Totally Revised: 2/2019

SPECIALTY GUIDELINE MANAGEMENT
leuprolide acetate injection

An Age Limit Prior Authorization will be in place for members who are ages 0-18 years of age.

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

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

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

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

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

I **V. REFERENCES**

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