SPECIALTY GUIDELINE MANAGEMENT

leuprolide acetate injection

POLICY

A. 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

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

Compendial Uses

- Use as a stimulation test to confirm the diagnosis of CPP\(^3-5\)
- Use in combination with growth hormone for children with growth failure and advancing puberty
- Prostate cancer:
  - Treatment of metastatic disease; node-positive disease; recurrent disease; or in combination with radiation therapy for patients with intermediate, high, or very high risk stratification; or without radiation therapy in patients with very high risk stratification who are not candidates for definitive therapy
  - Inhibition of premature luteinizing hormone (LH) surges in women undergoing controlled ovarian stimulation

B. REQUIRED DOCUMENTATION

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

- CPP:
  - Documentation of peak luteinizing hormone (LH) level after a gonadotropin-releasing hormone (GnRH) agonist stimulation test or basal LH level using a 3rd generation LH assay
- Ovarian stimulation:
  - Documentation of procedure type
- Prostate cancer:
  - Cancer type/location, tumor histology and grade, TNM staging, new cancer/recurrence, metastases, prior treatments, treatment intent (e.g., initial chemotherapy, neoadjuvant, adjuvant, or palliative)
  - Treatment plan with treatment regimen including dose, frequency, length of each cycle, number of cycles, and additional therapies (e.g., other medications, radiation)
  - Current PSA, baseline PSA, Gleason score

C. EXCLUSION

- Prostate cancer: use as neoadjuvant androgen deprivation therapy (ADT) for radical prostatectomy

D. CRITERIA FOR APPROVAL

1. Central Precocious Puberty

   a. Authorization up to age 12 may be granted to female members who are prescribed leuprolide acetate for the treatment of CPP when ALL of the following criteria are met:
      i. The diagnosis of CPP has been confirmed by a pubertal response to a GnRH agonist test OR a 3\(^{rd}\) generation assay basal LH level
      ii. The diagnosis of CPP has been confirmed by assessment of bone age versus chronological age
      iii. Appropriate diagnostic imaging of the brain has been done to exclude an intracranial tumor
      iv. The member was less than 8 years of age at the onset of secondary sexual characteristics

   b. Authorization up to age 13 may be granted to male members who are prescribed leuprolide acetate for the treatment of CPP when ALL of the following criteria are met:
i. The diagnosis of CPP has been confirmed by a pubertal response to a GnRH agonist test OR a 3rd
generation assay basal LH level
ii. The diagnosis of CPP has been confirmed by assessment of bone age versus chronological age
iii. Appropriate diagnostic imaging of the brain has been done to exclude an intracranial tumor
iv. The member was less than 9 years of age at the onset of secondary sexual characteristics

2. **Stimulation test for CPP diagnosis**
   a. Authorization of 1 dose may be granted to members who are prescribed leuprolide acetate for use as a
      stimulation test to confirm the diagnosis of CPP.

3. **Advancing puberty and growth failure**
   a. Authorization of 12 months may be granted to pediatric members who are prescribed leuprolide acetate in
      combination with growth hormone for treatment of advancing puberty and growth failure.

4. **Prostate Cancer**
   a. Authorization of 24 months may be granted to members prescribed leuprolide acetate for the treatment of
      metastatic prostate cancer
   b. Authorization of 24 months may be granted to members prescribed leuprolide acetate for the treatment of
      recurrent prostate cancer who experience biochemical failure after previous therapy
   c. Authorization of 24 months may be granted to members prescribed leuprolide acetate for the treatment of
      prostate cancer in members with positive lymph nodes
   d. Authorization of 6 months may be granted to members prescribed leuprolide acetate in combination with
      external beam radiation therapy for the treatment of prostate cancer with intermediate risk stratification
   e. Authorization of 24 months may be granted to members prescribed leuprolide acetate in combination with
      external beam radiation therapy for the treatment of prostate cancer with high and very high risk stratification
   f. Authorization of 24 months may be granted to members prescribed leuprolide acetate for the treatment of
      prostate cancer in members with very high risk stratification who are not candidates for definitive therapy

5. **Inhibition of Premature LH Surge**
   a. Authorization of 12 months may be granted to female members who are prescribed leuprolide acetate for the
      inhibition of LH surges and who are undergoing controlled ovarian stimulation with follitropins and/or
      menotropins for ovulation induction or as part of an assisted reproductive technology procedure

E. **CONTINUATION OF THERAPY**

1. **CPP**
   a. Authorization up to age 12 may be granted to female members who are prescribed leuprolide acetate for
      continuation of therapy for CPP if the member is currently less than 12 years of age.
   b. Authorization up to age 13 may be granted to male members who are prescribed leuprolide acetate for
      continuation of therapy for CPP if the member is currently less than 13 years of age.

2. **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.

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

1. **Dosing Limits**
   The following dosing limits apply to premature LH surges and prostate cancer: Maximum dose of leuprolide
   acetate is 1 mg per day
REFERENCES