Reference number(s)
4712-A

Standard Medicare Part B Management Eligard-Vabrinty

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
Vabrinty	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 Indication[1,2]

Treatment of advanced prostate cancer

Compendial Uses

- Prostate cancer[3]
- Androgen receptor-positive salivary gland tumors[3,8]
- Gender dysphoria (also known as transgender and gender diverse [TGD] persons)[5-7]

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

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Coverage Criteria

Prostate Cancer[1-4]

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

Gender Dysphoria[5-7]

Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member when both of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member has reached Tanner stage 2 of puberty or greater.

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

- The member has a diagnosis of gender dysphoria.
- The member will receive the requested medication concomitantly with gender-affirming hormones.

Salivary Gland Tumors[3,8]

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

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

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

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

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

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat prostate cancer.
- 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:

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- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat salivary gland tumor.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen AND
    - No evidence of disease progression while on the current regimen

Summary of Evidence

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

- The prescribing information for Eligard and Vabrinty.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Prostate cancer
- NCCN Guideline: Head and neck cancers
- Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline
- Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people.
- Standards of Care for the Health of Transgender and Gender Diverse People, Version 8

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

- Prostate cancer other than advanced prostate cancer
- Salivary gland tumors
- Gender dysphoria

Explanation of Rationale

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

Support for using leuprolide acetate 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 leuprolide acetate for gender dysphoria can be found in the Endocrine Society Clinical Practice Guideline for Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons. The

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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 leuprolide acetate for gender dysphoria can also be found in the World Professional Association for Transgender Health (WPATH). The Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, suggests to prescribe 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. WPATH 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 progestogens 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.

References

1. Eligard [package insert]. Fort Collins, CO: Tolmar Pharmaceuticals Inc.; May 2024.
2. Vabrinty [package insert]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc.; June 2025.
3. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 5, 2025.
4. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: Prostate Cancer. Version 1.2025. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed February 5, 2025.
5. 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.
6. 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.
7. 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
8. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: Head and neck tumors. Version 2.2025. http://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed February 5, 2025.

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