Reference number(s)
3890-A

SPECIALTY GUIDELINE MANAGEMENT

FENSOLVI (leuprolide 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.

FDA-Approved Indication
Fensolvi is indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

For central precocious puberty, submission of a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third-generation luteinizing hormone (LH) assay is required to initiate the prior authorization.

III. CRITERIA FOR INITIAL APPROVAL

Central precocious puberty (CPP)

A. Authorization of 12 months may be granted for treatment of CPP in a female member when all of the following criteria are met:
   1. Intracranial tumor has been evaluated by appropriate lab tests and diagnostic imaging, such as computed tomography (CT scan), magnetic resonance imaging (MRI), or ultrasound.
   2. 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.
   3. The assessment of bone age versus chronological age supports the diagnosis of CPP.
   4. The member was less than 8 years of age at the onset of secondary sexual characteristics.

B. Authorization of 12 months may be granted for treatment of CPP in a male member when all of the following criteria are met:
   1. Intracranial tumor has been evaluated by appropriate lab tests and diagnostic imaging, such as CT scan, MRI, or ultrasound.
   2. 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.
   3. The assessment of bone age versus chronological age supports the diagnosis of CPP.
   4. The member was less than 9 years of age at the onset of secondary sexual characteristics.

IV. CONTINUATION OF THERAPY

Central precocious puberty (CPP)

A. Authorization of up to 12 months may be granted for continuation of therapy for CPP in a female member if the member is currently less than 12 years of age and the member meets both of the following:
   1. The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
   2. The member is not experiencing treatment failure such as clinical pubertal progression, lack of growth deceleration, and continued excessive bone age advancement.

B. Authorization of up to 12 months may be granted for continuation of therapy for CPP in a male member if the member is currently less than 13 years of age and the member meets both of the following:
   1. The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
   2. The member is not experiencing treatment failure such as clinical pubertal progression, lack of growth deceleration, and continued excessive bone age advancement.

V. REFERENCES

1. Fensolvi [package insert]. Fort Collins, CO: Tolmar, Inc.; May 2020.
2. Kletter GB, Klein KO, Wong YY. A pediatrician's guide to central precocious puberty. *Clin Pediatr.* 2015;54:414-424.
3. 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.
4. Bangalor Krishna K, Fuqua JS, Rogol AD, et al. Use of gonadotropin-releasing hormone analogs in children: Update by an international consortium. *Horm Res Paediatr*. 2019;91(6):357-372.
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. Kaplowitz P, Bloch C, the Section on Endocrinology. Evaluation and referral of children with signs of early puberty. *Pediatrics.* 2016;137:e20153732.