

SPECIALTY EXCEPTIONS CRITERIA FOLLICLE STIMULATING HORMONE (FSH) PRODUCTS

PREFERRED PRODUCTS: GONAL-F®

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the follicle stimulating hormone (FSH) products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program does not apply to members currently undergoing treatment for infertility with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Targeted Follicle Stimulating Hormone Products

	Products
Preferred	<ul style="list-style-type: none"> • Gonal-f® (follitropin alfa)
Targeted	<ul style="list-style-type: none"> • Follistim® AQ (follitropin beta) • Bravelle® (urofollitropin)

II. EXCEPTION CRITERIA

Coverage for the targeted product is provided when any of the following criteria is met:

- A. Member is currently receiving treatment with the targeted product, excluding when the targeted product is obtained as samples or via manufacturer's patient assistance programs.
- B. Member has a documented contraindication to the preferred product or any of its drug components.
- C. Member has experienced a documented intolerable adverse event with the preferred product.

REFERENCES

1. Gonal-f Multi-Dose [package insert]. Rockland, MA: EMD Serono, Inc.; December 2012.
2. Gonal-f RFF [package insert]. Rockland, MA: EMD Serono, Inc.; January 2017.
3. Gonal-f RFF Redi-ject [package insert]. Rockland, MA: EMD Serono, Inc.; January 2017.
4. Follistim AQ [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; December 2013.
5. Follistim AQ Cartridge [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; December 2014.
6. Bravelle [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; February 2014.