AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Lupron Depot-PED	Page:	1 of 4
Effective Date:	7/11/2025	Last Review Date:	5/29/2025
Applies to:	☒New Jersey ☒Pennsylvania Kids	☒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.

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

B. Compendial Use
Gender dysphoria (also known as gender non-conforming or transgender persons)

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

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

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.

Prescriber Specialty:
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 patients less than 18 years of age.

Criteria for Initial Approval:

Central precocious puberty (CPP)

Requests for Lupron Depot-PED require that the 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.

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

Requests for gender dysphoria do not require trial and failure of a preferred product.

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.

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 Lupron Depot-PED 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)

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

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 Lupron Depot-PED 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.
- Before the start of therapy, the member has been informed of fertility preservation options.

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 12 months

References:

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