

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

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.

Automation: A patient with a of the Preferred Product within the 130-day look-back period is excluded from this Preferred Specialty Management program.

Preferred Products: Crinone 8% gel

Non-Preferred Products: Endometrin

RECOMMENDED EXCEPTION CRITERIA

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.