

## Infertility Prior Authorization Drug List A

<b>Drug(s) Applied:</b>	<b>Gonal-F</b> (follitropin alfa) FSH <b>Fyremadel</b> (ganirelix acetate), <b>ganirelix acetate</b> GnRH analogs <b>Menopur</b> (menotropins) menotropins <b>Pregnyl</b> (chorionic gonadotropin), <b>Novarel</b> (chorionic gonadotropin), <b>Ovidrel</b> (choriogonadotropin alfa) hCG <b>clomiphene citrate</b> SERM <b>Endometrin</b> (progesterone) vaginal progestins
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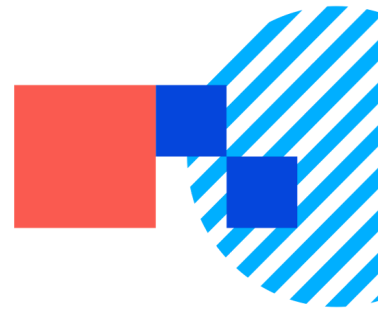
### Criteria:

Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

#### I. Initial Therapy Criteria

##### A. Ovulation induction/stimulation as indicated by chart notes within past 90 days

1. Infertility drugs are NOT restricted from coverage under the patient's benefit **and**
2. Diagnosis of infertility (e.g., inability to conceive after either at least 1 year of frequent unprotected sexual intercourse or therapeutic donor insemination in a female individual less than 30 years old or after 6 months if 30 to 45 years old) **and**
3. Requested drug is FSH, GnRH, hCG, or SERM **and**
4. If for Novarel, ONE of the following:
  - a) Patient has tried and had an inadequate response to Pregnyl and Ovidrel **or**
  - b) Patient has an intolerance or FDA labeled contraindication to Pregnyl and Ovidrel **and**
5. If for FSH, ONE of the following:
  - a) Patient has tried and had an inadequate response to 3 courses of at least 50 mg daily for 5 days of clomiphene citrate **or**
  - b) Patient has an intolerance or FDA labeled contraindication to clomiphene citrate **and**
6. If for FSH, hCG, or SERM, patient does not have primary ovarian failure **and**
7. Patient is not pregnant **and**
8. Patient will receive hCG following completion of FSH and/or GnRH and/or clomiphene citrate unless there are risks present for ovarian hyperstimulation syndrome (OHSS) **and**
9. Patient does NOT have any FDA labeled contraindications to the requested



agent **and**

10. Prescriber is a specialist in the area of the patient's diagnosis (e.g., reproductive endocrinology)

**Approval Duration:** 3 months

**B. Development of follicles as part of assisted reproductive technology (ART) as**

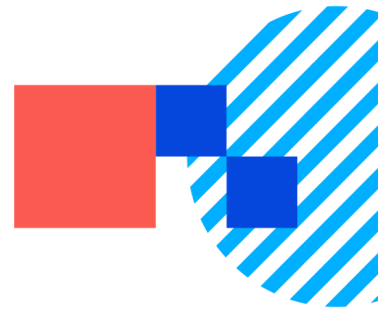
indicated by chart notes within past 90 days

1. Infertility drugs are NOT restricted from coverage under the patient's benefit **and**
2. Diagnosis of infertility (e.g., inability to conceive after either at least 1 year of frequent unprotected sexual intercourse or therapeutic donor insemination in a female individual less than 30 years old or after 6 months if 30 to 45 years old) **and**
3. Will be used in conjunction with ART **and**
4. Requested drug is FSH, hCG, or menotropins **and**
5. If for Novarel, ONE of the following:
  - a) Patient has tried and had an inadequate response to Pregnyl and Ovidrel **or**
  - b) Patient has an intolerance or FDA labeled contraindication to Pregnyl and Ovidrel **and**
6. Patient is not pregnant **and**
7. Patient does not have primary ovarian failure **and**
8. Patient will receive hCG following completion of FSH and/or clomiphene citrate and/or menotropins unless there are risks present for ovarian hyperstimulation syndrome (OHSS) **and**
9. Patient does NOT have any FDA labeled contraindications to the requested agent **and**
10. Prescriber is a specialist in the area of the patient's diagnosis (e.g., reproductive endocrinology)

**Approval Duration:** 3 months

**C. Vaginal Progesterone supplementation or replacement as part of an ART treatment as indicated by chart notes within past 90 days**

1. Infertility drugs are NOT restricted from coverage under the patient's benefit **and**
2. Diagnosis of infertility (e.g., inability to conceive after either at least 1 year of frequent unprotected sexual intercourse or therapeutic donor insemination in a female individual less than 30 years old or after 6 months if 30 to 45 years old) **and**
3. Will be used in conjunction with ART **and**
4. Requested drug is vaginal progestin **and**



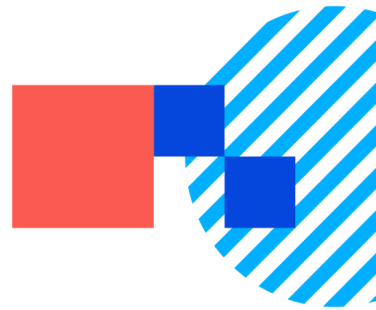
5. Duration of use does not exceed 10 weeks **and**
6. Patient does NOT have any FDA labeled contraindications to the requested agent **and**
7. Prescriber is a specialist in the area of the patient's diagnosis (e.g., reproductive endocrinology)

**Approval Duration:** 3 months

**D. Ovarian stimulation to preserve fertility** as indicated by chart notes within past 90 days

1. Patient is biologically capable of producing mature oocytes (e.g., postpubertal individual with ovaries) **and**
2. Documented need for fertility preservation due to at least ONE of the following:
  - a) Impending gonadotoxic medical treatment (e.g., chemotherapy, pelvic radiation) expected to directly or indirectly cause irreversible infertility **or**
  - b) Impairment of fertility caused directly or indirectly by a medically necessary treatment for sickle cell disease **or**
  - c) Impairment of fertility caused directly or indirectly by a medically necessary treatment for lupus **and**
3. The patient has expressed a desire to preserve fertility for future reproductive use **and**
4. The stimulation is for the purpose of cryopreserving oocytes or embryos, not for immediate conception **and**
5. Requested drug is FSH, GnRH, hCG, menotropins, or SERM **and**
6. If for Novarel, ONE of the following:
  - a) Patient has tried and had an inadequate response to Pregnyl and Ovidrel **or**
  - b) Patient has an intolerance or FDA labeled contraindication to Pregnyl and Ovidrel **and**
7. Patient is not pregnant **and**
8. Patient will receive hCG following completion of FSH and/or GnRH and/or menotropins and/or SERM unless there are risks present for ovarian hyperstimulation syndrome (OHSS) **and**
9. Patient does NOT have any FDA labeled contraindications to the requested agent **and**
10. Prescriber is a specialist in the area of the patient's diagnosis (e.g., reproductive endocrinology)

**Approval Duration:** 3 months



II. Continued Therapy Criteria

**A. All indications (except ovarian stimulation to preserve fertility)** as indicated by chart notes within past 90 days

1. Infertility drugs are NOT restricted from coverage under the patient's benefit **and**
2. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or meets the initial therapy criteria above **and**
3. If for Novarel, ONE of the following:
  - a) Patient has tried and had an inadequate response to Pregnyl and Ovidrel **or**
  - b) Patient has an intolerance or FDA labeled contraindication to Pregnyl and Ovidrel **and**
4. Chart notes indicate patient has been treated with the requested agent within the past 90 days and is a continuation of therapy (starting on samples is not approvable)

**Approval Duration:** 3 months

**Policy Owned by:** Curative PBM team