Clinical Policy: Degarelix Acetate (Firmagon)
Reference Number: ERX.SPMN.70
Effective Date: 07/16
Last Review Date: 06/16

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions® that degarelix acetate (Firmagon®) is medically necessary when one of the following criteria is met:

I. Initial Approval Criteria
   A. Prostate Cancer (must meet all):
      1. Age ≥ 18 years;
      2. Diagnosis of advanced prostate cancer (stage T3 through T4 or high risk through nodal/metastatic disease);
      3. Prescribed dose does not exceed 240 mg administered as two 120 mg subcutaneous injections followed by 80 mg administered every 28 days.

      Approval Duration: 12 months
   
   B. Other diagnoses/indications: Refer to ERX.SPMN.16 - Global Biopharm Policy.

II. Continued Approval
   A. Prostate Cancer (must meet all):
      1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria.

      Approval Duration: 12 months
   
   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
      2. Refer to ERX.SPMN.16 - Global Biopharm Policy.

Background
Description/Mechanism of Action:
Degarelix acetate is a gonadotropin-releasing hormone (GnRH) receptor antagonist that binds reversibly to the pituitary GnRH receptors, thereby reducing the release of gonadotropins and consequently testosterone.

FDA Approved Indication:
Firmagon is a GnRH receptor antagonist/injectable suspension indicated for treatment of advanced prostate cancer.
Reviews, Revisions, and Approvals

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References

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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