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

Effective: July 14, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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, such as 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 Together Preferred Drug List without restriction.

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 the diagnosis of infertility, the Member's plan covers fertility services, and the Member has already been approved for fertility services or other fertility medications

OR

2. 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 Together 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; Watson: August 2018.

3. Prometrium capsules (progesterone 100 mg, 200 mg) [prescribing information]. St. Petersburg, FL; Catalent Pharma Solutions: June 2017.

APPROVAL HISTORY

July 19, 2012: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. October 18, 2012: No changes.
2. June 4, 2014: No changes.
3. April 14, 2015: Approval duration modified to two years; non-covered progesterone formulations removed from the document.
4. September 16, 2015: Criteria modified to include Crinone vaginal gel; approval duration modified to life of plan.
5. January 1, 2016: Administrative change to rebranded template.
6. September 13, 2016: No changes.
7. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template.
8. September 12, 2017: No changes.
9. November 13, 2018: Administrative changes made to template.
10. October 15, 2019: No changes.
11. July 14, 2020: 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.