

**Blue Cross Blue Shield of Vermont and The Vermont Health Plan**  
**Prior Approval Guidelines**  
**Pergonal® (Follicle Stimulating Hormone and Luteinizing Hormone)**  
**Non-IVF Fertility Uses**

- Description:** A potent agonist of follicle stimulating hormone and luteinizing hormone.
- Covered Indications:**
- 1) Ovulation induction in women who are anovulatory infertile in whom the cause of the infertility is functional and not due to primary ovarian failure who have not responded to adequate clomiphene citrate therapy
  - 2) Non-in vitro fertilization (IVF) fertility (Natural methods only)
- Reasons for Prior Authorization:**
- |  |   |
|--|---|
| <input checked="" type="checkbox"/> Cost | <input type="checkbox"/> Potential for misuse   |
| <input type="checkbox"/> Toxicity        | <input checked="" type="checkbox"/> Prevention of use for infertility- via in vitro fertilization |
- Criteria for Approval:**
- 1) Diagnosis is an FDA-labeled indication **and**
  - 2) Patient does not have any contraindications to use (see below)
- Reasons for Denial of Benefit:**
- 1) Patient does not meet Criteria for Approval
  - 2) Patient has any of the following **contraindications**
    - a) Pregnancy or lactation
    - b) Undiagnosed abnormal vaginal bleeding
    - c) Ovarian cysts or enlargement not due to polycystic ovary syndrome
    - d) Uncontrolled thyroid or adrenal function
    - e) High levels of FSH indicating primary gonadal failure (ovarian)
    - f) Sex hormone dependent tumors of the reproductive tract and accessory organs
  - 3) Patient has not had adequate trial of clomiphene citrate therapy
  - 4) Patient is planning pregnancy via in vitro fertilization
  - 5) Patient has already had a trial of an ovulation induction medication in the last 12 months.
- Benefit Approval:**
- 1) Non-IVF pregnancy; 4-cycles per calendar year (4 months);  
***Limited to one ovulation induction medication per year.***
- Notes:**
- 1) This medication will not be approved for purposes of IVF fertility
- References:**
1. Olin BR, ed. Drug Facts and Comparisons. Facts and Comparisons. St. Louis, 2004
  2. Package insert, Pergonal® Serono® Rockland, MA 02370
  3. AHFS Drug Information 2004, Bethesda, MD 20814