Clinical Policy Title:	Progesterone gel
Policy Number:	RxA.367
Drug(s) Applied:	Crinone
Original Policy Date:	03/06/2020
Last Review Date:	2/1/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Diagnosis of secondary amenorrhea;
2. Trail 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. All Indications in Section I (must meet all)**:**

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

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 June 06, 2023.
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 June 06, 2023.
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 June 06, 2023.
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 June 06, 2023.
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/. Accessed June 06, 2023.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	03/06/2020
Policy was reviewed. 1. Clinical policy table was updated 2. Added alternative authorized brand (Prometrium®) 3. Added Prometrium initial and continued therapy approval criteria for prevention of endometrial hyperplasia associated with conjugated estrogen replacement therapy 4. Initial Therapy and Continued Therapy Approval duration separated for Commercial & Medicaid 5. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 6. Reference reviewed and updated.	07/30/2020	09/14/2020
Policy was reviewed. 1. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 2. Continued Approval Therapy Criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…” 3. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". 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". 5. Appendix C was updated to include Boxed Warning for Prometrium®,	5/31/2021	9/14/2021

"Prometrium®: Cardiovascular Disorders, Breast Cancer & Probable Dementia…" 6. References were reviewed and updated.		
Policy was reviewed. 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.	03/16/2022	07/18/2022
Policy was reviewed. 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.	06/06/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed. 1. Removed age criteria. 2. Removed dose criteria. 3. Removed reauthorization requirement for positive response to therapy.	12/12/2023	11/30/2023