Pharmacy Medical Necessity Guidelines: Infertility Medications

Effective: February 9, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	PRECERT / MM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
All plans except Tufts Health Direct – Health Connector:
PRECERT: 617.972.9409

Tufts Health Direct – Health Connector only:
MM: 888.415.9055

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

In Massachusetts, as per M.G.L.c. 175, section 47H and 211 C.M.R 37.09, "Infertility shall mean the condition of an individual who is unable to conceive or produce conception during a period of 1 year if the female is age 35 or younger or during a period of 6 months if the female is over the age of 35. For purposes of meeting the criteria for infertility in this section, if a person conceives but is unable to carry that pregnancy to live birth, the period of time she attempted to conceive prior to achieving that pregnancy shall be included in the calculation of the 1 year or 6 month period, as applicable."

Rhode Island General Law defines infertility as "the condition of an otherwise presumably healthy individual who is unable to conceive or sustain a pregnancy during the period of one year."

In New Hampshire infertility "means a disease, caused by an illness, injury, underlying disease, or condition, where an individual's ability to become pregnant or to carry a pregnancy to live birth is impaired, or where an individual's ability to cause pregnancy and live birth in the individual's partner is impaired."

COVERAGE GUIDELINES

A. The plan may authorize coverage of **gonadotropin therapy for females** if the following criteria are met:
   1. The Member meets the definition of infertility (See **Overview**).
      - The plan must receive documentation indicating that the Member has been unable to conceive or produce conception during a period of 12 menstrual cycles of exposure to sperm, or 6 cycles for women $\geq$ age 35.
   2. Member or partner does not have a history of voluntary sterilization.
   3. Member has no history of smoking within last 12 months (if history of smoking within past year needs to provide negative urine or serum nicotine level).
   4. Member is Rubella immune.
   5. Member has normal hormonal values.
      - FSH on day 3 is < 15 pg/mL & Estradiol (E2) on day 3 is $\leq$ 80 pg/mL for females < age 42.
      - FSH on day 3 is < 12 pg/mL & Estradiol (E2) on day 3 is $\leq$ 80 pg/mL for females $\geq$ age 42.
      - Clomiphene citrate challenge test (CCCT) performed within 1 year, and FSH level tested within 6 months required for women $\geq$ age 40.

B. The plan may authorize coverage for the following **non-preferred medications** for Members meeting any of the clinical criteria listed below:
- Bravelle®
- Follistim AQ®
- Ganirelix
- Novarel®
- Pregnyl®

Physician documented allergy or significant intolerable idiosyncratic reaction(s) or side effects that are reasonably attributed to at least one of the associated preferred formulary alternatives for the requested non-preferred medication:

Non-preferred Medication	Associated Preferred Formulary Alternative
Ganirelix®	Cetrotide®
Bravelle®, Follistim AQ®	Gonal-F®, Gonal-F RFF®
Novarel®, Pregnyl®	Ovidrel®
	Menopur®

OR

1. Patient has initiated therapy with a non-preferred agent and at the time of request is within that cycle of treatment.

OR

2. Patient has a significant amount of medication remaining from a previous cycle, and the practitioner has documented the medical necessity of one final cycle of a non-preferred agent in order to utilize this medication.

C. **Gonadotropin Dose Recommendation:** Gonadotropin dosing within any given cycle should remain within the following limits:
- IUI: 1800 IU per cycle
- IVF: 3600 IU per cycle

Note: The plan's Designated Infertility Specialty Pharmacies will dispense gonadotropins in accordance with the following **Dispensing Guidelines**. In cases where a Member requires doses outside of these limits, the prescriber must indicate, to the Specialty Pharmacy, the reason why the dose limit is to be exceeded.

Dispensing Guidelines

Procedure	Maximum Number of Gonadotropin Units		
	Initial Fill	Refill	Per Cycle
Intrauterine insemination (IUI)	1800 IU	N/A	1800 IU
In vitro fertilization (IVF)	2700 IU	900 IU	3600 IU

A. Menotropin Dispensing Guidelines:

The plan's Designated Infertility Specialty Pharmacies will dispense menotropins in accordance with the following **Dispensing Guidelines**. In cases where a Member requires doses outside of these limits, the prescriber must indicate, to the Specialty Pharmacy, the reason why the dose limit is to be exceeded.

Dispensing Guidelines

Product	Maximum Number of Units	
	Initial Fill	Refill
Menopur	900 IU	900 IU

LIMITATIONS

- The Gonadotropin medications are not covered when the infertility procedures for which they will be used are not covered and/or do not comply with the plan's Medical Necessity Coverage Guidelines for Infertility Services.
- Coverage for these medications is limited to the designated special pharmacy provider unless otherwise stated in their benefit documents.
- Females ≥ 44 years of age are generally not appropriate for IUI, gonadotropins or ART using their own eggs and should discuss alternative intervention(s) with their providers.
- Maximum dosing for gonadotropins should not exceed doses greater than 600 IU/day, as there is no proven medical necessity or efficacy to support utilization beyond this amount.
- Gonadotropin dosing for each cycle should remain within the limits outlined in Section C. In cases where a Member requires doses outside of these limits, the prescriber must indicate the reason why the dose limit is to be exceeded.

Note: The complete infertility guidelines are available at: tuftshealthplan.com/provider/resource-center#/Guidelines//Commercial///Medical_Necessity_Guidelines

CODES

Medical billing codes may not be used for these medications. These medications must be obtained via the Member's pharmacy benefit.

REFERENCES

1. Tufts Health Plan Medical Necessity Guidelines: Infertility Services: Massachusetts Products (Document ID# 1035177). May 9, 2019.
2. Tufts Health Plan Medical Necessity Guidelines: Infertility Services: Rhode Island Products (Document ID# 2128475). July 17, 2019.

APPROVAL HISTORY

October 2004: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. November 14, 2006: Removed "**(Effective Date: August 1, 2006)**" from statement, "Tufts Health Plan may authorize coverage of **gonadotropin therapy for females** if the following criteria are met:" Removed "**(Effective Date: April 11, 2006)**" from statement, "**For Females Age 40 to 43,** Tufts Health Plan may authorize coverage of gonadotropin therapy if the following additional criteria are met:" Removed Menopur.
2. November 13, 2007: No changes
3. May 13, 2008 (for effective date of 8/1/08): Section B: Changed the following drugs to preferred products to: Cetrotide, Gonal F, Gonal-F RFF, Luveris, Ovidrel. Moved the following drugs to non-preferred products: Follistim AQ, Ganirelix, Pregnyl. Added Limitation #5, "Maximum dosing for gonadotropins should not exceed doses greater than 600 IU/day, as there is no proven medical necessity or efficacy to support utilization beyond this amount." Added Section C. Gonadotropin Dose Recommendation and Dispensing Guidelines. Added Limitation #6, "Gonadotropin dosing for each cycle should remain within the limits outlined in Section C. In cases where a Member requires doses outside of these limits, the prescriber must indicate the reason why the dose limit is to be exceeded."
4. May 12, 2009: No changes
5. September 8, 2009 (for effective date January 1, 2010): Changed IVF dispensing guidelines from 4500 IU per cycle to 3600 IU per cycle
6. January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred)
7. March 9, 2010: Removed additional criteria for coverage of gonadotropin therapy with IUI for women age 40 to 43
8. November 9, 2010: Effective October 2010: For the definition of infertility, lowered the age requirement from > age 40 to > age 35 for female Members unable to conceive or produce conception during a period of 6 menstrual cycles of exposure to sperm
9. May 10, 2011: Effective 8/1/2011, dispensing guidelines for menotropins added
10. May 8, 2012: No changes
11. August 14, 2012: Removed Luveris (lutropin alfa for injection) from medical necessity guidelines, product has been discontinued
12. August 6, 2013: No changes
13. February 11, 2014: Updated age limits for normal hormone values in accordance with the Tufts Health Plan Medical Necessity Guidelines: Infertility Services effective 1/1/2014.

14. February 10, 2015: Removed requirement for 10 day FSH testing.
15. January 1, 2016: Administrative change to rebranded template.
16. February 9, 2016: No changes
17. October 24, 2016: Administrative update to help clarify which preferred formulary alternatives should be considered before approval of a non-preferred medication (criterion B1). Removed Repronex (menotropins [FSH;LH]) from guideline as it has been discontinued.
18. April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
19. August 1, 2017: Updated the Rhode Island definition of Infertility, removing "married" as a requirement.
20. August 7, 2018: No changes
21. September 10, 2019: No changes
22. October 15, 2019: Administrative update to add the definition of infertility for New Hampshire in the Overview Section.
23. February 9, 2021: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.