Approval Criteria Department of Pharmacy Services

**Generic Name:** progesterone vaginal

**Brand Name:** Crinone®

**Medication Class:** hormone - progestin

**FDA Approved Uses**
- Assisted reproductive technology
  - For progesterone supplementation or replacement as part of an ART treatment for infertile women with progesterone deficiency
  - To support embryo implantation and early pregnancy by supplementation of corpus luteal function as part of an ART treatment program for infertile women

**Criteria for use**
- Being used during pregnancy as a progesterone supplementation
- Singleton gestation
- Diagnosis of cervical insufficiency, defined by Transvaginal ultrasound measured cervical length <25 mm and/or advanced cervical changes on physical examination before 24 weeks of gestation in women with one or more prior pregnancy losses/births at 14 to 36 weeks

**Not Approved For**
- Any other diagnosis other than use during pregnancy
- Use when cervical length is ≥ 25 mm

**Required Medical Information**
- Clinical documentation of high risk pregnancy

**Contraindications**
- Thromboembolic disorders, such as active arterial or venous thromboembolism or severe thrombophlebitis, or history of these events
- Known or suspected breast cancer
- Known or suspected malignancy of the genital organs
- Known sensitivity to progesterone or any of the ingredients
- Liver dysfunction or disease
- Missed abortion

**Dosing**
- 90mg (8% gel) administered vaginally once daily

**Authorization**
- Three (3) months

**References**