Pharmacy Medical Necessity Guidelines:
Progesterone Medications (progesterone oil injectable; Crinone gel)

Effective: November 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

FDA-APPROVED INDICATIONS

Intramuscular progesterone is indicated for amenorrhea and for abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology like submucous fibroids or uterine cancer.

Progesterone vaginal gel (Crinone) 8% is indicated for progesterone supplementation or replacement as part of an Assisted Reproductive Technology ("ART") treatment for infertile women with progesterone deficiency. **Crinone 4%** is indicated for the treatment of secondary amenorrhea. Crinone 8% is indicated for use in women who have failed to respond to treatment with Crinone 4%.

Oral progesterone is indicated for secondary amenorrhea and for the prevention of endometrial hyperplasia in postmenopausal women with a uterus who are receiving daily conjugated estrogen tablets.

Progesterone oral capsules are covered on the Tufts Health RITogether Preferred Drug List without restriction. Medications used for the treatment of infertility are excluded from coverage for Tufts Health RITogether.

COVERAGE GUIDELINES

The plan may authorize coverage of a non-preferred progesterone medication for Members when the following criteria are met:

1. The request is for a non-infertility diagnosis, and the Member tried and failed therapy with progesterone oral capsules or the provider indicates clinical inappropriateness of therapy with progesterone oral capsules

LIMITATIONS

1. Medications for infertility are excluded for Tufts Health RITogether Members.

CODES

None

REFERENCES

1. Crinone Progesterone Gel (progesterone 4% and 8%) [prescribing information]. Irvine, CA; Allergan USA, Inc: June 2017.
2. Progesterone injection, solution (progesterone intramuscular) [prescribing information]. Parsippany, NJ: Actavis Pharma, Inc.; August 2018.
3. Prometrium capsules (progesterone 100 mg, 200 mg) [prescribing information]. Langhorne, PA: Virtus Pharmaceuticals, LLC; March 2021.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. November 14, 2023: Administrative update; effective December 1, 2023, removed from criteria stipulation that member has a diagnosis of infertility, the member's plan covers fertility services, and the member has been approved for fertility services or other fertility medications; infertility medications and services are excluded from coverage for Tufts Health RITogether, as noted in the limitations section. Updated the fax number for Pharmacy UM.
2. November 12, 2024: No changes
3. November 4, 2025: No changes
4. November 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