Reference number
C14414-A

SPECIALTY GUIDELINE MANAGEMENT

North Carolina State Health Plan: Fertility Agents

PROGRAM RATIONALE

Client Requested: The intent of the criteria is to ensure that patients follow selection elements established by North Carolina State Health Plan's Commercial Prior Authorization Approval policy.

PRIOR AUTHORIZATION CRITERIA[1]

- Coverage is provided for female infertility treatment and in males for non-infertility indications.
- Coverage is **NOT** provided for patients using fertility medication in conjunction with any type of Artificial Reproductive Technology (ART) procedure. ART procedures include In Vitro Fertilization (IVF), Gamete Intrafallopian Transfer (GIFT), Zygote Intrafallopian Transfer (ZIFT), *Intracytoplasmic Sperm Injection (ICSI)* and Intrauterine (IUI) or Artificial Insemination.

COVERED FERTILITY AGENTS*

Medication	Generic Name	Covered Indications
Gonadotropins		
Follicle Stimulating Hormone (FSH)		
Follistim AQ†	follitropin beta	▪ Ovulation induction ▪ Hypogonadotropic hypogonadism in males
Gonal-F/ Gonal-F RFF Pen	follitropin alfa	▪ Ovulation induction ▪ Hypogonadotropic hypogonadism in males
Human Chorionic Gonadotropin (hCG)		
Novarel†, Pregnyl†, hcG (generic)†	chorionic gonadotropin	▪ Ovulation induction ▪ Selected cases of hypogonadotropic hypogonadism in males (i.e., hypogonadism secondary to a pituitary deficiency) ▪ Prepubertal cryptorchidism
Ovidrel	choriogonadotropin alfa	▪ Ovulation induction ▪ Selected cases of hypogonadotropic hypogonadism in males (i.e., hypogonadism secondary to a pituitary deficiency) ▪ Prepubertal cryptorchidism
Human Menopausal Gonadotropin (hMG)		
Menopur	menotropin	▪ Ovulation induction
Gonadotropin Releasing Hormone (GnRH) Analogs		
GnRH Agonist		
Lupron SC 14-day kit‡	leuprolide acetate	▪ Ovulation induction
GnRH Antagonists		
Cetrotide	cetrorelix acetate	▪ Inhibition of premature LH surges in women undergoing controlled ovarian stimulation
Ganirelix acetate	ganirelix acetate	▪ Inhibition of premature LH surges in women undergoing controlled ovarian hyperstimulation

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**Note: For other covered fertility medications (i.e. Clomid (clomiphene), Synarel (nafarelin), Crinone (vaginal progesterone), Endometrin (vaginal progesterone), Prochieve (vaginal progesterone), please refer to their respective criteria for approval.*

†Formulary exceptions criteria will be applied to these non-formulary medications.
‡Refer to Lupron NCSHP SGM criteria for non-fertility indications.

CRITERIA FOR APPROVAL

1. What is the diagnosis?
    a. Female infertility → *Go to #7*
    b. Hypogonadotropic hypogonadism in a male patient → *Go to #2*
    c. Prepubertal cryptorchidism in a male patient → *Go to #6*
    d. Other → *Deny*

2. What is the prescribed medication?
    a. Follistim AQ → *Go to #3*
    a. Novarel → *Deny*
    b. Pregnyl→ *Deny*
    c. hCG (generic) → *Deny*
    d. Gonal-F → *Go to #4*
    e. Gonal-F RFF Pen → *Go to #4*
    f. Ovidrel → *Go to #4*
    g. Menopur → *Deny*
    h. Lupron SC 14-day kit → *Deny*
    i. Cetrotide → *Deny*
    j. Ganirelix → *Deny*
    k. Other → *Deny*

3. Has the patient tried and experienced intolerance to Gonal-F?
    Yes → *Go to #4*
    No → *Deny*

4. Does the patient have a low pretreatment testosterone level?
    a. Yes → *Go to #5*
    b. No → *Deny*

5. Does the patient have:
    a. Low or low-normal follicle stimulating hormone (FSH) level → *Approve for 12 months*
    b. Low or low-normal luteinizing hormone (LH) level → *Approve for 12 months*
    c. Neither → *Deny*

6. What is the prescribed medication?
    a. Novarel → *Deny*
    b. Pregnyl→ *Deny*
    c. hCG (generic hCG) → *Deny*
    d. Follistim AQ → *Deny*
    e. Gonal-F → *Deny*
    f. Gonal-F RFF Pen → *Deny*

g. Ovidrel → *Approve for 12 months*
h. Menopur → *Deny*
i. Lupron SC 14-day kit → *Deny*
j. Cetrotide → *Deny*
k. Ganirelix → *Deny*
l. Other → *Deny*

7. Is the prescriber requesting ANY of the following agent(s)? If yes, please indicate agent(s).
   - Novarel
   - Pregnyl
   - hCG (generic hCG)
   - Follistim AQ
   - Gonal-F
   - Gonal-F RFF Pen
   - Ovidrel
   - Menopur
   - Lupron SC 14-day kit
   - Cetrotide
   - Ganirelix

   Yes → Indicate agent(s): _____and *Go to #8*
   No → *Deny*

8. Is one of the prescribed agents Follistim AQ?
   Yes → *Go to #9*
   No → *Go to #10*

9. Has the patient tried and experienced intolerance to Gonal-F?
   Yes → *Go to #10*
   No → *Deny*

10. Is one of the prescribed agents any of the following?
    a. Novarel
    b. Pregnyl
    c. hCG (generic hCG)

    Yes → *Deny*
    No → *Go to #11*

11. What is the patient's age?
    a. <18 years of age → *Deny*
    b. 18 years to 45 years of age → *Go to #12*
    c. > 45 years of age → *Deny*

12. Is the patient using fertility medication(s) in conjunction with any type of Artificial Reproductive Technology (ART) procedure *(e.g., ART procedures include In Vitro Fertilization (IVF), Gamete Intrafallopian Transfer (GIFT), Zygote Intrafallopian Transfer (ZIFT), Intracytoplasmic Sperm Injection (ICSI), Intrauterine (IUI) or Artificial Insemination)?*

Yes → *Deny*
No → *Go to #13*

13. Has the prescriber performed an evaluation for other causes of infertility (e.g., prescriber has considered/rules out hyperprolactinemia, thyroid dysfunction, premature or impending ovarian failure)?
    Yes → *Go to #14*
    No → *Deny*

14. Has the prescriber evaluated the male partner for the presence of male factor infertility?
    Yes → *Approve 12 months*
    No → *Deny*

REFERENCES

1. North Carolina State Health Plan Commercial Prior Authorization Approval Policy for Fertility Agents.

DOCUMENT HISTORY

Written:	Specialty Clinical Development (ST) 05/2016
Revised:	ST 06/2016, 06/2016 (added Menopur, removed Repronex [D/C]), 10/2016 (added Q#4 per CRU request), 01/2017 (added FSH FE criteria per CRU request), TE 08/2018 (removed Bravelle and made Gonal-F preferred), TE 05/2019 (Ovidrel preferred)
Reviewed:	CDPR/LCB 06/2016, CW 11/2018, MCM 06/2019

The Participating Group signed below hereby accepts and adopts as its own the criteria for use with Specialty Guideline Management, as administered by CVS Caremark.

_____ _____
Signature Date

_____
Client Name