SPECIALTY GUIDELINE MANAGEMENT

LUPRON DEPOT-PED (leuprolide acetate for depot suspension)

POLICY

I. 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.

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 transgender and gender diverse [TGD] persons)

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

II. 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.

III. PRESCRIBER SPECIALTIES

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.

IV. CRITERIA FOR INITIAL APPROVAL

A. Central precocious puberty (CPP)

- 1. Authorization of 12 months may be granted for treatment of CPP in a female member when all of the following criteria are met:
 - i. Member has been evaluated for intracranial tumors (e.g., lab tests, computed tomography [CT] scan, magnetic resonance imaging [MRI]).
 - ii. 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.
 - iii. The assessment of bone age versus chronological age supports the diagnosis of CPP.
 - iv. The member was less than 8 years of age at the onset of secondary sexual characteristics.

Lupron Depot-PED 1972-A, 6051-A SGM P2024a

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- 2. Authorization of 12 months may be granted for treatment of CPP in a male member when all of the following criteria are met:
 - i. Member has been evaluated for intracranial tumors (e.g., lab tests, CT scan, MRI).
 - ii. 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.
 - iii. The assessment of bone age versus chronological age supports the diagnosis of CPP.
 - iv. The member was less than 9 years of age at the onset of secondary sexual characteristics.

B. Gender dysphoria

- 1. Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member when all of the following criteria are met:
 - i. The member has a diagnosis of gender dysphoria.
 - ii. The member is able to make an informed decision to engage in treatment.
 - iii. The member has reached Tanner stage 2 of puberty or greater.
 - iv. The member's comorbid conditions are reasonably controlled.
 - v. The member has been educated on any contraindications and side effects to therapy.
 - vi. The member has been informed of fertility preservation options.
- 2. Authorization of 12 months may be granted for gender transition when all of the following criteria are met:
 - i. The member has a diagnosis of gender dysphoria.
 - ii. The member is able to make an informed decision to engage in treatment.
 - iii. The member will receive the requested medication concomitantly with gender-affirming hormones.
 - iv. The member's comorbid conditions are reasonably controlled.
 - v. The member has been educated on any contraindications and side effects to therapy.
 - vi. The member has been informed of fertility preservation options.

V. CONTINUATION OF THERAPY

A. Central precocious puberty (CPP)

- 1. 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:
 - The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
 - ii. The member is not experiencing treatment failure (e.g., clinical pubertal progression, lack of growth deceleration, continued excessive bone age advancement).
- 2. 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:
 - The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
 - ii. The member is not experiencing treatment failure (e.g., clinical pubertal progression, lack of growth deceleration, continued excessive bone age advancement).

B. Gender dysphoria

- 1. 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:
 - i. The member has a diagnosis of gender dysphoria.
 - ii. The member is able to make an informed decision to engage in treatment.
 - iii. The member has previously reached Tanner stage 2 of puberty or greater.

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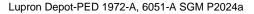
- iv. The member's comorbid conditions are reasonably controlled.
- v. The member has been educated on any contraindications and side effects to therapy.
- vi. Before the start of therapy, the member has been informed of fertility preservation options.
- 2. Authorization of 12 months may be granted for continued treatment for gender transition in members requesting reauthorization when all of the following criteria are met:
 - i. The member has a diagnosis of gender dysphoria.
 - ii. The member is able to make an informed decision to engage in treatment.
 - iii. The member will receive the requested medication concomitantly with gender-affirming hormones.
 - iv. The member's comorbid conditions are reasonably controlled.
 - v. The member has been educated on any contraindications and side effects to therapy.
 - vi. Before the start of therapy, the member has been informed of fertility preservation options.

VI. OTHER

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

VII. REFERENCES

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