Pharmacy Management Drug Policy

SUBJECT: Infertility Medications
POLICY NUMBER: PHARMACY-24
EFFECTIVE DATE: 1/03
LAST REVIEW DATE: 11/06/19

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. Medical or drug policies apply to commercial and Health Care Reform products only when a contract benefit for the specific service exists.

Note: Refer to the section regarding Medicaid Managed Care product members at the end of this policy for coverage criteria for those members.

DESCRIPTION:

Infertility is a disease or condition characterized by the incapacity to impregnate another person or to conceive, defined by the failure to establish a clinical pregnancy after twelve months of regular, unprotected sexual intercourse or therapeutic donor insemination, or after six months of regular, unprotected sexual intercourse or therapeutic donor insemination for a female thirty-five years of age or older. Earlier evaluation and treatment may be warranted based on an individual's medical history or physical findings.

The treatment of infertility may include a variety of diagnostic procedures, therapeutic drugs and assistive reproductive technology (ART) procedures. This policy pertains to medications including, but not limited to, leuprolide, chorionic gonadotropins, follitropins, menotropins and gonadotropin-releasing hormone antagonists that would be used in conjunction with the appropriate diagnostic and ART procedures. Current medications under this policy include: chorionic gonadotropin, Novarel, Pregnyl, Ovidrel, Gonal-f, Follistim AQ, Menopur, Cetrotide, Ganirelix, Endometrin and leuprolide.

Artificial insemination, includes IUI (intrauterine insemination), is where fertilization takes place within the human body. Assisted Reproductive Technologies (ART), includes, but is not limited to IVF, GIFT or ZIFT and is where fertilization takes place outside the human body.

As of September 1, 2002 New York, State Law has mandated the following benefits for treatment of infertility, under most managed care and health insurance policies. *(Refer to the member's subscriber contract for the specific benefit effective date.)*

- Policies providing coverage for prescription drugs that also cover hospital or medical/surgical benefits must provide coverage for FDA approved drugs for the diagnosis and treatment of infertility, including the induction of pregnancy.
- In-vitro Fertilization (IVF), Gamete Intrafallopian Transfer (GIFT), Zygote Intrafallopian Transfer (ZIFT), reversal of elective sterilization, sex change procedures, and cloning or medical/surgical or procedures are excluded from this mandate; thus, any medications used in conjunction with these procedures are also excluded from coverage under the mandate.
- Persons age 21 to 44 years, for policies and contracts issued, renewed, modified, altered or amended before January 1, 2020.

The final 2019-2020 adopted New York State Budget made several changes to the existing infertility mandate, to take effect January 1, 2020 and apply to policies and contracts issued, renewed, modified, altered or amended on or after that date.

Changes to the mandate include the following:

- Elimination of age restrictions
- Coverage of standard fertility preservation services when a medical treatment may directly or indirectly cause "iatrogenic infertility", which is defined as an impairment of fertility by surgery, radiation, chemotherapy, or other medical treatment affecting reproductive organs or processes.
    - Standard fertility preservation services include the collecting, preserving, and storing of ova and sperm.
- Large group policies that provide medical, major medical or similar comprehensive type coverage shall provide coverage for three cycles of in-vitro fertilization used in the treatment of infertility.
    - A cycle is defined as "either all treatment that starts when: preparatory medications are administered for ovarian stimulation for oocyte retrieval with the intent of undergoing in-vitro fertilization using a fresh embryo transfer; or medications are administered for endometrial preparation with the intent of undergoing in-vitro fertilization using a frozen embryo transfer."
    - The three-cycle limit is a lifetime maximum of three cycles per enrollment with Excellus.

POLICY:

Based upon our criteria and assessment of the peer-reviewed literature, infertility medications have been medically proven to be effective and therefore **medically appropriate** in the treatment of infertility if the request meets **all** of the following criteria:

I. **For policies and contracts issued, renewed, modified, altered or amended BEFORE January 1, 2020:**

1. The determination of appropriate candidates for the treatment of infertility and the identification of the required training, experience and other standards for health care providers who wish to diagnose and treat infertility must be in accordance with the standards and guidelines adopted by American College of Obstetrics and Gynecology (ACOG) AND American Society for Reproductive Medicine (ASRM) **AND**
2. Member must be age 21 to 44 years old **AND**
3. The patient's diagnosis must fall into **one** of the following categories:
    a. Diagnosis of infertility for a duration of 1 year or more in women under 35
    b. Diagnosis of infertility for a duration of at least 6 months in women age 35 and older
    c. For the induction of spermatogenesis with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure, the following applies:

i. Coverage of follitropins (Gonal-f, Follistim) or menotropins (Menopur) require member must have a trial of hCG therapy alone for 6 months to normalize serum testosterone levels
ii. Coverage of follitropins (Gonal-f, Follistim) or menotropins (Menopur) require documentation of normal serum testosterone levels (300 – 1,000ng/dL)
iii. Member must use follitropins (Gonal-f, Follistim) or menotropins (Menopur) in conjunction WITH hCG therapy
iv. Follitropins (Gonal-f, Follistim,) or menotropins (Menopur) will be covered for males even if being used during an IVF cycle as increasing sperm count is independent of IVF status
v. The recommended dose of hCG for males is 500u – 4000u IM 3x/wk and for Gonal-f is 150u – 300u AQ 3x/wk for up to 18 months.
vi. Approval will be granted in 6-month intervals. Recertification will require documentation of continued monitoring for the induction of spermatogenesis (progress notes or any labs and tests, such as semen analysis).
vii. Gonal-f & Follistim-AQ are the only follitropins approved for use in males. The use of Menopur (menotropin) off-label will also be covered.

4. Medications used in conjunction with In-vitro Fertilization (IVF), Gamete Intrafallopian Transfer (GIFT), Zygote Intrafallopian Transfer (ZIFT) are excluded from coverage unless covered by the member's benefit or otherwise specified
5. Step therapy applies: All new starts on Follistim AQ must have a trial and failure of Gonal-f first

II. <u>For policies and contracts issued, renewed, modified, altered or amended ON or AFTER January 1, 2020:</u>

1. The determination of appropriate candidates for the treatment of infertility and the identification of the required training, experience and other standards for health care providers who wish to diagnose and treat infertility must be in accordance with the standards and guidelines adopted by American College of Obstetrics and Gynecology (ACOG) AND American Society for Reproductive Medicine (ASRM) **AND**
2. The member must have a diagnosis of infertility characterized by:
    a. the incapacity to impregnate another person or to conceive, defined by the failure to establish a clinical pregnancy after twelve months of regular, unprotected sexual intercourse or therapeutic donor insemination, or after six months of regular, unprotected sexual intercourse or therapeutic donor insemination for a female thirty-five years of age or older, or

b. Earlier evaluation and treatment may be warranted based on the member's medical history or physical findings.

3. For the induction of spermatogenesis with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure, the following applies:
    i. Coverage of follitropins (Gonal-f, Follistim) or menotropins (Menopur) require member must have a trial of hCG therapy alone for 6 months to normalize serum testosterone levels
    ii. Coverage of follitropins (Gonal-f, Follistim) or menotropins (Menopur) require documentation of normal serum testosterone levels (300 – 1,000ng/dL)
    iii. Member must use follitropins (Gonal-f, Follistim) or menotropins (Menopur) in conjunction WITH hCG therapy
    iv. Follitropins (Gonal-f, Follistim) or menotropins (Menopur) will be covered for males even if being used during an IVF cycle as increasing sperm count is independent of IVF status
    v. The recommended dose of hCG for males is 500u – 4000u IM 3x/wk and for Gonal-f is 150u – 300u AQ 3x/wk for up to 18 months.
    vi. Approval will be granted in 6-month intervals. Recertification will require documentation of continued monitoring for the induction of spermatogenesis (progress notes or any labs and tests, such as semen analysis).
    vii. Gonal-f & Follistim AQ are the only follitropins approved for use in males. The use of Menopur (menotropin) off-label will also be covered.

4. Medications to be used for standard fertility preservation (collecting, preserving, and storing of ova and sperm) will be covered:
    a) when a medical treatment may directly or indirectly cause “iatrogenic infertility”, which is defined as an impairment of fertility by surgery, radiation, chemotherapy, or other medical treatment affecting reproductive organs or processes.

    OR

    b) As specified in the member’s benefit plan.
5. Medications used in conjunction with in-vitro fertilization in the treatment of infertility will be covered:

a) For three cycles for members covered under large group policies that provide medical, major medical or similar comprehensive type coverage.
   (i) A cycle is defined as "either all treatment that starts when: preparatory medications are administered for ovarian stimulation for oocyte retrieval with the intent of undergoing in-vitro fertilization using a fresh embryo transfer; or medications are administered for endometrial preparation with the intent of undergoing in-vitro fertilization using a frozen embryo transfer."

   (ii) The three-cycle limit is a lifetime maximum of three cycles per enrollment with Excellus.
   OR
b) As specified in the member's benefit plan.

6. Medications used in conjunction with in-vitro fertilization or fertility preservation due to "iatrogenic infertility", when IVF limits have not been exceeded, are covered, subject to prior authorization requirements, regardless of whether the Health Plan member has drug coverage under his/her policy. Coverage for any other uses are excluded for members who do not have drug coverage under his/her policy.

7. Step therapy applies: All new starts on Follistim AQ must have a trial and failure of Gonal-f first

III. The following fertility products will be subject to quantity limits:

Drug Name	Strength/Form			Limits per month		Actual Unit Limit/month (based on package size)	Quantity Limit (mLs)
Follistim AQ	300	IU/0.36mL	Cartridge	12	Cartridges	3600	5
Follistim AQ	600	IU/0.72mL	Cartridge	6	Cartridges	3600	5
Follistim AQ	900	IU/1.08mL	Cartridge	4	Cartridges	3600	5
Gonal-f	450	IU/mL	M-D vial	10	M-D vials	4500	10
Gonal-f	1050	IU/mL	M-D vial	4	M-D vials	4200	4
Gonal-f RFF	75	IU/mL	PFS	47	Prefilled Syringes	3525	47
Gonal-f RFF	300	IU/0.5 mL	Pen/Rediject	15	Pens	4500	7.5
Gonal-f RFF	450	IU/0.75mL	Pen/Rediject	10	Pens	4500	7.5
Gonal-f RFF	900	IU/1.5 mL	Pen/Rediject	5	Pens	4500	7.5
Chorionic gonadotropin	10,000	Unit	Vial	6	Vials	60,000	-
Novarel	5,000	Unit	Vial	12	Vials	60,000	-
Novarel	10,000	Unit	Vial	6	Vials	60,000	-
Pregnyl	10,000	Unit	Vial	6	Vials	60,000	-

POLICY GUIDELINES:

1. The plan does not discriminate based on a member's expected length of life, present or predicted disability, degree of medical dependency, perceived quality of life, or other health conditions, nor based on personal characteristics, including age, sex, sexual orientation, marital status or gender identification.

2. Prior-authorization is contract dependent.
3. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
    - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
    - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
    - The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
    - The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
    - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
    - The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
4. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Coverage Exception Evaluation Policy for All Lines of Business Formularies policy for review guidelines.
5. Approval duration will be for:
    a. 2 months for induction of ovulation
    b. 6 months for the induction of spermatogenesis with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure

UPDATES:

Date:	Revision:
11/19	Revision
09/19	Revision
11/18	Revision
10/18	Review
08/18	Revision
10/17	Revision
7/16	Revision
5/16	Revision
2/16	Revision
7/15	Review
8/14	Revision
8/13	Revision
2/11	Revision
3/10	Revision
9/09	Review
11/8	Revision
9/8	Revision
1/03	Created

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2. New York State Insurance Department Opinion regarding Coverage for Infertility Medications, November 8, 2005
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12. Menopur prescribing information Ferring Pharmaceuticals Inc., Revised February 2014 accessed online July 2015
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NY STATE COVERAGE FOR MEDICAID MANAGED CARE PRODUCT MEMBERS

As of October 1, 2019, Medicaid Managed Care (MMC) plans will include medically necessary ovulation enhancing drugs and medical services related to the prescribing and monitoring the use of such drugs for individuals ages twenty-one through forty-four experiencing infertility.

The following ovulation enhancing drugs are included under this benefit and will be limited to three cycles of treatment per lifetime:

- Bromocriptine
- Clomiphene citrate
- Letrozole
- Tamoxifen

For the purposes of this benefit, "infertility" means a condition characterized by the inability to conceive, defined by the failure to establish a clinical pregnancy after twelve months of regular, unprotected sexual intercourse for individuals twenty-one through thirty-four years of age, or after six months for individuals thirty-five through forty-four years of age.

References:

1. June 2019 Medicaid Update Bulletin: https://www.health.ny.gov/health_care/medicaid/program/update/2019/2019-06.htm#ovulation.