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.

Compendial Uses
• 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
• Central precocious puberty (CPP)
• Use as a stimulation test to confirm the diagnosis of CPP
• Use in combination with growth hormone for children with growth failure and advancing puberty
• Inhibition of premature luteinizing hormone (LH) surges in women undergoing assisted reproductive technology (ART)

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
• Female infertility: documentation of ART type is required (e.g.: IVF, ZIFT, GIFT, TET)
• 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 of up to age 12 may be granted to female members who are prescribed leuprolide acetate for 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 basal luteinizing hormone (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 of up to age 13 may be granted to male members who are prescribed leuprolide acetate for 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 basal luteinizing hormone (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. Prostate Cancer
a. Authorization of 24 months may be granted to patients prescribed leuprolide acetate for the treatment of metastatic prostate cancer
b. Authorization of 24 months may be granted to patients 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 patients prescribed leuprolide acetate for the treatment of prostate cancer in patients with positive lymph nodes
d. Authorization of 6 months may be granted to patients 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 patients 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 patients prescribed leuprolide acetate for the treatment of prostate cancer in patients with very high risk stratification who are not candidates for definitive therapy

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

4. Advancing puberty and growth failure
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.

5. Infertility
Authorization of 12 months may be granted to female members who are prescribed leuprolide acetate for treatment of infertility when ALL of the following criteria are met:
   a. The intent of therapy is to inhibit premature LH surges
   b. The member is undergoing ART (documentation of ART type is required)

E. CONTINUATION OF THERAPY
1. CPP
   a. Authorization of 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 of 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 for the treatment of female infertility and prostate cancer:
   • Maximum dose of leuprolide acetate is 1 mg per day
REFERENCES