curative

Infertility Prior Authorization

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

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 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**
5. If for FSH, hCG, or SERM, patient does not have primary ovarian failure **and**
6. Patient is not pregnant **and**
7. 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**
8. Patient does NOT have any FDA labeled contraindications to the requested agent **and**
9. 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. Patient is not pregnant **and**
6. Patient does not have primary ovarian failure **and**
7. 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**
8. Patient does NOT have any FDA labeled contraindications to the requested agent **and**
9. 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. Patient is not pregnant **and**
7. 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**
8. Patient does NOT have any FDA labeled contraindications to the requested agent **and**
9. 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. 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