



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2020 P 3017-12
Program	Step Therapy
Medication/Therapeutic Class	Gonal-f <sup>®</sup> (follitropin alfa)
P&T Approval Date	8/2009, 9/2010, 9/2011, 8/2012, 5/2013, 5/2014, 5/2015, 5/2016, 5/2017, 5/2018, 5/2019, 8/2019, 8/2020
Effective Date	11/1/2020; Oxford only: N/A

**1. Background:**

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires members to use Follistim AQ (follitropin beta) before providing coverage for Gonal-f or Gonal-f RFF (follitropin alfa).

Gonal-f, Gonal-f RFF and Follistim AQ are all follicular stimulating hormone products. These products are indicated for ovulation induction and follicular development in women as part of assisted reproductive technology (ART).

Follistim and Gonal-f are also indicated for induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure.<sup>1-3</sup>

Members continuing and new to therapy will be required to meet the coverage criteria below.

**2. Coverage Criteria<sup>a</sup>:**

**A. Gonal-f or Gonal-f RFF will be approved based on the following criterion\*:**

1. History of failure, contraindication, or intolerance to Follistim AQ

**Authorization will be issued for 2 months.**

<sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**3. Other Clinical Programs:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Notification criteria may also be in place.

\*Infertility is typically excluded from coverage for UnitedHealthcare. Please refer to member's specific benefits for coverage determination.

**4. References:**

1. Gonal-f [package insert]. Rockland, MA: EMD Serono, Inc.; May 2018.
2. Gonal-f RFF [package insert]. Rockland, MA: EMD Serono, Inc.; February 2020.



3. Follistim AQ [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; June 2020.

Program	Step Therapy – Gonal-F (follitropin alpha)
<b>Change Control</b>	
5/2014	Annual review. Added sample pack language. Added authorization duration of 2 months.
5/2015	Added sample pack language. Updated background and references.
10/2015	Administrative update. Added Maryland Continuation of Care.
5/2016	Annual review. No changes to coverage criteria. Updated reference.
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
5/2017	Annual review. Revised sample pack language. Updated state mandate reference language.
5/2018	Annual review. No changes to coverage criteria.
5/2019	Annual review. No changes to coverage criteria. Updated references.
8/2019	Updated target medication to Gonal-F products. Require trial of Follistim AQ before Gonal F. Bravelle removed from program due to market withdrawal. Updated background and references.
8/2020	Annual review with no changes to coverage criteria. Updated background and references.