Medical Necessity Guidelines

Medical Benefit Drugs

Gonadotropin-releasing Hormone (GnRH) Agonists: Fensolvi®, Lupron Depot®, Lupron Depot-Ped®, and Supprelin LA®

Effective: January 1,2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☐ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual-eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration - Approved Indications

Fensolvi (leuprolide acetate) is indicated for treatment of pediatric patients 2 years of age and older with central precocious puberty.

Lupron Depot (leuprolide acetate for depot suspension) 3.75 mg for 1-month and 11.25 mg for 3- month administration is indicated:

- For management of endometriosis, including pain relief and reduction of endometriotic lesions.
- For use with iron therapy before fibroid surgery to improve anemia from fibroids.

Lupron Depot-Ped (leuprolide acetate for depot suspension) is indicated in the treatment of pediatric patients with central precocious puberty.

Supprelin LA (histrelin) is indicated for the treatment of children with central precocious puberty.

Clinical Guideline Coverage Criteria

Central Precocious Puberty

The Plan may authorize coverage of Fensolvi, Supprelin LA, or Lupron Depot-Ped for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of central precocious puberty

AND

2. Documentation of **one** of the following:
    a. Fensolvi and Lupron Depot-Ped: The Member is ≤18 years of age

b. Supprelin LA: The Member is ≤12 years of age

AND

3. If the request is for Fensolvi, documentation of an inadequate response to or clinical inappropriateness to **ALL** of the following: Triptodur (triptorelin), Supprelin LA (histrelin) and Lupron Depot-Ped (leuprolide)

Endometriosis

The Plan may authorize coverage of Lupron-Depot 3.75 mg and 11.25 mg for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of endometriosis

AND

2. Documentation of **one (1)** of the following:
   a. The Member has tried and failed therapy with or the provider has indicated clinical inappropriateness or contraindication to treatment with nonsteroidal anti-inflammatory drugs (NSAIDs) and at least **two** different hormonal contraceptives
   b. The Member is new to the plan and stable on Lupron Depot for endometriosis prior to enrollment

Fibroids

The Plan may authorize coverage of Lupron-Depot 3.75 mg and 11.25 mg for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of anemia due to fibroids (uterine leiomyomata)

AND

2. Documentation that Lupron Depot will be used prior to surgery for fibroids (uterine leiomyomata)

Gender Dysphoria in Adolescents

The Plan may authorize coverage of a Lupron Depot-Ped or Supprelin LA for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of gender dysphoria

AND

2. Documentation that the Member is an adolescent

AND

3. Documentation the Member has experienced puberty development to at least Tanner stage 2

Gender Dysphoria in Adults

The Plan may authorize coverage of a Lupron Depot-Ped or Supprelin LA for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of gender dysphoria

AND

2. Documentation the Member is at least 18 years of age

AND

3. Documentation the Member will receive the requested agent concomitantly with cross sex hormones (testosterone or estrogen and spironolactone)

Limitations

- The Plan does not provide coverage for Fensolvi, Lupron Depot, Lupron Depot-Ped, or Supprelin LA for the treatment of idiopathic short stature.
- Requests for central precocious puberty will be approved based on the following:
  - Fensolvi and Lupron Depot-Ped: Until 19 years of age
  - Supprelin LA: Until 13 years of age
- Requests for endometriosis will be authorized for 6 months. Based on package labeling concerns regarding the adverse impact of long-term treatment on bone thinning, Members will be approved for a total of two 6-month authorizations total if coverage criteria are met.
- Requests for fibroids will be authorized as a one-time 3-month approval.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9226	Histrelin implant (Supprelin LA), 50 mg
J1950	Injection, leuprolide acetate (for depot suspension), per 3.75 mg
J1951	Injection, leuprolide acetate for depot suspension, 0.25 mg (Fensolvi)

References

1. Bodri D, Sunkara SK, Coomarasamy A. Gonadotropin-releasing hormone agonists versus antagonists for controlled ovarian hyperstimulation in oocyte donors: A systematic review and meta- analysis. *Fertil Steril*. 2011;95(1):164-169.
2. Cara JF, Kreiter ML, Rosenfield RL. Height prognosis of children with true precocious puberty and growth hormone deficiency: Effect of combination therapy with gonadotropin releasing hormone agonist and growth hormone. *J Pediatr*. 1992;120(5):709-715.
3. Coleman E, Bockting W, Botzer M, et al. Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7. International Journal of Transgenderism. 2012; Vol. 13, Iss. 4
4. Crawford ED, Eisenberger MA, McLeod DG, et al. A controlled trial of leuprolide with and without flutamide in prostatic carcinoma. *N Engl J Med*. 1989;321(7):419-24.
5. Fensolvi (leuprolide acetate) [package insert]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc.; September 2025.
6. Friedman AJ, Harrison-Atlas D, Barbieri RL, et al. A randomized, placebo-controlled, double-blind study evaluating the efficacy of leuprolide acetate depot in the treatment of uterine leiomyomata. *Fertil Steril*. 1989;51(2):251-6.
7. Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2009 Sep;94(9):3132-54.
8. Hornstein MD, Surrey ES, Weisberg GW, et al. Leuprolide acetate depot and hormonal addback in endometriosis: a 12-month. study. Lupron Add-Back Study Group. *Obstet Gynecol*. 1998;91(1):16- 24.
9. Lupron Depot (leuprolide acetate for depot suspension 11.25 mg) [package insert]. North Chicago, IL: AbbVie Inc.;September 2025.
10. Lupron Depot (leuprolide acetate for depot suspension 3.75 mg) [package insert]. North Chicago, IL: AbbVie Inc; September 2025.
11. Lupron Depot-Ped (leuprolide acetate for depot suspension 7.5 mg, 11.25 mg, 15 mg, 30 mg) [package insert]. North Chicago, IL: Abbott Laboratories; September 2025.
12. Mul D, Wit JM, Oostdijk W, et al. The effect of pubertal delay by GnRH agonist in GH-deficient children on final height. *J Clin Endocrinol Metab*. 2001;86(10):4655-4656.
13. National Comprehensive Cancer Network (NCCN). NCCN Drugs & Biologics Compendium. Leuprolide acetate. 2014. NCCN: Fort Washington, PA.
14. Ohyama K, Tanaka T, Tachibana K, et al. Timing for discontinuation of treatment with a long-acting gonadotropin-releasing hormone analog in girls with central precocious puberty. TAP-144SR CPP Study Group. *Endocr J*. 1998;45(3):351-6.
15. Partsch CJ, Sippell WG. Treatment of central precocious puberty. *Clinical Endocrinol and Metobol.*2002;16(1):165-189.
16. Rosenthal SM. Approach to the patient: transgender youth: endocrine considerations. *J Clin Endocrinol Metab*. 2014 Dec;99(12):4379-89.
17. Seidenfeld J, Samson DJ, Hasselblad V, et al. Single-therapy androgen suppression in men with advanced prostate cancer: A systematic review and meta-analysis. *Ann Intern Med*, 2000;132(7):566-577.
18. Sklar CA, Rothenberg S, Blumberg D, et al. Suppression of the pituitary-gonadal axis in children with central precocious puberty: effects on growth, growth hormone, insulin-like growth factor-I, and prolactin secretion. *J Clin Endocrinol Metab*. 1991 ;73(4):734-8.
19. Supprelin LA (histrelin) [package insert]. Malvern, PA: Endo Pharmaceuticals;September 2025.
20. Tato L, Savage MO, Antoniazzi F, et al. Optimal therapy of pubertal disorders in precocious puberty/early puberty. *J of Ped Endcr Metabol*. 2001; 14(Suppl 2): 985-995.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- December 12, 2023: No changes
- December 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One are for 2024.

- October 8, 2024: No changes (eff 10/8/24)
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 2025 E-Vote: No changes (eff 1/1/26)

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.