SPECIALTY GUIDELINE MANAGEMENT

Lupron Depot-PED (leuprolide acetate for depot suspension)

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 Indication

Lupron Depot-PED is indicated for the treatment of children with central precocious puberty (CPP).

B. Compendial Use

Gender dysphoria (also known as gender non-conforming or transgender persons)

NOTE: Some plans may opt-out of coverage for gender dysphoria.

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

II. 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. Gender dysphoria

1. Authorization of 12 months may be granted for pubertal suppression in preparation for gender reassignment in an adolescent member when ALL of the following criteria are met:
   a. The member has a diagnosis of gender dysphoria
   b. The member has reached Tanner stage 2 of puberty

2. Authorization of 12 months may be granted for gender reassignment in an adult member when ALL of the following criteria are met:
   a. The member has a diagnosis of gender dysphoria
   b. The member will receive Lupron Depot-PED concomitantly with cross sex hormones
III. CONTINUATION OF THERAPY

A. CPP
   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. Gender Dysphoria
   All members (including new members) requesting authorization for continuation of therapy must meet ALL
   initial authorization criteria.

IV. REFERENCES
   4. Houk CP, Kunselman AR, Lee PA. Adequacy of a single unstimulated luteinizing hormone level to
   5. Kaplowitz P, Bloch C, the Section on Endocrinology. Evaluation and referral of children with signs of early
   6. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-
   7. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment
      of gender variant people. UK Department of Health. Published March 10, 2008.
   8. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, 7th