

Supprelin LA (histrelin acetate) Effective 01/01/2024

Plan	□ MassHealth UPPL ⊠Commercial/Exchange	Due sue True s	Prior Authorization
Benefit	Pharmacy BenefitMedical Benefit	Program Type	Quantity Limit Step Therapy
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

A. <u>FDA-Approved Indication</u> Supprelin LA is indicated for the treatment of children with central precocious puberty (CPP).

- B. <u>Compendial Uses</u>
 - 1. Gender dysphoria (also known as gender non-conforming or transgender persons)
 - 2. Preservation of ovarian function
 - 3. Prevention of recurrent menstrual related attacks in acute porphyria

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

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted when the following diagnosis-specific criteria is met:

A. Central precocious puberty (CPP)

- 1. Authorization may be granted for treatment of CPP in a female member when all of the following criteria are met:
 - i. Intracranial tumor has been evaluated by appropriate lab tests and diagnostic imaging (e.g., 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.

- 2. Authorization may be granted for treatment of CPP in a male member when all of the following criteria are met:
 - i. Intracranial tumor has been evaluated by appropriate lab tests and diagnostic imaging (e.g., 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 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 has reached Tanner stage 2 of puberty or greater.
 - iii. The member's comorbid conditions are reasonably controlled.
 - iv. The member has been educated on any contraindications and side effects to therapy.
 - v. The member has been informed of fertility preservation options.
 - vi. The medication is 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.
- 2. Authorization 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 will receive Supprelin LA concomitantly with gender-affirming hormones.
 - iii. The member's comorbid conditions are reasonably controlled.
 - iv. The member has been educated on any contraindications and side effects to therapy.
 - v. The member has been informed of fertility preservation options.
 - vi. The medication is 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.

C. Preservation of ovarian function

Authorization may be granted for preservation of ovarian function when the member is premenopausal and undergoing chemotherapy.

D. Prevention of recurrent menstrual related attacks in acute porphyria

Authorization may be granted for prevention of recurrent menstrual related attacks in members with acute porphyria when the requested medication is prescribed by or in consultation with a physician experienced in the management of porphyrias.

Continuation of Therapy

A. Central precocious puberty (CPP)

- 1. Authorization 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:
 - i. 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 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:
 - i. 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 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 has previously reached Tanner stage 2 of puberty or greater.
 - iii. The member's comorbid conditions are reasonably controlled.
 - iv. The member has been educated on any contraindications and side effects to therapy.
 - v. Before the start of therapy, the member has been informed of fertility preservation options.
- 2. Authorization 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 will receive Supprelin LA concomitantly with gender-affirming hormones.
 - iii. The member's comorbid conditions are reasonably controlled.
 - iv. The member has been educated on any contraindications and side effects to therapy.
 - v. Before the start of therapy, the member has been informed of fertility preservation options.

C. All other indications

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

Limitations

- 1. For preservation of ovarian function: Initial approvals will be granted for 3 months.
- 2. For all other indications: Initial approvals and reauthorizations will be granted for 12 months.

References

- 1. Supprelin LA [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; April 2022.
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- 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.

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- 10. Moore HCF, Unger JM, Phillips K-A, et al. Goserelin for ovarian protection during breast-cancer adjuvant chemotherapy. *N Engl J Med.* 2015;372:923-32. doi:10.1056/NEJMoa1413204.
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- 16. Health Care for Transgender and Gender Diverse Individuals. ©2021 The American College of Obstetricians and Gynecologists. Available at: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals.

Review History

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024