Clinical Policy: Degarelix Acetate (Firmagon)
Reference Number: CP.PHAR.170
Effective Date: 02/16
Last Review Date: 02/17

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

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for the use of Degarelix Acetate (Firmagon®).

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® 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. Meets a or b:
         a. FDA approved use:
            i. Prescribed for advanced prostate cancer (stage T3 through T4 or high risk through nodal/metastatic disease);
         b. Off-label NCCN recommended use (one of the following):
            i. As adjuvant therapy (i.e., administered after radical prostatectomy [RP] if positive for pelvic lymph nodes);
            ii. As initial androgen deprivation therapy (ADT);
            iii. As ADT for biochemical failure* following RP;
            iv. As ADT for positive digital rectal examination following radiation therapy;
            v. For progressive castration-naive disease (i.e., not on ADT at time of progression) or castration-recurrent/resistant disease (i.e., no longer responsive to traditional ADT);
      3. Member has no known hypersensitivity to degarelix.

*Biochemical failure: 1) Failure of prostate specific antigen (PSA) to fall to undetectable levels (PSA persistence) or 2) undetectable PSA after RP with a subsequent detectable PSA that increases on 2 more determinations (PSA recurrence).

Approval duration: 12 months

B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.
   1. The following NCCN recommended uses for Firmagon, meeting NCCN categories 1, 2a, or 2b, are approved per the CP.PHAR.57 Global Biopharm Policy:
      a. Invasive breast cancer.

II. Continued Approval
   A. Prostate Cancer (must meet all):
      1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
      2. Member is responding positively to therapy;
3. Member has no known hypersensitivity to degarelix.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):
   1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
   2. Refer to CP.PHAR.57 - 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.

Formulations:
Firmagon (degarelix acetate) for subcutaneous administration:
- Start-up kit containing two vials each with 120 mg of degarelix acetate powder for reconstitution to 40 mg/mL
- Maintenance kit containing one vial with 80 mg of degarelix acetate powder for reconstitution to 20 mg/mL (administered every 28 days)

FDA Approved Indications:
Firmagon is a GnRH receptor antagonist/injectable suspension indicated for treatment of advanced prostate cancer.

Appendices
Appendix A: Abbreviation Key
ADT: Androgen deprivation therapy
PSA: Prostate specific antigen
RP: Radical prostatectomy

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>J9155</td>
<td>Injection, degarelix, 1 mg</td>
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Reviews, Resivions, and Approvals

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<th>Policy split from CP.PHAR.118.GnRH Analogs. Max dose added; removed preferencing; staging of advanced prostate cancer restated as stage T3 through T4 or high risk through nodal/metastatic disease per guidelines; approval period extended to 12 months</th>
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<th>Age removed. Off-label NCCN recommended uses added (prostate and breast cancer; doses removed). Formulations added.</th>
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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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan
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policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is
not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to
recommend treatment for members. Members should consult with their treating physician in
connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent
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Providers, members and their representatives are bound to the terms and conditions expressed
herein through the terms of their contracts. Where no such contract exists, providers, members
and their representatives agree to be bound by such terms and conditions by providing services to
members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the
coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence.
Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical
policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage
Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs
and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this

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