

STANDARD MEDICARE PART B 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
3. Gender dysphoria (also known as transgender and gender diverse (TGD) persons)

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. **Prostate cancer**

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

B. **Gender dysphoria**

1. Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member when all of the following criteria are met:
 - a. The member has a diagnosis of gender dysphoria.
 - b. The member has reached Tanner stage 2 of puberty or greater.
2. Authorization of 12 months may be granted for gender transition when all of the following criteria are met:
 - a. The member has a diagnosis of gender dysphoria.
 - b. The member will receive the requested medication concomitantly with gender-affirming hormones.

C. **Salivary gland tumors**

Authorization of 12 months may be granted for treatment of recurrent salivary gland tumors when the tumor is androgen receptor positive.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested medication.

Reference number(s)
4712-A

Authorization for 12 months may be granted when all of the following criteria are met:

- A. The member is currently receiving therapy with the requested medication.
- B. The requested medication is being used to treat gender dysphoria.
- C. The member is receiving benefit from therapy.

Authorization for 12 months may be granted when all of the following criteria are met:

- A. The member is currently receiving therapy with the requested medication.
- B. The requested medication is being used to treat prostate cancer.
- C. The member is receiving benefit from therapy (e.g., serum testosterone less than 50 ng/dL) and has not experienced an unacceptable toxicity.

Authorization for 12 months may be granted when all of the following criteria are met:

- A. The member is currently receiving therapy with the requested medication.
- B. The requested medication is being used to treat salivary gland tumors.
- C. The member is receiving benefit from therapy and has not experienced an unacceptable toxicity.

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Eligard.
2. The available compendium
 - a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
 - b. Micromedex DrugDex
 - c. American Hospital Formulary Service- Drug Information (AHFS-DI)
 - d. Lexi-Drugs
3. NCCN Guideline: Prostate cancer
4. NCCN Guideline: Head and neck cancers

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Eligard are covered in addition to the following:

1. Prostate cancer other than advanced prostate cancer
2. Salivary gland tumors
3. Gender dysphoria

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Eligard to treat prostate cancer and salivary gland tumors can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for using Eligard for gender dysphoria can be found in the Endocrine Society Clinical Practice guideline for Endocrine Treatment of gender-dysphoric/gender-incongruent persons. The guidelines support GnRH agonist use in both transgender males and transgender females. Specific products are not listed; therefore, coverage is applied to the entire class of GnRH agonists.

Support for using Eligard for gender dysphoria can also be found in the World Professional Association for Transgender Health (WPATH). According to the Standards of Care for the Health of Transgender and Gender

Diverse People, Version 8, prescribing GnRH agonists to suppress sex steroids without concomitant sex steroid hormone replacement in eligible transgender and gender diverse adolescents seeking such intervention who are well into or have completed pubertal development (defined as past Tanner stage 3) but are unsure about or do not wish to begin sex steroid hormone therapy. PATH also recommends to begin pubertal hormone suppression in eligible transgender and gender diverse adolescents after they first exhibit physical changes of puberty (Tanner stage 2).

WPATH recommends health care professionals prescribe progestins or a GnRH agonist for eligible transgender and gender diverse adolescents with a uterus to reduce dysphoria caused by their menstrual cycle when gender-affirming testosterone use is not yet indicated.

WPATH also recommends health care professionals prescribe testosterone-lowering medications (including GnRH agonists) for eligible transgender and gender diverse people with testes taking estrogen as part of a hormonal treatment plan if their individual goal is to approximate levels of circulating sex hormone in cisgender women.

VI. REFERENCES

1. Eligard [package insert]. Fort Collins, CO: Tolmar Pharmaceuticals; April 2019.
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3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: Prostate Cancer. Version 3.2022. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed February 2, 2023.
4. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869–3903.
5. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
6. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, 8th version. ©2022 World Professional Association for Transgender Health. Available at <http://www.wpath.org>.
7. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: Head and Neck tumors. Version 1.2022. http://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed February 2, 2023.