Clinical Policy: Degarelix Acetate (Firmagon)
Reference Number: ERX.SPA.16
Effective Date: 07.01.16
Last Review Date: 11.17

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

Description
Degarelix acetate (Firmagon®) is a gonadotropin-releasing hormone (GnRH) receptor antagonist.

FDA Approved Indication(s)
Firmagon is indicated for the treatment of advanced prostate cancer.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Firmagon is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Prostate Cancer (must meet all):
      1. Diagnosis of prostate cancer;
      2. Age ≥ 18 years;
      3. Meets (a or b):
         a. FDA approved use:
            i. Advanced prostate cancer;
         b. NCCN recommended use - categories 1 and 2A (any of the following):
            i. Adjuvant androgen deprivation therapy (ADT) as a single agent if positive lymph nodes found during pelvic lymph node dissection;
            ii. Initial ADT as a single agent (a, b, or c):
               a) With radiation therapy for (1, 2, or 3):
                  1) Intermediate risk disease;
                  2) High or very high risk disease +/- docetaxel;
                  3) Regional disease (any T, N1, M0);
               b) For very high risk disease if not a candidate for definitive therapy;
               c) For regional disease (any T, N1, M0) or metastatic disease (M1);
         iii. ADT as a single agent (a or b):
            a) For biochemical failure following radical prostatectomy (1 or 2):
               1) With radiation therapy if no distant metastases;
               2) +/- radiation therapy if distant metastases;
            b) For positive digital rectal examination following radiation therapy (1 or 2):
               1) If biopsy is negative and there are no distant metastases;
               2) If not a candidate for local therapy;
            iv. For progressive castration-naive disease (a or b):
               a) As a single agent;
               b) With docetaxel +/- prednisone for metastatic (M1) disease;
            v. For castration-recurrent disease to maintain castrate levels of serum testosterone;
      4. Request meets one of the following (a, b, or c):
         a. Starting dose does not exceed 240 mg given as two injections of 120 mg each;
         b. Maintenance dose does not exceed 80 mg as a single injection/28 days;
         c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration: 12 months

B. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy
A. Prostate Cancer (must meet all):
   1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Firmagon for prostate cancer and has received this medication for at least 30 days;
   2. Member is responding positively to therapy (e.g., improved quality of life; no unacceptable toxicity);
   3. If request is for a dose increase, request meets one of the following (a or b):
      a. New dose does not exceed 80 mg/28 days;
      b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

   Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):
   1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.  

   Approval duration: Duration of request or 6 months (whichever is less); or
   2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:
A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information
Appendix A: Abbreviation/Acronym Key
ADT: androgen deprivation therapy
GnRH: gonadotropin-releasing hormone

Appendix B: General Information
Biochemical failure is defined as either: 1) failure of prostate specific antigen (PSA) to fall to undetectable levels (PSA persistence) or 2) undetectable PSA after radical prostatectomy with a subsequent detectable PSA that increases on 2 more determinations (PSA recurrence).  

Appendix C: Therapeutic Alternatives
N/A

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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<tbody>
<tr>
<td>Advanced prostate cancer</td>
<td>Starting dose: 240 mg SC given as two 120 mg injections</td>
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<tr>
<td></td>
<td>Maintenance dose: 80 mg SC given as one injection/28 days</td>
<td>See regimen</td>
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</tbody>
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VI. Product Availability
Vial: 80 mg (20 mg/mL), 120 mg (40 mg/mL)

VII. 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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