			Vae	etna™		
AETNA BETTER HEALTH®						
Coverage Policy/Guideline						
Name:	Lupron Depot-PED	Page:		1 of 4		
Effective Date:	7/11/2025	Last Rev	iew 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.

- <u>FDA-Approved Indication</u>
 Lupron Depot-PED is indicated for the treatment of pediatric patients with central precocious puberty (CPP).
- B. <u>Compendial Use</u> 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)

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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 <u>pubertal hormonal suppression in an</u> <u>adolescent member</u> when ALL of the following criteria are met:

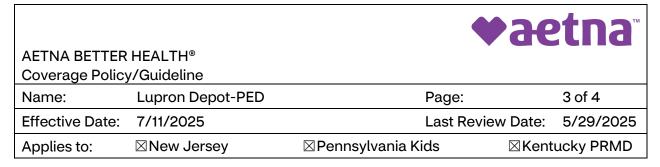
- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member has reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications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

Authorization of 12 months may be granted for <u>gender transition</u> 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 <u>continued treatment for pubertal hormonal</u> <u>suppression in adolescent members</u> 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 <u>gender transition</u> in members requesting reauthorization when ALL of the following criteria are met:

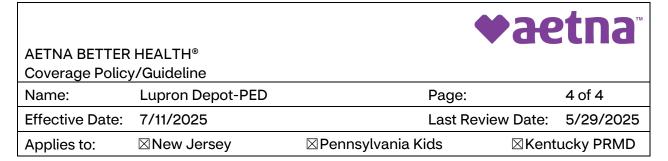
- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member will receive Lupron Depot-PED concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated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