Pharmacy Medical Necessity Guidelines: Gonadotropin-releasing Hormone (GnRH) Agonists: Lupron Depot®, Lupron Depot-Ped®

Effective: February 10, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

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.

COVERAGE GUIDELINES

Central Precocious Puberty

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

1. Documented diagnosis of central precocious puberty

AND

2. Documentation the Member is ≤18 years of age

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 Lupron Depot or Lupron Depot-Ped 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 Lupron Depot or Lupron Depot-Ped 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 or older

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 Lupron Depot or Lupron Depot-Ped for the treatment of idiopathic short stature.
- 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

None

REFERENCES

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APPROVAL HISTORY

February 11, 2025: Reviewed by Pharmacy and Therapeutics Committee (P&T)
Subsequent endorsement date(s) and changes made:

- February 10, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be 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 the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy 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 Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

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

Provider Services