Reference number(s)
1989-A, 1990-A, 2117-A

Specialty Guideline Management leuprolide products

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	Dosage Form
Not applicable	leuprolide acetate	injection solution
Vobrig	leuprolide acetate	injection solution

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 Indications[1,2]

Leuprolide acetate is indicated in the palliative treatment of advanced prostate cancer.

Vobrig is indicated for the treatment of central precocious puberty in pediatric patients.

Compendial Uses

- Central precocious puberty (CPP)[3-10]
- Use as a stimulation test to confirm the diagnosis of CPP[4-7]
- Use in combination with growth hormone for children with growth failure and advancing puberty[11-16]
- Prostate cancer[17]
- Inhibition of premature luteinizing hormone (LH) surges in members undergoing ovulation induction or assisted reproductive technology[18,19]

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- Triggering of oocyte maturation and ovulation in assisted reproductive technology cycle[18]

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

Documentation

Submission of the following information is necessary to initiate the prior authorization review: For central precocious puberty initial requests, laboratory report or medical record documentation of a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal basal level of luteinizing hormone (LH) on a third-generation LH assay.

Coverage Criteria

Central Precocious Puberty (CPP)[2-10]

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

- The diagnosis of CPP has been confirmed by either of the following criteria based on laboratory reference range:
  - A pubertal response to a gonadotropin releasing hormone (GnRH) agonist test
  - A pubertal basal level of luteinizing hormone (LH) on a third-generation LH assay
- The assessment of bone age versus chronological age supports the diagnosis of CPP.
- The member meets either of the following criteria:
  - The member is a female and was less than 8 years of age at the onset of secondary sexual characteristics.
  - The member is a male and was less than 9 years of age at the onset of secondary sexual characteristics.
- The pathologic cause of CPP has been assessed (e.g., imaging screening for intracranial tumors, genetic testing for familial CPP [e.g., MKRN3 or DLK1 variants]).

Stimulation Test for CPP Diagnosis (leuprolide acetate only)[4-10]

Authorization of one dose may be granted for use as a stimulation test to confirm the diagnosis of CPP.

Advancing Puberty and Growth Failure (leuprolide acetate only)[11-16]

Authorization of 12 months may be granted for treatment of advancing puberty and growth failure in a pediatric member when leuprolide acetate is used in combination with growth hormone.

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Prostate Cancer (leuprolide acetate only)[1,17]

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

Inhibition of Premature Luteinizing Hormone (LH) Surges (leuprolide acetate only)‡[18,19]

Authorization of 12 months may be granted for the inhibition of premature LH surges in members undergoing ovulation induction or assisted reproductive technology (ART).

Oocyte Maturation and Ovulation Trigger (leuprolide acetate only)‡[20,21]

Authorization of 12 months may be granted for members undergoing ovulation induction or assisted reproductive technology (ART).

‡ Specialty Guideline Management coverage review will be bypassed for leuprolide if it is being requested for a procedure that has been approved under a member's medical benefit plan. Such members will be exempt from the requirements listed in the coverage criteria. A medical authorization number and confirmation of the approved procedure(s) will be required. NOTE: Some plans may opt-out of medical benefit alignment. Members receiving coverage under such plans must meet the requirements listed in the coverage criteria.

Continuation of Therapy

Central Precocious Puberty[2-10]

Authorization of up to 12 months may be granted for continued treatment of CPP when the member meets both of the following criteria:

- The member is either a female less than 12 years of age or a male less than 13 years of age.
- The member is not experiencing treatment failure (e.g., clinical pubertal progression, lack of growth deceleration, continued excessive bone age advancement).

Prostate Cancer (leuprolide acetate only)

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

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All Other Indications (leuprolide acetate only)

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

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