

<b>Clinical Policy Title:</b>	Progesterone gel
<b>Policy Number:</b>	RxA.367
<b>Drug(s) Applied:</b>	Crinone
<b>Original Policy Date:</b>	03/06/2020
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Secondary Amenorrhea (must meet all):

1. Diagnosis of secondary amenorrhea;
2. Trial and failure of one progestin product (medroxyprogesterone, norethindrone tablets, progesterone capsule) unless contraindicated or clinically significant adverse effects are experienced;

#### Approval duration

**All Lines of Business (except Medicare): 6 months**

### II. Continued Therapy Approval

#### A. Secondary Amenorrhea (must meet all):

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met initial approval criteria.

#### Approval duration

**All Lines of Business (except Medicare): 6 months**

## References

1. Hassan SS, Romero R, Vidyadhari D, et al. Vaginal progesterone reduces the rate of preterm birth in women with a sonographic short cervix: a multicenter, randomized, double-blind, placebo-controlled trial. *Ultrasound in Obstet Gynecol.* 2011;38:18-31. Available at: <https://pubmed.ncbi.nlm.nih.gov/21472815/>. Accessed March 24, 2025.
2. Fonseca EB, Celik E, Parra M, et al. Progesterone and the Risk of Preterm Birth among Women with a Short Cervix. *NEJM.* 2007;357:462-469. Available at: <https://pubmed.ncbi.nlm.nih.gov/17671254/>. Accessed March 24, 2025.
3. DeFranco E, Obrien JM, Adair CD et al. Vaginal progesterone is associated with a decrease in risk for early preterm birth and improved neonatal outcome in women with a short cervix: a secondary analysis from a randomized, double-blind, placebo-controlled trial. *Ultrasound Obstet Gynecol.* 2007;30:697-705. Available at: <https://pubmed.ncbi.nlm.nih.gov/17899571/>. Accessed March 24, 2025.
4. daFonseca EB, Bittar RE, Carvalho MHB et al. Prophylactic administration of progesterone by vaginal suppository to reduce the incidence of spontaneous preterm birth in women at increased risk: A randomized placebo-controlled double-blind study. *Am J Obstet Gynecol* 2003;188:419-424. Available at: <https://pubmed.ncbi.nlm.nih.gov/12592250/>. Accessed March 24, 2025.
5. Norwitz E, Phaneuf L, Caughey Progesterone Supplementation and the Prevention of Preterm Birth. *Obstetrics and Gynecology.* 2011; 4(2): 60-72. Available at: <https://pubmed.ncbi.nlm.nih.gov/22102929/>.

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Accessed March 24, 2025.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	03/06/2020
<p>Policy was reviewed.</p> <ol style="list-style-type: none"> <li>1. Clinical policy table was updated</li> <li>2. Added alternative authorized brand (Prometrium®)</li> <li>3. Added Prometrium initial and continued therapy approval criteria for prevention of endometrial hyperplasia associated with conjugated estrogen replacement therapy</li> <li>4. Initial Therapy and Continued Therapy Approval duration separated for Commercial &amp; Medicaid</li> <li>5. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..."</li> <li>6. Reference reviewed and updated.</li> </ol>	07/30/2020	09/14/2020
<p>Policy was reviewed.</p> <ol style="list-style-type: none"> <li>1. Statement about provider sample "The provision of provider samples does not guarantee coverage..." was added to Clinical Policy.</li> <li>2. Continued Approval Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance..."</li> <li>3. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..".</li> <li>4. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only".</li> <li>5. Appendix C was updated to include Boxed Warning for Prometrium®, "Prometrium®: Cardiovascular</li> </ol>	5/31/2021	9/14/2021

Disorders, Breast Cancer & Probable Dementia..."		
6. References were reviewed and updated.		
Policy was reviewed.	03/16/2022	07/18/2022
1. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C.		
2. References were reviewed and updated.		
Policy was reviewed.	06/06/2023	07/13/2023
1. Initial approval criteria I.A.5 updated from Dose does not exceed 180 mg per day Crinone® 8% or 300 mg per day Endometrin® to Request meets one of the following (a or b):		
a. Crinone 8%: Dose does not exceed 180 mg per day for up to 12 weeks;		
b. Endometrin: Dose does not exceed 300 mg per day for up to 10 weeks;		
2. Initial approval criteria I.C.4: Updated dosing criteria from Dose does not exceed 180 mg per day Crinone® to Dose does not exceed 90 mg per day Crinone® 8%.		
3. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed.	12/12/2023	11/30/2023
1. Removed age criteria.		
2. Removed dose criteria.		
3. Removed reauthorization requirement for positive response to therapy.		
Policy was reviewed.	03/24/2025	04/10/2025
1. Updated continuation of therapy language.		
2. References were reviewed and updated.		
Policy was reviewed.	12/11/2025	12/11/2025