Reference number(s)
2077-A

Specialty Guideline Management
Lupron Depot-PED

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage form
Lupron Depot-PED	leuprolide acetate	depot suspension

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[1]

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

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

Documentation

Submission of the following information is necessary to initiate the prior authorization review: For central precocious puberty, laboratory report or medical record of a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third-generation luteinizing hormone (LH) assay.

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Coverage Criteria

Central precocious puberty (CPP)[1-7]

Authorization of 12 months may be granted for treatment of CPP when all of the following criteria are met:

- 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.
- The assessment of bone age versus chronological age supports the diagnosis of CPP.
- The member meets either of the following criteria:
    - The member is a female and was less than 8 years of age at the onset of secondary sexual characteristics.
    - The member is a male and was less than 9 years of age at the onset of secondary sexual characteristics.
- The pathologic cause of CPP has been assessed (e.g., imaging screening for intracranial tumors, genetic testing for familial CPP [e.g., MKRN3 or DLK1 mutations]).

Continuation of Therapy

Central precocious puberty (CPP)[2,4,7]

Authorization of up to 12 months may be granted for continued treatment for CPP when the member meets all of the following criteria:

- The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
- The member is either a female less than 12 years of age or a male less than 13 years of age.
- The member is not experiencing treatment failure (e.g., clinical pubertal progression, lack of growth deceleration, continued excessive bone age advancement).

References

1. Lupron Depot-PED [package insert]. North Chicago, IL: AbbVie Inc.; April 2023.
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. Bangalore 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. Bangalore Krishna K, Silverman LA. Diagnosis of central precocious puberty. Endocrinol Metab Clin North Am. 2024;53(2):217-227.
6. Kaplowitz P, Bloch C, the Section on Endocrinology. Evaluation and referral of children with signs of early puberty. Pediatrics. 2016;137:e20153732.
7. Cheuiche AV, da Silveira LG, de Paula LCP, et al. Diagnosis and management of precocious sexual maturation: an updated review. Eur J Pediatr. 2021;180(10):3073-3087.
8. Popovic J, Geffner ME, Rogol AD, et al. Gonadotropin-releasing hormone analog therapies for children with central precocious puberty in the United States. Front Pediar. 2022;10:968485. doi:10.3389/fped.2022.968485