VENTURA COUNTY HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

PROGESTERONE (Crinone, Endometrin)

Effective Date: 1/28/14

Date Developed: 1/28/14 by Catherine Sanders, MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 10/30/19, 2/18/20, 2/2/21, 8/3/21, 2/1/22, 1/31/23, 2/13/24, 2/18/25

Progesterone is a natural steroid hormone that induces secretory changes in the endometrium, promotes mammary gland development, relaxes uterine smooth muscle, blocks follicular maturation and ovulation, and maintains pregnancy. When used as part of an ART program in the luteal phase, progesterone supports embryo implantation.

Pre-Authorization Criteria:
Progesterone is used as part of assisted reproductive technology (ART) for infertile women with progesterone deficiency. If pregnancy occurs, progesterone may be continued for 10-12 weeks.

Note: This guideline addressed the use of progesterone for infertility, not for other medical uses such as amenorrhea, functional uterine bleeding or endometrial hyperplasia prevention.

Note: VCHCP requires that Progesterone, for this indication, be prescribed by an infertility specialist.

Dosing: Adult:
ART in patients who require progesterone supplementation:
Intravaginal gel*:* 90 mg (8% gel) once daily. If pregnancy occurs, may continue treatment for 10-12 weeks.
Intravaginal tablet*:* 100 mg 2-3 times daily starting at oocyte retrieval and continuing for up to 10 weeks.
ART in patients with partial or complete ovarian failure:
Intravaginal gel*:* 90 mg (8% gel) twice daily. If pregnancy occurs, continue treatment for 10-12 weeks.

Dosing: Hepatic Impairment:
Use is contraindicated in liver dysfunction or disease.

Hazardous agent; use appropriate precautions for handling and disposal (NIOSH, 2012).

Precautions:
Progesterone use is contraindicated in liver dysfunction or disease.

Adverse Reactions:
>10%: Somnolence, headache, nervousness, depression, breast enlargement, breast pain, libido decreased, constipation, nausea, cramps, abdominal pain, perineal pain, nocturia.
Other Serious Less Common Adverse Reactions: thromboembolism, ovarian hyperstimulation syndrome, breast cancer

Contraindications:
Hypersensitivity to progesterone or any component of the formulation; undiagnosed abnormal vaginal bleeding; history of or current thrombophlebitis or venous thromboembolic disorders (including DVT, PE); active or history of arterial thromboembolic disease (eg, stroke, MI); history of or known or suspected carcinoma of the breast or genital organs; hepatic dysfunction or disease; missed abortion or ectopic pregnancy; diagnostic test for pregnancy; capsules are also contraindicated for use during pregnancy

References:

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Prometrium (progesterone) [prescribing information]. Langhorne, PA: Virtus Pharmaceuticals, LLC; March 2021

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9. van der Linden M, Buckingham K, Farquhar C, Kremer JA, Metwally M. Luteal phase support for assisted reproduction cycles. Cochrane Database Syst Rev. 2015;2015(7):CD009154.

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Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
10/30/19	Yes	Howard Taekman, MD; Robert Sterling, MD	Added *Intramuscular*

			Progesterone oil: 50 ml vial, 10 ml IM daily. This is used in conjunction with the intravaginal tablet. It is used every 3 days if pregnancy is achieved for 10-12 weeks.
2/18/20	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/2/21	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
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2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Structural changes under preauthorization criteria. Updated dosing and references. Removed exclusions, administration and added precautions section