Harvard Pilgrim Health Care – Pharmacy Prior Authorization Guideline

Guideline Name	**Gonadotropins and Antigonadotropins**: Bravelle (urofollitropin), Cetrotide (cetrorelix), chorionic gonadotropin, Ganirelix, Gonal-F (follitropin alfa), Follistim AQ (follitropin beta), Menopur (menotropin), Novarel (chorionic gonadotropin), Ovidrel (choriogonadotropin alfa), and Pregnyl (chorionic gonadotropin)

1 . Criteria

Product Name: Bravelle, Cetrotide, generic chorionic gonadotropin, Ganirelix, Gonal-F, Gonal-F RFF, Menopur, Novarel, Ovidrel, Pregnyl	
Diagnosis	Gonadotropin therapy for females with infertility**
Approval Length	As requested up to 7 Month(s)*
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has been approved for infertility services through a Harvard Pilgrim Health Care (HPHC) medical authorization^	
Notes	^ The approval duration for formulary infertility medications (authorized by HPHC Pharmacy Benefit) will be approved 1 month prior to the date of the medical infertility services authorization (authorized by HPHC Medical Benefit) plus an additional 6 months unless specified otherwise on PA request (for a total of up to 7 months). *For approvals: Please approve at GPI List Name HPHCMEDIVF. **Some plans EXCLUDE gonadotropin products for infertility and claims will reject as Plan Exclusion: Plan excludes meds for infertility.

Product Name: Follistim AQ	
Diagnosis	Gonadotropin therapy for females with infertility**
Approval Length	As requested up to 7 Month(s)
Guideline Type	Non-Formulary
Approval Criteria **1** - Patient has been approved for infertility services through a Harvard Pilgrim Health Care (HPHC) medical authorization^ **AND** **2** - Patient has tried and failed ONE preferred gonadotropin/antigonadotropin formulary alternative (e.g., Gonal-F) for their condition	

Notes	The approval duration for formulary infertility medications (authorized by HPHC Pharmacy Benefit) will be approved 1 month prior to the date of the medical infertility services authorization (authorized by HPHC Medical Benefit) plus an additional 6 months unless specified otherwise on PA request (for a total of up to 7 months). **Some plans EXCLUDE gonadotropin products for infertility and claims will reject as Plan Exclusion: Plan excludes meds for infertility.

Product Name: Bravelle, Cetrotide, generic chorionic gonadotropin, Ganirelix, Gonal-F, Gonal-F RFF, Follistim AQ, Menopur, Novarel, Ovidrel, Pregnyl	
Diagnosis	Gonadotropin therapy for males with prepubertal cryptorchidism or hypogonadotropic hypogonadism
Approval Length	3 Month(s) for prepubertal cryptorchidism; 6 Month(s) for hypogonadotropic hypogonadism*
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization, Non-Formulary

Approval Criteria

1 - Diagnosis of gonadotropin therapy for males with prepubertal cryptorchidism or hypogonadotropic hypogonadism

AND

2 - Prescribed by or in consultation with an appropriate specialist (e.g., reproductive endocrinologist or urologist)

AND

3 - ONE of the following:

- The requested medication is on formulary; OR
- The requested medication is non-formulary AND the patient has tried and failed ONE preferred gonadotropin/antigonadotropin formulary alternative (e.g., Gonal-F) for their condition

Notes	*For approvals (excluding Non-Formulary medications, i.e., Follistim AQ): Please approve at GPI List Name HPHCMEDIVF.

Product Name: Bravelle, Cetrotide, generic chorionic gonadotropin, Ganirelix, Gonal-F, Gonal-F RFF, Follistim AQ, Menopur, Novarel, Ovidrel, Pregnyl	
Diagnosis	Off-Label Requests: for females with uterine leiomyoma or polycystic ovary syndrome (PCOS)
Approval Length	12 Month(s)*
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization, Non-Formulary

Approval Criteria

1 - Diagnosis of uterine leiomyoma or polycystic ovary syndrome (PCOS) for females

AND

2 - Patient has tried and failed ONE formulary alternative^

AND

3 - Prescribed by or in consultation with an appropriate specialist (e.g., gynecologist or endocrinologist)

AND

4 - ONE of the following:

- The requested medication is on formulary; OR
- The requested medication is non-formulary AND the patient has tried and failed ONE preferred gonadotropin/antigonadotropin formulary alternative (e.g., Gonal-F) for their condition

Notes	^Formulary alternatives examples: For Uterine leiomyoma: NSAIDs, hormonal therapy (e.g., estrogen-progestin contraceptives); For PCOS: oral contraceptives, spironolactone, metformin. *For approvals (excluding Non-Formulary medications, i.e., Follistim AQ): Please approve at GPI List Name HPHCMEDIVF.

Product Name: Bravelle, Cetrotide, generic chorionic gonadotropin, Ganirelix, Gonal-F, Gonal-F RFF, Follistim AQ, Menopur, Novarel, Ovidrel, Pregnyl	
Diagnosis	Gonadotropin therapy for males with prepubertal cryptorchidism or hypogonadotropic hypogonadism; Off-Label Requests: for females with uterine leiomyoma or polycystic ovary syndrome (PCOS)
Approval Length	3 Month(s) for prepubertal cryptorchidism; 12 Month(s) for hypogonadotropic hypogonadism or PCOS*
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization, Non-Formulary

Approval Criteria

1 - Prescribed by or in consultation with an appropriate specialist (e.g., gynecologist or endocrinologist)

AND

2 - Documentation of positive response to therapy and the continued need for treatment	
Notes	*For approvals (excluding Non-Formulary medications, i.e., Follistim AQ): Please approve at GPI List Name HPHCMEDIVF.

2 . Background

Benefit/Coverage/Program Information

RATIONALE
To ensure appropriate utilization of infertility medications.

Please see the HPHC Commercial Medical/Clinical Policies for specifics regarding infertility services.

FDA APPROVED INDICATIONS
Bravelle (urofollitropin)
- Assisted reproductive technology - Controlled ovarian stimulation, in women who have previously received pituitary suppression
- Ovulation induction

Cetrotide (cetrorelix), Ganirelix
- Inhibition of premature LH surges in women undergoing controlled ovarian hyperstimulation.

Gonal-F (follitropin alfa)
- Induction of ovulation and pregnancy in oligo-anovulatory women in whom the cause of infertility is functional and not due to primary ovarian failure
- Development of multiple follicles in ovulatory women as part of an Assisted Reproductive Technology (ART) cycle
- Induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure.

Follistim AQ (follitropin beta)
- Induction of ovulation and pregnancy in anovulatory infertile women in whom the cause of infertility is functional and not due to primary ovarian failure
- Pregnancy in normal ovulatory women undergoing controlled ovarian stimulation as part of an In Vitro Fertilization (IVF) or Intracytoplasmic Sperm Injection (ICSI) cycle
- Induction of spermatogenesis in men with primary and secondary Hypogonadotropic Hypogonadism (HH) in whom the cause of infertility is not due to primary testicular failure

Menopur (menotropin)
- Development of multiple follicles and pregnancy in ovulatory women as part of an Assisted Reproductive Technology (ART) cycle.

Novarel (chorionic gonadotropin), Pregnyl (chorionic gonadotropin), chorionic gonadotropin
- Prepubertal cryptorchidism not due to anatomic obstruction. In general, HCG is thought to induce testicular descent in situations when descent would have occurred at puberty. HCG thus may help to predict whether or not orchiopexy will be needed in the future. Although, in some cases, descent following HCG administration is permanent, in most cases the response is temporary. Therapy is usually instituted between the ages of 4 and 9.

- Selected cases of hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency) in males.
- Induction of ovulation and pregnancy in the anovulatory, infertile woman in whom the cause of anovulation is secondary and not due to primary ovarian failure, and who has been appropriately pretreated with human menotropins.

Ovidrel (choriogonadotropin alfa)

- Induction of final follicular maturation and early luteinization in infertile women who have undergone pituitary desensitization and who have been appropriately pretreated with follicle stimulating hormones as part of an Assisted Reproductive Technology (ART) program such as in vitro fertilization and embryo transfer.
- Induction of ovulation (OI) and pregnancy in anovulatory infertile patients in whom the cause of infertility is functional and not due to primary ovarian failure.

REFERENCES

- Bravelle (urofollitropin) [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals; February 2014.
- Cetrotide (cetrorelix acetate) [prescribing information]. Rockland, MA: EMD Serono, Inc; May 2018.
- Follistim AQ Cartridge (follitropin beta) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; June 2020.
- Ganirelix acetate injection [prescribing information]. Whitehouse Station, NJ: Merck & Co; February 2019.
- Gonal-f for injection (follitropin alfa) [prescribing information]. Rockland, MA: EMD Serono, Inc; February 2020.
- Menopur (menotropin) [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals: May 2018.
- Micromedex Healthcare Series [database online]. Greenwood Village, Colo: Thomson Healthcare. Available at: https://www.thomsonhc.com/hcs/librarian.
- Novarel (chorionic gonadotropin) [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals Inc; May 2018.
- Ovidrel (choriogonadotropin alfa) [prescribing information]. Rockland, MA: Serono; June 2018.
- Pregnyl (chorionic gonadotropin) [prescribing information]. Roseland, NJ: Organon USA Inc; January 2015.

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Revised: • 3/9/20 - Separated infertility criteria for Follistim AQ (effective: 4/15/20) • 7/29/20 - Annual review: background updates; added renewal criteria for non-infertility diagnoses and updated approval durations for non-infertility indications (effective: 1/1/21) • 6/10/21 - Updated approval directives to clarify how to approve gonadotropin therapy for females with infertility (effective: 7/1/21) • 8/2/21 - Clarified approval directives/length
P&T Approval: 12/7/20
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