

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2023P 3105-6 |
| Program | Step Therapy – Vaginal Progesterone |
| Medication | Crinone® (progesterone gel) |
| P&T Approval Date | 2/2018, 2/2019, 2/2020, 2/2021, 2/2022, 1/2023 |
| Effective Date | 4/1/2023; Oxford only: 4/1/2023 |

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 6 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 6 months

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:

a. History of failure, contraindication or intolerance to Endometrin

- OR -

b. Continuation of current therapy

Authorization will be issued for 6 months

^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; January 2018.
4. Prometrium [package insert]. Langhorne, PA: Virtus Pharmaceuticals, LLC; March 2021.

| Program | Step Therapy – Vaginal Progesterone |
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| 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. |