

leuprolide acetate (Fensolvi)

Medical Benefit Drug Policy

Place of Service

Office Administration

Infusion Center Administration

Home Infusion Administration

Outpatient Facility Administration

Drug Details

USP Category: HORMONAL AGENTS, SUPPRESSANT (ADRENAL OR PITUITARY)

Mechanism of Action: Gonadotropin releasing hormone (GnRH) agonist

HCPCS:

J1951: Injection, leuprolide acetate for depot suspension (fensolvi), 0.25 mg

How Supplied:

45 mg of leuprolide acetate supplied in a kit

Condition(s) listed in policy *(see coverage criteria for details)*

- Central Precocious Puberty
- Gender Dysphoria in Adolescents

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Central Precocious Puberty

Meets medical necessity if all the following are met:

Documented diagnosis of central precocious puberty (neurogenic or idiopathic)

Covered Doses:

Up to 45 mg given subcutaneously once every six months

Coverage Period:

Indefinite

ICD-10:

E30.1

Gender Dysphoria in Adolescents

Meets medical necessity if all the following are met:

Covered Doses:

Up to 45 mg given subcutaneously once every six months

Coverage Period:

Indefinite

ICD-10:

F64.0, F64.1, F64.2, F64.9

References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com>
3. Fensolvi (leuprolide acetate) Prescribing Information. Tolmar Pharmaceuticals, Inc. Fort Collins, CO. 11/2022.
4. Hembree WC, Cohen-Kettenis PT, Gooren L, Hannema SE, Meyer WJ, Murad MH, Rosenthal SM, Safer JD, Tangpricha V, T'Sjoen GG. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017;102(11):3869-3903.
5. World Professional Association for Transgender Health Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (Version 8). 2022. Available at: <https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644>

Review History

Date of Last Annual Review: 2Q2025

Changes from previous policy version:

- No clinical change to policy following annual review.

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*