HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

FOLLITROPIN BETA (FOLLISTIM AQ)

Generic	Brand	HICL	GCN	Exception/Other
FOLLITROPIN BETA, RECOMB	FOLLISTIM AQ	12848		

NOTE: Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the member does not meet the initial step therapy criteria, then the prescription will deny at point of service with a message indicating that prior authorization (PA) is required.

Members who do not meet the step therapy criteria at point of service will need to submit a Medication Request Form (MRF) to MedImpact for clinical review. First level drug therapy required include the following:
- Gonal-F;
- Lookback is 120 days.

GUIDELINES FOR USE

1. Does the member have a non-overridable member restriction on category B drugs in the system?

    If yes, do not approve. Please use status code #238 and the denial text provided.
    DENIAL TEXT: Per your health benefits materials, your plan does not cover drugs prescribed as part of a course of treatment that we do not cover. Our records indicate that you have not been approved for coverage of Infertility treatment and therefore your request was not approved.
    If no, continue to #2.

2. Has the patient failed or been intolerant to Gonal-F within the previous 120 days (as stated on MRF or evidenced in patient profile)?

    If yes, continue to #4.
    If no, continue to #3.

3. Has patient initiated therapy with Follistim and at the time of request is within that cycle of treatment or does the patient have a significant amount of medication remaining from a previous cycle, and requires additional supply to complete cycle in order to utilize this?

    If yes, continue to #5.
    If no, do not approve. Please use status code #238 and the denial text provided.
    DENIAL TEXT: Per your health plan's Follitropin Beta (Follistim AQ) guideline, a trial of Gonal-F (follitropin alfa) within the previous 120 days is required, prior to approving coverage for Follistim AQ (follitropin beta). Your provider did not indicate that you have been treated with Gonal-F and therefore your request was not approved.

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GUIDELINES FOR USE (CONTINUED)

4. **Approve Follistim AQ for 12 months by GPID.** Please use status code #057.

   Requests for products on formulary with a restriction, please use the approval text provided.
   APPROVAL TEXT: Your request has been approved for Follistim AQ (follitropin beta) for your condition for a 12 month period, within the limits of your infertility benefit approval.

   Requests for products not on formulary, please use the approval text provided.
   APPROVAL TEXT: Your request has been approved for Follistim AQ (follitropin beta) for your condition for a 12 month period, within the limits of your infertility benefit approval and at the highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

5. **Approve Follistim AQ (by GPID) for the amount requested to complete this month's cycle.** Please use status code #057.

   Requests for products on formulary with a restriction, please use the approval text provided.
   APPROVAL TEXT: Your request has been approved for Follistim AQ (follitropin beta) for the requested amount to complete your current treatment cycle, within the limits of your infertility benefit approval.

   Requests for products not on formulary, please use the approval text provided.
   APPROVAL TEXT: Your request has been approved for Follistim AQ (follitropin beta) for the requested amount to complete your current treatment cycle, within the limits of your infertility benefit approval and at the highest cost share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

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RATIONALE
Gonal F and Follistim share indications and similar clinical efficacy. This PA is to ensure Gonal F is being prescribed as the preferred recombinant follitropin product used for the treatment of infertility.

FDA APPROVED INDICATIONS
Follistim is indicated for the development of multiple follicles in ovulatory patients participating in an Assisted Reproductive Technology program. It is also indicated for the induction of ovulation and pregnancy in anovulatory infertile patients in whom the cause of infertility is functional and not due to primary ovarian failure. Follistim AQ is also indicated for the induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure.
Gonal-f is indicated for the induction of ovulation and pregnancy in the anovulatory infertile patient in whom the cause of infertility is functional and not due to primary ovarian failure. Gonal-f is also indicated for the development of multiple follicles in the ovulatory patient participating in an Assisted Reproductive Technology (ART) program.
Gonal-f is indicated for the induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure.

REFERENCES
- Follistim AQ Product Information. Organon USA Inc. Available at http://www.follistim.com/HCP/index.asp. Accessed December 2016.
- Organon. Follistim AQ Package Insert. Roseland, NJ December 2014.
- Gonal-F [prescribing information]. EMD Serono, Inc. Rockland, MA. December 2012.

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