

## SPECIALTY GUIDELINE MANAGEMENT

### Supprelin LA (histrelin acetate)

#### 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

Supprelin LA is indicated for the treatment of children with central precocious puberty.

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. REQUIRED DOCUMENTATION

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

For CPP:

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

##### III. 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 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. 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 Supprelin LA concomitantly with cross sex hormones

#### **IV. 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.

#### **V. DOSAGE AND ADMINISTRATION**

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

The following dosing limit applies for CPP: One 50mg implant per 12 months

#### **VI. REFERENCES**

1. Supprelin LA [package insert]. Chadds Ford, PA: Endo Pharmaceuticals Solutions Inc.; June 2013.
2. Kletter GB, Klein KO, Wong YY. A pediatrician's guide to central precocious puberty. *Clin Pediatr.* 2015;54(5):414-24.
3. Carel J, Leger J. Precocious puberty. *N Engl J Med.* 2008;358:2366-2377.
4. Carel J, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics.* 2009;123:e752-e762.
5. Houk CP, Kunselman AR, Lee PA. Adequacy of a single unstimulated luteinizing hormone level to diagnose central precocious puberty in girls. *Pediatrics.* 2009;123:e1059-e1063.
6. Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2009;94:3152-3154.
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 version. ©2012 World Professional Association for Transgender Health. Available at <http://www.wpath.org>.