Leuprolide acetate (Fensolvi®)	Place of Service Office Administration Infusion Center Administration Home Infusion Administration Outpatient Facility Administration HCPCS: **J1951** per 0.25 mg

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

- Central precocious puberty
- Gender dysphoria in adolescents

AHFS therapeutic class: Gonadotropin

Mechanism of action: Gonadotropin releasing hormone (GnRH) agonist

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Fensolvi® (leuprolide acetate) not listed in section (3) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Central precocious puberty

- Documented diagnosis of central precocious puberty (neurogenic or idiopathic)

Covered Doses
45 mg SC injection once every six months

ICD-10:
E30.1

Gender dysphoria in adolescents

Covered Doses
45 mg SC injection once every six months

ICD-10:
F64,0, F64.1, F64.2, F64.9

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Fensolvi® (leuprolide acetate) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
45 mg of leuprolide acetate supplied in a kit

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com
- Fensolvi® (leuprolide acetate) [Prescribing Information]. Tolmar Pharmaceuticals, Inc. Fort Collins, CO. 2020.
- 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.
- 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

(7) Policy Update

Date of last review: 3Q2023
Date of next review: 3Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee