

# 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 Indications<sup>1</sup>

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

#### Compendial Uses<sup>7-9</sup>

Gender dysphoria (also known as transgender and gender diverse (TGD) persons)

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.

## Prescriber Specialties<sup>12,E</sup>

For gender dysphoria, the medication must be prescribed by or in consultation with a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist) that has collaborated care with a mental health provider for members less than 18 years of age.

## Coverage Criteria

### Central precocious puberty (CPP)<sup>1-6,10,A,B</sup>

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]).

### Gender dysphoria<sup>7-9,D</sup>

Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member has reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

Reference number(s)
1972-A, 6051-A

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

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member will receive the requested medication concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

## Continuation of Therapy

### Central precocious puberty (CPP)<sup>2,4,10</sup>

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).

### Gender dysphoria<sup>11,E</sup>

Authorization of 12 months may be granted for continued treatment for pubertal hormonal suppression in adolescent members requesting reauthorization when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member has previously reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

Authorization of 12 months may be granted for continued treatment for gender transition in members requesting reauthorization when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member will receive the requested medication concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.

Reference number(s)
1972-A, 6051-A

- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

## Other

Per state regulatory guidelines around gender dysphoria, age restrictions may apply.

## References<sup>F</sup>

1. Lupron Depot-PED [package insert]. North Chicago, IL: AbbVie Inc.; April 2023.
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11. Mahfouda S, Moore JK, Siafarikas A, et al. Puberty Suppression in transgender children and adolescents. *Lancet Diabetes Endocrinol*. 2017; 5: 816-26.
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13. Popovic J, Geffner ME, Rogol AD, et al. Gonadotropin-releasing hormone analog therapies for children with central precocious puberty in the United States. *Front Pediatr*. 2022;10:968485. doi:10.3389/fped.2022.968485

## Internal References

- A. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Pediatric Endocrinology Clinical Programs. May 15, 2013.
- B. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Pediatric Endocrinology Clinical Programs. March 18, 2019.
- C. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Pediatric Endocrinology Clinical Programs. September 09, 2019.
- D. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Gender Dysphoria Clinical Programs. July 2020.
- E. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Gender Dysphoria Clinical Programs. September 2022.
- F. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Pediatric Endocrinology – Central Prococious Puberty Clinical Programs. January 21, 2025.

## Document History

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