

## SPECIALTY GUIDELINE MANAGEMENT

### leuprolide acetate injection

#### 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 Indications

1. Prostate cancer: Leuprolide acetate is indicated in the palliative treatment of advanced prostate cancer.
2. Central precocious puberty (CPP): Leuprolide acetate is indicated in the treatment of children with central precocious puberty.

###### B. Compendial Uses

1. Use as a stimulation test to confirm the diagnosis of CPP
2. Use in combination with growth hormone for children with growth failure and advancing puberty
3. Prostate cancer
  - a. Adjuvant therapy for lymph node-positive disease found during pelvic lymph node dissection (PLND)
  - b. Initial androgen deprivation therapy (ADT) for:
    - i. Intermediate risk group
    - ii. High or very high risk group
    - iii. Regional disease
    - iv. Metastatic disease
  - c. Recurrent disease in patients who experience biochemical failure after previous therapy
  - d. Progressive castration-naïve disease
4. Inhibition of premature luteinizing hormone (LH) surges in women undergoing assisted reproductive technology

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. EXCLUSIONS

Coverage will not be provided for members with prostate cancer if leuprolide acetate is used as neoadjuvant androgen deprivation therapy (ADT) for radical prostatectomy.

##### III. CRITERIA FOR INITIAL APPROVAL

###### A. **Central precocious puberty (CPP)**

1. Authorization up to age 12 may be granted for the treatment of CPP in a female member when all of the following criteria are met:

- a. 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
  - b. The diagnosis of CPP has been confirmed by assessment of bone age versus chronological age
  - c. The member was less than 8 years of age at the onset of secondary sexual characteristics
2. Authorization up to age 13 may be granted for the treatment of CPP in a male member when all of the following criteria are met:
    - a. The diagnosis of CPP has been confirmed by a pubertal response to a GnRH agonist test or a pubertal level of a third generation LH assay
    - b. The diagnosis of CPP has been confirmed by assessment of bone age versus chronological age
    - c. The member was less than 9 years of age at the onset of secondary sexual characteristics

**B. Stimulation test for CPP diagnosis**

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

**C. Advancing puberty and growth failure**

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

**D. Prostate cancer**

1. Authorization of 12 months may be granted for treatment of lymph node-positive disease found during pelvic lymph node dissection (PLND) when leuprolide acetate is used as adjuvant therapy.
2. Authorization of 12 months may be granted for treatment of prostate cancer with intermediate, high or very high risk stratification when leuprolide acetate is used as initial androgen deprivation therapy (ADT).
3. Authorization of 12 months may be granted for treatment of regional or metastatic prostate cancer when leuprolide acetate is used as initial androgen deprivation therapy (ADT).
4. Authorization of 12 months may be granted for treatment of recurrent prostate cancer in members who experience biochemical failure after previous therapy.
5. Authorization of 12 months may be granted for treatment of progressive castration-naïve prostate cancer.

**E. Inhibition of premature LH surge<sup>‡</sup>**

1. Authorization of 12 months may be granted for the inhibition of LH surge in a member with infertility.

<sup>‡</sup> 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 in Section III E. 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 in Section III E.*

**IV. CONTINUATION OF THERAPY**

**A. Central precocious puberty**

1. Authorization up to age 12 may be granted for continuation of therapy for CPP in a female member if the member is currently less than 12 years of age.
2. Authorization up to age 13 may be granted for continuation of therapy for CPP in a male member if the member is currently less than 13 years of age.

**B. Prostate cancer, stimulation test for CPP diagnosis, advancing puberty and growth failure, and infertility**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

**V. REFERENCES**

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