MEDICAL MUTUAL®

Drug Policy

Policy:	**Follitropins** **Preferred Specialty Management**	**Annual Review Date:** **08/24/2023**
Impacted Drugs:	**Bravelle (urofollitropin, purified injection)** **Follistim AQ (follitropin beta injection)** **Gonal-f (follitropin alfa injection)** **Gonal-f RFF (follitropin alfa injection)** **Gonal-f RFF Redi-ject (follitropin alfa injection)**	**Last Revised Date:** **08/24/2023**

OVERVIEW

Gonadotropins such as Gonal-F and Gonal-F RFF, Gonal-f RFF Redi-ject, Bravelle, Follistim AQ, are hormones used to stimulate ovaries to release oocyte. Woman who may not respond to clomiphene may use a gonadotropin to support fertility. Clomiphene citrate tablet is indicated for the treatment of ovulatory dysfunction in women desiring pregnancy. Patients most likely to achieve success with clomiphene therapy include patients with polycystic ovarian syndrome (PCOS), amenorrhea-galactorrhea syndrome, psychogenic amenorrhea, post-oral-contraceptive amenorrhea, and certain cases of secondary amenorrhea of undetermined etiology.

POLICY STATEMENT

The Preferred Specialty Management (PSM) program requires the patient to try the preferred product, when clinically appropriate, prior to the approval of the non-preferred product. The use of preferred brands is recommended for prescription benefit coverage for follitropin products if the patient's benefit includes infertility coverage. All approvals for preferred and non-preferred products are provided 1 year in duration unless otherwise noted below.

Automation: Patients with a history of either clomiphene citrate tablets or the Gonal-F injectable products (including Gonal-F RFF and Gonal-F Redi-ject pens) within the 130-day look-back period are excluded from this PSM program.

Preferred Medications

- Clomiphene Citrate tablets (generics)

Non-Preferred Step 2 Medications

- Gonal-F (follitropin alfa injection)
- Gonal-F RFF (follitropin alfa injection)
- Gonal-f RFF Redi-ject (follitropin alfa injection)

Non-Preferred Step 3 Medications

- Bravelle (urofollitropin, purified injection)
- Follistim AQ (follitropin beta injection)

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PREFERRED STEP THERAPY CRITERIA

Trade Name	Exception
Gonal-F Gonal-F RFF Gonal-F RFF Redi-ject	**1.** Approve if the patient meets the following criteria (A or B): **A.** The patient meets one of the following criteria (i, ii, iii, iv, or v): **i.** The patient has tried clomiphene tablets; OR **ii.** The patient has tried Femara® (letrozole tablets) for ovulatory dysfunction; OR **iii.** The patient has previously received and/or is continuing infertility treatment with injectable agents (e.g., patient has tried injectable infertility agents in previous cycles and is re-starting new cycle of treatments); OR **iv.** The patient has other causes of infertility other than due to ovulatory dysfunction; OR **v.** Follitropins are used for the induction of spermatogenesis in patients with primary or secondary hypogonadism. **B.** Patient already started on a cycle of treatment with a Gonal-f product: approve for the duration needed to complete the current cycle.
Follistim AQ Bravelle	**1.** Approve if the patient has tried at least one of Gonal-F, Gonal-F RFF, or Gonal-F RFF Redi-ject. **2.** Patient already started on a cycle of treatment with Follistim AQ for the induction of spermatogenesis in patients with primary or secondary hypogonadism: approve for 1 year **3.** Patient already started on a cycle of treatment with Follistim AQ or Bravelle: approve for the duration needed to complete the current cycle

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days
B) *Extended Approval:* 365 days

Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period

AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR

2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

REFERENCES

1. Gonal-F RFF Redi-ject Pens [prescribing information]. Rockland, MA: EMD Serono, Inc.; May 2018.
2. Gonal-F Multi-Dose 450 IU Vials [prescribing information]. Rockland, MA: EMD Serono, Inc.; May 2018.
3. Gonal-F RFF Vials [prescribing information]. Rockland, MA: EMD Serono, Inc.; May 2018.
4. Follistim AQ Cartridge [prescribing information]. Roseland, NJ: Organon USA Inc.; December 2014.
5. Follistim AQ Vials [prescribing information]. Roseland, NJ: Organon USA Inc.; December 2013.
6. Bravelle [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; July 2015.
7. Fauser, B. Patient information:Infertility treatment with gonadotropins (Beyond the Basics). UptoDate. Last Updated May 18, 2015.
8. Legro RS, Arslanian SA, Ehrmann DA, et al. Diagnosis and treatment of polycystic ovary syndrome: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2013;98:4565-4592.
9. Clomiphene Citrate Tablets [prescribing information]. Spring Valley, NY: Par Pharmaceuticals Inc.; June 2016.
10. American Society for Reproductive Medicine. Use of clomiphene citrate in infertile women: a committee opinion. The Practice Committee of the American Society for Reproductive Medicine. Available at: https://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Committee_Opinions/use_of_clomiphene%281%29.pdf. Accessed on August 8, 2017.
11. Urofollitropin, In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 21 July 2020. Accessed 11 August 2020.
12. Follitropin alfa. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 27 July 2020. Accessed 11 August 2020.
13. Follitropin beta. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 23 July 2020. Accessed 11 August 2020.