

**Blue Cross Blue Shield of Vermont and The Vermont Health Plan**  
**Prior Approval Guidelines**  
**Bravelle™ (Urofollitropin)**  
**Non-IVF Fertility Uses**

- Description:** A potent agonist of gonadotropin-releasing hormone.
- Covered Indications:**
- 1) Ovulation induction in women in conjunction with human chorionic gonadotropin (hCG) who have previously have received pituitary suppression.
  - 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
  - 1) Patient has any of the following **contraindications**
    - ) A high FSH level indicating primary ovarian failure
    - ) Uncontrolled thyroid and adrenal dysfunction
    - ) An organic intracranial lesion such as pituitary tumor
    - ) The presence of any cause of infertility other than anovulation
    - ) Abnormal bleeding of undetermined origin
    - ) Ovarian cysts or enlargement not due to polycystic ovary syndrome
    - ) Prior hypersensitivity to urofollitropins, purified
    - ) Pregnancy and lactation
  - 3) Patient is planning pregnancy via in vitro fertilization
  - 4) 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
  1. Package insert, Bravelle™ Ferring Pharmaceuticals Inc. Suffern, NY, 2002