Gonadotropin Hormones Prior Authorization with Quantity Limit

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Target Agents

Chorionic Gonadtropin
Follistim AQ
Ganirelix Acetate
Menopur
Novarel
Pregnyl

Module	Clinical Criteria for Approval
Follicle Stimulating Hormone	**Follicle Stimulating Hormone Evaluation** **Follistim AQ** will be approved when ALL of the following are met: 1. The patient's benefit plan covers agents for infertility **AND** 2. ONE of the following: A. The requested agent will be used for ovulation induction AND ONE of the following: 1. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy A. Information has been provided that indicates the patient has been treated with the requested agent within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR** 2. ALL of the following: A. ONE of the following: 1. The patient has tried and had an inadequate response to 3 courses of at least 50 mg daily for 5 days of clomiphene citrate **OR** 2. The patient has an intolerance or hypersensitivity to clomiphene citrate **OR** 3. The patient has an FDA labeled contraindication to clomiphene citrate **AND** B. The patient is NOT pregnant **AND** C. The patient does NOT have primary ovarian failure **AND** D. The patient will receive human chorionic gonadotropin (hCG) following completion of the requested agent unless there are risks present for ovarian hyperstimulation syndrome (OHSS) **AND**

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E. ONE of the following:

1. The requested agent is a preferred agent **OR**
2. The patient has tried and had an inadequate response to ONE of the preferred agent(s) **OR**
3. The patient has an intolerance or hypersensitivity to ONE of the preferred agent(s) that is NOT expected to occur with the requested agent **OR**
4. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) that is NOT expected to occur with the requested agent **OR**

B. The requested agent will be used for the development of multiple follicles as part of an assisted reproductive technology (ART) [e.g., invitro fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), tubal embryo transfer (TET), cryopreservation, intracytoplasmic sperm injection (ICSI)] AND ONE of the following:

1. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents are eligible for continuation of therapy

A. Information has been provided that indicates the patient has been treated with the requested agent within the past 90 days **OR**
B. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR**

2. ALL of the following:
   A. The patient is NOT pregnant **AND**
   B. The patient does NOT have primary ovarian failure **AND**
   C. The patient will receive human chorionic gonadotropin (hCG) following completion of the requested agent unless there are risks present for ovarian hyperstimulation syndrome (OHSS) **AND**
   D. ONE of the following:The requested agent is a preferred agent **OR**

1. The patient has tried and had an inadequate response to ONE of the preferred agent(s) **OR**
2. The patient has an intolerance or hypersensitivity to ONE of the preferred agent(s) that is NOT expected to occur with the requested agent **OR**
3. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) that is NOT expected to occur with the requested agent **OR**

C. The requested agent will be used for hypogonadotropic hypogonadism AND ALL of the following:

1. The requested agent is Follistim AQ **AND**
2. The patient does not have primary testicular failure **AND**
3. The requested agent will be used in combination with human chorionic gonadotropin (hCG) **AND**
4. The requested agent will not be started until the patient's serum testosterone level is at normal levels **AND**

A. ONE of the following:The requested agent is a preferred agent **OR**

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	1. The patient has tried and had an inadequate response to ONE of the preferred agent(s) **OR** 2. The patient has an intolerance or hypersensitivity to ONE of the preferred agent(s) that is NOT expected to occur with the requested agent **OR** 3. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) that is NOT expected to occur with the requested agent **AND** 3. The patient has undergone a complete medical and endocrinologic evaluation **AND** 4. The fertility status of the patient's partner has been evaluated (if applicable) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of approval:** 3 months for ART or ovulation induction 6 months for hypogonadotropic hypogonadism NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents
Gonadotropin Releasing Hormone (GnRH) Analogs	**Gonadotropin Releasing Hormone (GnRH) Analogs Evaluation** **Ganirelix acetate** will be approved when BOTH of the following are met: 1. The patient's benefit plan covers agents for infertility **AND** 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following:Information has been provided that indicates the patient has been treated with the requested agent within the past 90 days **OR** 1. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR** B. ALL of the following: 1. The patient is undergoing ovarian stimulation **AND** 2. The patient is NOT pregnant **AND** 3. The patient has undergone a complete medical and endocrinologic evaluation **AND** 4. The fertility status of the patient's partner has been evaluated (if applicable) **AND** 5. The patient will receive human chorionic gonadotropin (hCG) following completion of the requested agent unless there are risks present for ovarian hyper-stimulation syndrome (OHSS) **AND** 6. ONE of the following:The requested agent is a preferred agent **OR** A. The patient has tried and had an inadequate response to ONE of the preferred agent(s) **OR** B. The patient has an intolerance or hypersensitivity to ONE of the preferred agent(s) that is NOT expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) that is NOT expected to occur with the requested agent **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents
Human Chorionic	**Human Chorionic Gonadotropin Evaluation**

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Gonadotropin Evaluation	**Novarel, , Pregnyl, and Chorionic gonadotropin** will be approved when BOTH of the following are met: 1. ONE of the following: A. The requested agent will be used for a diagnosis of cryptorchidism AND ALL of the following: 1. The requested agent is Novarel, Pregnyl, or hCG **AND** 2. The diagnosis is not due to an anatomical obstruction **AND** 3. The patient is prepubertal **AND** 4. ONE of the following: A. The patient has had surgery to correct the cryptorchidism **OR** B. The patient will have surgery to correct the cryptorchidism after using the requested agent **OR** C. The patient is unable to have surgery to correct the cryptorchidism **OR** B. The requested agent will be used for a diagnosis of hypogonadotropic hypogonadism AND BOTH of the following: 1. The requested agent is Novarel, Pregnyl, or hCG **AND** 2. ONE of the following: A. The patient is not currently receiving treatment for the diagnosis AND has ONE of the following pretreatment levels 1.Total serum testosterone level that is below the testing laboratory's normal range or is less than 300 ng/dL **OR** 2.Free serum testosterone level that is below the testing laboratory's normal range **OR** B. The patient is currently receiving treatment for the diagnosis AND has ONE of the following current levels: 1.Total serum testosterone level that is within OR below the testing laboratory's normal range OR is less than 300 ng/dL **OR** 2.Free serum testosterone level is within OR below the testing laboratory's normal range **OR** C. The requested agent will be used for the development of multiple follicles as part of an assisted reproductive technology (ART) [e.g., invitro fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), tubal embryo transfer (TET), cryopreservation, intracytoplasmic sperm injection (ICSI)] OR for ovulation induction AND BOTH of the following: 1. The patient's benefit plan covers agents for infertility **AND** 2. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: 1. Information has been provided that indicates the patient has been treated with the requested agent within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR** B. ALL of the following: 1. The patient is NOT pregnant **AND** 2. The patient does NOT have primary ovarian failure **AND** 3. The patient will receive follicle stimulating hormone (FSH) OR clomiphene before the requested agent unless there are risks present for ovarian hyperstimulation syndrome (OHSS) **AND** 4. The patient has undergone a complete medical and endocrinologic evaluation **AND**

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	5. The fertility status of the partner been evaluated (if applicable) **AND** 6. ONE of the following:The requested agent is a preferred agent **OR** A. The patient has tried and had an inadequate response to ONE of the preferred agent(s) **OR** B. The patient has an intolerance or hypersensitivity to ONE preferred agent(s) that is NOT expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) that is NOT expected to occur with the requested agent **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months for ovulation induction or ART 6 months for hypogonadotropic hypogonadism 3 months for cryptorchidism NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents
Menotropins	**Menotropins Evaluation** **Menopur** will be approved when ALL of the following are met: 1. The patient's benefit plan covers agents for infertility **AND** 2. ONE of the following: 1. The requested agent is eligible for continuation of therapy AND ONE of the following:Information has been provided that indicates the patient has been treated with the requested agent within the past 90 days **OR** A. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR** 2. ALL of the following: A. The requested agent will be used for the development of multiple follicles as part of an assisted reproductive technology (ART) [e.g., invitro fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), tubal embryo transfer (TET), cryopreservation, intracytoplasmic sperm injection (ICSI) **AND** B. The patient is NOT pregnant **AND** C. The patient does NOT have primary ovarian failure **AND** D. The patient will receive human chorionic gonadotropin (hCG) following completion of the requested agent unless there are risks present for ovarian hyperstimulation syndrome (OHSS) **AND** E. The patient has undergone a complete medical and endocrinologic evaluation **AND** F. The fertility status of the patient's partner has been evaluated (if applicable) **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents