UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2019 P 3017-10
Program	Step Therapy
Medication/Therapeutic Class	Follistim® AQ (follitropin beta) and Bravelle® (urofollitropin)*
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
Effective Date	8/1/2019; Oxford only: N/A

1. Background:

Gonal-f® (follitropin alfa), Follistim AQ (follitropin beta), and Bravelle (urofollitropin) are all follicular stimulating hormone products. All three 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.[1-3]

Members currently on a course of therapy as documented in claims history will be allowed to continue on their therapy. Members new to therapy will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. Follistim AQ or **Bravelle** will be approved based on **one** of the following criteria*:

1. History of failure, contraindication, or intolerance to Gonal-f

-OR-

2. **Both** of the following:

   a. Patient is currently on Follistim AQ or Bravelle therapy

   -AND-

   b. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Merck (Follistim AQ) or Ferring (Bravelle) sponsored support programs (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Follistim AQ or Bravelle*

*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Merck (Follistim AQ) or Ferring (Bravelle) sponsored support programs **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 2 months.

[a] 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. Bravelle [package insert]. Parsippany, NY: Ferring Pharmaceuticals; July 2015.
2. Gonal-F [package insert]. Rockland, MA: EMD Serono, Inc.; May 2018.
3. Follistim AQ [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; December 2014.

Program	Step Therapy - Follistim AQ (follitropin beta) and Bravelle (urofollitropin)
Change Control	
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.