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 without external beam radiation therapy (EBRT) for lymph node-positive disease found during pelvic lymph node dissection (PLND)
   b. Initial androgen deprivation therapy (ADT)
      i. Intermediate risk group with EBRT
      ii. High or very high risk group with EBRT
      iii. High or very high risk group with EBRT and docetaxel
      iv. Very high risk group who are not candidates for definitive therapy without EBRT
      v. Regional disease
      vi. 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. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

A. CPP:
   1. Laboratory report: Peak luteinizing hormone (LH) level after a gonadotropin-releasing hormone (GnRH) agonist stimulation test or
   2. Laboratory report: Basal LH level using a third generation LH assay

III. 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.

IV. CRITERIA FOR INITIAL APPROVAL
A. Central precocious puberty
   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 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. Appropriate diagnostic imaging of the brain has been done to exclude an intracranial tumor
      d. 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. Appropriate diagnostic imaging of the brain has been done to exclude an intracranial tumor
      d. 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 24 months may be granted for the treatment of lymph node-positive disease found during PLND when leuprolide acetate is used as adjuvant therapy without EBRT.
   2. Authorization of 6 months may be granted for the treatment of prostate cancer in a member with intermediate risk stratification when leuprolide acetate is used in combination with EBRT as initial ADT.
   3. Authorization of 24 months may be granted for the treatment of prostate cancer in a member with high and very high risk stratification when leuprolide acetate is used in combination with EBRT or EBRT and docetaxel as initial ADT.
   4. Authorization of 24 months may be granted for the treatment of prostate cancer in a member with very high risk stratification who is not a candidate for definitive therapy when leuprolide acetate is used as initial ADT without EBRT.
   5. Authorization of 24 months may be granted for the treatment of regional or metastatic prostate cancer when leuprolide acetate is used as initial ADT.
   6. Authorization of 24 months may be granted for the treatment of recurrent prostate cancer in member who experience biochemical failure after previous therapy.
   7. Authorization of 24 months may be granted for the treatment of progressive castration-naïve prostate cancer.

E. Inhibition of premature LH surge
   1. Authorization of 12 months may be granted for the inhibition of LH surge in a member with infertility undergoing ovulation induction or an assisted reproductive technology procedure.

V. 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.

VI. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

VII. REFERENCES