



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Lupron Depot-PED Page: 1 of 3

Effective Date: 1/1/2024 Last Review Date: 11/2023

Applies to:	<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> Florida Kids
	<input type="checkbox"/> New Jersey	<input checked="" type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input type="checkbox"/> Pennsylvania Kids	<input checked="" type="checkbox"/> Virginia	<input type="checkbox"/> Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Lupron Depot-PED under the patient’s prescription drug benefit.

Description:

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

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.

Applicable Drug List:

Lupron Depot-PED

Policy/Guideline:

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.

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 (e.g., computed tomography [CT] scan, magnetic resonance imaging [MRI]).
 - 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.



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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.
 5. Patient is unable to take leuprolide acetate injection kit 1mg/0.2mL for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.
- 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 (e.g., CT scan, MRI).
 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.
 5. Patient is unable to take leuprolide acetate injection kit 1mg/0.2mL for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

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:
- a. The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
 - b. The member is not experiencing treatment failure (e.g., clinical pubertal progression, lack of growth deceleration, 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 (e.g., clinical pubertal progression, lack of growth deceleration, continued excessive bone age advancement).



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Approval Duration and Quantity Restrictions:

Approval: 12 months

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. 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.
7. Cheuiche AV, da Silveira LG, de Paula LCP, Lucena IRS, Silveiro SP. Diagnosis and management of precocious sexual maturation: an updated review. *Eur J Pediatr*. 2021;180(10):3073-3087.