UnitedHealthcare

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 3105-8
Program	Step Therapy
Medication	Crinone® (progesterone gel)
P&T Approval Date	2/2018, 2/2019, 2/2020, 2/2021, 2/2022, 1/2023, 1/2024, 1/2025
Effective Date	4/1/2025

1. Background:

Crinone (progesterone gel) is indicated for secondary amenorrhea and also for progesterone supplementation or replacement as part of Assisted Reproductive Technology (ART) for treatment for infertile women with progesterone deficiency. Endometrin® (progesterone inserts) is indicated to support embryo implantation and early pregnancy by supplementation of corpus luteal function as part of an ART treatment program for infertile women. This program is designed to require the use of other progesterone products prior to the approval of Crinone. Patients established on Crinone therapy for the continuation of an ART regimen or maintaining an active pregnancy will be allowed to continue with their current therapy.

2. Coverage Criteria[a]:

A. Infertility*

1. **Crinone 8%** will be approved based on **ONE** the following criteria:

    a. History of failure, contraindication or intolerance to Endometrin

    -OR-

    b. Continuation of current ART

Authorization will be issued for 12 months

B. Secondary Amenorrhea

1. Crinone 4%, Crinone 8% will be approved based on the following criteria:

    a. History of failure, contraindication or intolerance to **one** of the following:

        1) progesterone oral capsules (generic Prometrium)
        2) medroxyprogesterone (generic Provera)

Authorization will be issued for 12months

C. Other non-infertility indications (e.g. reduce the risk of recurrent spontaneous preterm birth)

1. **Crinone 4% and Crinone 8%** will be approved based on **ONE** of following criteria:

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a. History of failure, contraindication or intolerance to Endometrin

- OR-

b. Continuation of current therapy

Authorization will be issued for 12months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

* Typically excluded from benefit coverage. Coverage is determined by the member's prescription drug benefit plan.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Prior Authorization - Notification may be in place

4. References:

1. Crinone [package insert]. Irvine, CA: Allergan USA, Inc; June 2017.
2. Endometrin [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; January 2018.
3. Provera [package insert]. New York, NY: Pfizer; March 2024.
4. Prometrium [package insert]. Manhasset, NY: Acertis Pharmaceuticals, LLCMarch 2024.

Program	Step Therapy – Crinone® (progesterone gel)
Change Control	
Date	Change
2/2018	New program.
2/2019	Annual review. Updated references.
2/2020	Annual review. Updated references.
2/2021	Annual review. Updated references.
2/2022	Annual review. Updated references.
1/2023	Annual review. No changes.
1/2024	Annual review. No changes.
1/2025	Annual review. Updated authorization to 12 months. Updated references.

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