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P&T Date: 10/09/2025

Gonadotropin-Releasing Hormone (GnRH) Agonists for Central Precocious Puberty

Fensolvi® (leuprolide acetate)
Lupron Depot-PED® (leuprolide acetate)
Supprelin® LA (histrelin acetate)
Triptodur® (triptorelin)

HCPCS: Fensolvi: J1951; Lupron Depot-PED: J1950; Supprelin LA: J9226; Triptodur: J3316

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved indication
 - b. FDA approved age
 - c. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list.
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limit: Align with FDA recommended dosing
 - b. Authorization Period: One year at a time
 - c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit.

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Central precocious puberty (CPP) is the early onset of sexual characteristics in children, typically before 8 years of age in girls and 9 years of age in boys. It is caused by early maturation of the hypothalamic-pituitary-gonadal (HPG) axis. Children with CPP experience accelerated growth for their age, advanced bone age, and hormone levels comparable to those seen in puberty. CPP is generally idiopathic and more common in females; however, it can also be caused by central nervous system lesions and specific, very rare genetic mutations.

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- Guidance on the evaluation and referral of children with signs of early puberty from the American Academy of Pediatrics (2016) indicate treatment of CPP with gonadotropin-releasing hormone (GnRH) agonists may be warranted to preserve height potential as progressive CPP can result in premature growth cessation and short stature. Other reasons provided in consideration of treatment include prevention of early menarche and the psychological effects that accompany it and the suppression of sexual maturation in girls that are emotionally immature and in boys suppressing the hormonal changes that may result in aggressive or sexual behaviors.
- GnRH agonists inhibit gonadotropin secretion, with continuous administration resulting in reversible suppression of ovarian and testicular steroidogenesis. Fensolvi, Lupron Depot-PED, Supprelin LA, and Triptodur are FDA-approved GnRH agonists indicated for pediatric patients with CPP. Fensolvi, Supprelin LA, and Triptodur are approved for pediatrics 2 years of age and older, while Lupron Depot-PED can be used in patients as young as 1 year old. All four products require administration by a healthcare provider.
- Height and bone age should be assessed at regular intervals ranging from every 3-6 months or every 6-12 months depending on the product, as should response to therapy with a GnRH stimulation test, basal luteinizing hormone or serum concentration of sex steroid. Refer to the FDA-approved labeling for recommended monitoring frequency for each individual product.
- Clinical indicators that treatment is successful include slowing of growth velocity to <7 cm/year and shrinkage or softening of breast tissue or the testes. Endocrinologists may also document HPG axis suppression via a GnRH stimulation test. Treatment with GnRH agonists is usually stopped at the discretion of the physician when continued pubertal suppression is no longer beneficial to the child, typically at the appropriate time point for puberty onset.

References:

1. Fensolvi [prescribing information]. Fort Collins, CO: Tolmar; October 2025.
2. Harrington J, Palmert MR. Precocious puberty: Treatment. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on September 11, 2025).
3. IPD Analytics. Payer & Provider Insights. Endocrinology and Metabolic Agents: Central Precocious Puberty. [Accessed September 12, 2025]. <https://www.ipdanalytics.com>.
4. Kaplowitz P, Bloch C, the SECTION ON ENDOCRINOLOGY. Evaluation and Referral of Children with Signs of Early Puberty. Pediatrics. 2016;137(1):e20153732
5. Lupron Depot-PED [prescribing information]. North Chicago, IL: AbbVie Inc.; May 2025
6. Supprelin LA [prescribing information]. Malvern, PA: Endo USA; April 2022.
7. Triptodur [prescribing information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; November 2023.

Policy History		
#	Date	Change Description
1.1	Effective Date: 01/01/2026	UM medical management system update for BCBS and BCN for Fensolvi and Triptodur
1.0	Effective Date: 10/09/2025	New policy

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.*