

Specialty Guideline Management-FEHB

Eligard

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
|------------|--------------------|
| Eligard | leuprolide acetate |

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 Indication¹

Treatment of advanced prostate cancer.

Compendial Uses

- Prostate cancer²
- Androgen receptor positive salivary gland tumors^{2,8}
- Gender dysphoria (also known as transgender and gender diverse [TGD] persons)³⁻⁷

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

Coverage Criteria

Prostate Cancer¹⁻²

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

Gender Dysphoria^{3-7,9}

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

- The member has a diagnosis of gender dysphoria.
- Member is at least 19 years of age or older.
- The member is able to make an informed decision to engage in treatment.
- The member will receive the requested medication concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

Salivary Gland Tumors^{2,8}

Authorization of 12 months may be granted for treatment of recurrent, unresectable, or metastatic salivary gland tumors as a single agent or in combination with abiraterone and prednisone when the tumor is androgen receptor positive.

Continuation of Therapy

Salivary Gland Tumors

Authorization of 12 months may be granted for continued treatment of salivary gland tumors in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Prostate Cancer

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.

Gender Dysphoria^{6,9}

Authorization of 12 months may be granted for continued treatment for gender transition in members requesting reauthorization when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.

- Member is at least 19 years of age or older.
- The member is able to make an informed decision to engage in treatment.
- The member will receive the requested medication concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

References

1. Eligard [package insert]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc.; May 2024.
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3. 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.
4. 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.
5. Coleman E, Radix AE, Brown GR, et al. Standards of care for the health of transgender and gender diverse people, version 8. 2022;23(Suppl 1):S1-S259. doi: 10.1080/26895269.2022.2100644
6. Mahfouda S, Moore JK, Siafarikas A, et al. Puberty suppression in transgender children and adolescents. *Lancet Diabetes Endocrinol*. 2017;5:816-26.
7. Health Care for Transgender and Gender Diverse Individuals. ©2021 The American College of Obstetricians and Gynecologists. Available at: <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals>.
8. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Head and Neck Cancers. Version 2. 2025. Accessed February 4, 2025. https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf.
9. FEHB Program Carrier Letter. Letter Number 2025-01A. <https://www.opm.gov/healthcare-insurance/carriers/fehb/2025/2025-1a.pdf>. Accessed May 15, 2025.