UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1082-6
Program	Prior Authorization/Notification - Progesterone
Medication	Crinone® (progesterone gel), Endometrin® (progesterone vaginal insert), and FIRST™ -Progesterone VGS (progesterone vaginal suppository USP compounding kit), Progesterone bulk powder
P&T Approval Date	2001, 2/2009, 1/2010, 1/2011, 1/2012, 02/2013, 10/2013, 10/2014, 2/2015, 2/2016, 2/2017, 2/2018
Effective Date	5/1/2018; Oxford only: N/A

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. First Progesterone (vaginal suppository compounding kit) and progesterone bulk powder are compounded progesterone products that may also be utilized for non-infertility and infertility uses. This program is designed to provide coverage for non-infertility uses for all members and use in conjunction with fertility regimen for those with benefit coverage which includes infertility.

2. Coverage Criteria:

A. Infertility*

1. **Crinone 8%, Endometrin, Progesterone bulk powder or FIRST Progesterone** will be approved based on **both** of the following criteria:

   a. Used as part of an Assisted Reproductive Technology program

   AND

   b. Infertility is not a benefit exclusion

   Authorization will be issued for 6 months

B. Non- Infertility

1. **Crinone 4%, Crinone 8%, Endometrin, Progesterone bulk powder or FIRST Progesterone** will be approved based on the following criterion:

a. Treatment is for non-infertility use (e.g., secondary amenorrhea, reduce the risk of recurrent spontaneous preterm birth)

Authorization will be issued for 6 months

* Typically excluded from benefit coverage. Coverage is determined by the member's prescription drug benefit plan.

3. Additional Clinical Programs:

- Notification for Compounds and Bulk Powders may also be in place

4. References:

1. Crinone package insert. Columbia Laboratories, Inc. Livingston, NJ. August, 2014.
2. Endometrin package insert. Ferring Pharmaceuticals Inc. Parsippany, NJ. October 2012.
3. First Progesterone package insert. CutisPharma, Inc. Woburn, MA May 2015.

Program	Prior Authorization/Notification - Progesterone
Change Control	
Date	Change
10/2013	Separated out Crinone 8% from 4%. Added infertility criteria and examples of non-infertility uses.
10/2014	Annual review. Revised authorization approval period to 3 months for infertility uses.
2/2015	Added progesterone bulk powder to the criteria.
2/2016	Annual Review. Updated references. Increased authorization period for infertility.
2/2017	Annual Review. Minor revisions to formatting. Updated references.
2/2018	Annual Review. Added additional examples of non-infertility. Decreased non-infertility authorization period to 6 months.