Pharmacy Medical Necessity Guidelines: Infertility Medications

Effective: August 7, 2018

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

This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan – large group plans
- Tufts Health Freedom Plan – small group plans

**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:** For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

**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.”

**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 ≥ 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 ≤ 80 pg/mL for females < age 42.
   - FSH on day 3 is < 12 pg/mL & Estradiol (E2) on day 3 is ≤ 80 pg/mL for females ≥ age 42.
   - Clomiphene citrate challenge test (CCCT) performed within 1 year, and FSH level tested within 6 months required for women ≥ 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®
1. 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:

<table>
<thead>
<tr>
<th>Non-preferred Medication</th>
<th>Associated Preferred Formulary Alternative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ganirelix®</td>
<td>Cetrotide®</td>
</tr>
<tr>
<td>Bravelle®, Follistim AQ®</td>
<td>Gonal-F®, Gonal-F RFF®</td>
</tr>
<tr>
<td>Novarel®, Pregnyl®</td>
<td>Ovidrel®</td>
</tr>
<tr>
<td></td>
<td>Menopur®</td>
</tr>
</tbody>
</table>

OR

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

OR

3. 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**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Maximum Number of Gonadotropin Units</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Initial Fill</td>
</tr>
<tr>
<td>Intrauterine insemination (IUI)</td>
<td>1800 IU</td>
</tr>
<tr>
<td>In vitro fertilization (IVF)</td>
<td>2700 IU</td>
</tr>
</tbody>
</table>

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**

<table>
<thead>
<tr>
<th>Product</th>
<th>Maximum Number of Units</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Initial Fill</td>
</tr>
<tr>
<td>Menopur</td>
<td>900 IU</td>
</tr>
</tbody>
</table>

**LIMITATIONS**

1. 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.
2. Coverage for these medications is limited to the designated special pharmacy provider unless otherwise stated in their benefit documents.
3. 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.
4. 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.
5. 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
Pharmacy Medical Necessity Guidelines:
Infertility Medications

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

REFERENCES

APPROVAL HISTORY
October 2004: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- 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.
- November 13, 2007: No changes
- 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, Ganirelax, 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.”
- May 12, 2009: No changes
- September 8, 2009 (for effective date January 1, 2010): Changed IVF dispensing guidelines from 4500 IU per cycle to 3600 IU per cycle
- January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred)
- March 9, 2010: Removed additional criteria for coverage of gonadotropin therapy with IUI for women age 40 to 43
- 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
- May 10, 2011: Effective 8/1/2011, dispensing guidelines for menotropins added
- May 8, 2012: No changes
- August 14, 2012: Removed Luveris (luteinizing hormone), product has been discontinued
- August 6, 2013: No changes
- 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.
- February 10, 2015: Removed requirement for 10 day FSH testing.
- January 1, 2016: Administrative change to rebranded template.
- February 9, 2016: No changes
- 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.
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- August 1, 2017: Updated the Rhode Island definition of Infertility, removing “married” as a requirement.
- August 7, 2018: 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. They are used in conjunction with a member’s benefit document and in coordination with the member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan members or to certain delegated service arrangements. Unless otherwise noted in the member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.