SPECIALTY GUIDELINE MANAGEMENT

LUPRON DEPOT-PED 7.5 mg-1 MONTH
LUPRON DEPOT-PED 11.25 mg-1 MONTH
LUPRON DEPOT-PED 15 mg-1 MONTH
LUPRON DEPOT-PED 11.25 mg-3 MONTH
LUPRON DEPOT-PED 30 mg-3 MONTH
(leuprolide acetate for depot suspension)

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
• Central precocious puberty
  o Lupron Depot-PED is indicated in the treatment of children with central precocious puberty (CPP). CPP is defined as early onset of secondary sexual characteristics (generally earlier than 8 years of age in girls and 9 years of age in boys) associated with pubertal pituitary gonadotropin activation. It may show a significantly advanced bone age that can result in diminished adult height. Prior to initiation of treatment a clinical diagnosis of CPP should be confirmed by measurement of blood concentrations of luteinizing hormone (LH) (basal or stimulated with a gonadotropin releasing hormone [GnRH] analog), sex steroids, and assessment of bone age versus chronological age. Baseline evaluations should include height and weight measurements, diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor), and adrenal steroid measurements to exclude congenital adrenal hyperplasia.

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

B. CRITERIA FOR APPROVAL
1. CPP
   a. Authorization of up to age 12 may be granted to female members who are prescribed Lupron Depot-PED 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 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 Lupron Depot-PED 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 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

C. CONTINUATION OF THERAPY
1. CPP
   a. Authorization of up to age 12 may be granted to female members who are prescribed Lupron Depot-PED for continuation of therapy for CPP AND 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 Lupron Depot-PED for continuation of therapy for CPP AND the member is currently less than 13 years of age.

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

REFERENCES