PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Infertility – Vaginal Progesterone Preferred Specialty Management Policy
- Crinone® (progesterone 8% vaginal gel – Allergan)
- Endometrin® (progesterone vaginal insert – Ferring)

REVIEW DATE: 03/27/2024; selected revision 04/03/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Crinone 8% vaginal gel and Endometrin vaginal insert are indicated for the following uses:
- Crinone 8%: **Progesterone supplementation or replacement** as part of an **Assisted Reproductive Technology (ART)** treatment for infertile women with progesterone deficiency.[1]
- Endometrin: To **support embryo implantation and early pregnancy** by supplementation of corpus luteal function as part of an **ART treatment program** for infertile women.[2]

Crinone 4% gel is indicated for the treatment of **secondary amenorrhea** and Crinone 8% gel is additionally indicated for this use in women who have failed to respond to treatment with Crinone 4% gel.[1] Crinone 4% gel is not part of this preferred specialty management program since it is not indicated for ART.

A randomized study comparing Endometrin with Crinone 8% vaginal gel found that **Endometrin was non-inferior to Crinone 8% gel** with regards to ongoing

pregnancy rates in patients < 35 years of age or with follicle stimulating hormone level < 10 IU/L.[2,3]

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product. Utilization of some vaginal progesterone products are not managed by *Prior Authorization* criteria, but is based on whether the patient's benefit includes infertility coverage. The program directs the patient to try the Preferred Product prior to the approval of the Non-Preferred Product. Requests for the Non-Preferred Product will be reviewed using the exception criteria (below). All approvals are provided for the duration noted below.

Preferred Products: Crinone 8% gel
Non-Preferred Products: Endometrin

Infertility – Vaginal Progesterone non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Endometrin	**1.** Approve if the patient meets ONE of the following (A or B): **A)** Patient has tried Crinone 8% gel; OR **B)** Patient already started on a course of therapy with Endometrin for progesterone supplementation/replacement to achieve or maintain a pregnancy, approve to complete the current course of therapy.

REFERENCES

1. Crinone® 4%/Crinone® 8% vaginal gel [prescribing information]. Irvine, CA: Allergan; June 2017.
2. Endometrin® vaginal insert [prescribing information]. Parsippany, NJ: Ferring; January 2018.
3. Doody KJ, Schnell VL, Foulk RA, et al. Endometrin for luteal phase support in a randomized, controlled, open-label, prospective in-vitro fertilization trial using a combination of Menopur and Bravelle for controlled ovarian hyperstimulation. *Fertil Steril*. 2009;91(4):1012-1017.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	03/27/2024
Selected Revision	Removed "and according to the prescriber, has experienced inadequate efficacy OR significant intolerance with".	04/03/2024