

# Specialty Guideline Management

## leuprolide

### 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.

Generic Name	Dosage Form
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<sup>1</sup>

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

#### Compendial Uses

- Central precocious puberty (CPP)<sup>2-7,17</sup>
- Use as a stimulation test to confirm the diagnosis of CPP<sup>3-6</sup>
- Use in combination with growth hormone for children with growth failure and advancing puberty<sup>8-12</sup>
- Prostate cancer<sup>13</sup>
- Inhibition of premature luteinizing hormone (LH) surges in members undergoing ovulation induction or assisted reproductive technology<sup>14,15</sup>
- Androgen receptor positive salivary gland tumors<sup>13,19</sup>
- Triggering of oocyte maturation and ovulation in assisted reproductive technology cycle<sup>16</sup>

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: laboratory report or medical record of a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third-generation luteinizing hormone (LH) assay.

## Coverage Criteria

### Central precocious puberty (CPP)<sup>2-7,17</sup>

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 a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third-generation luteinizing hormone (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 mutations]).

### Stimulation test for CPP diagnosis<sup>3-6,17</sup>

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

### Advancing puberty and growth failure<sup>8-12</sup>

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.

### Prostate cancer<sup>1,13</sup>

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

## Salivary gland tumors<sup>13,19</sup>

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

## Inhibition of premature luteinizing hormone (LH) surges<sup>‡14,15</sup>

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<sup>‡16,18</sup>

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<sup>2-7,17</sup>

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

- The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
- 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

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.

## Salivary gland tumors

Authorization of 12 months may be granted for continued treatment of salivary gland tumors in members requesting authorization who are experiencing clinical benefit to therapy and who have not experienced an unacceptable toxicity.

## All other indications

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

## References

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1989-A, 1990-A, 2117-A

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