may be granted for treatment of prostate cancer.

B. Salivary gland tumors
Authorization of 12 months may be granted for treatment of recurrent salivary gland tumors as a single agent when the tumor is androgen receptor positive.

III. CONTINUATION OF THERAPY

A. Authorization of 12 months may be granted for continued treatment of salivary gland tumors in members requesting reauthorization who are experiencing clinical benefit to therapy and who have not experienced an unacceptable toxicity.
B. Authorization of 12 months may be granted for continued treatment of prostate cancer in members requesting reauthorization who are experiencing clinical benefit to therapy (e.g., serum testosterone less than 50 ng/dL) and who have not experienced an unacceptable toxicity.

IV. REFERENCES

1. Eligard [package insert]. Fort Collins, CO: Tolmar Pharmaceuticals; April 2019.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 1, 2022.

Reference number(s)
2084-A