

Clinical Policy: Degarelix Acetate (Firmagon)

Reference Number: PA.CP.PHAR.170

Effective Date: 01/18

Last Review Date: 02/17

[Revision Log](#)

Description

The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness[®] clinical policy for the use of Degarelix Acetate (Firmagon[®]).

Policy/Criteria

It is the policy of Pennsylvania Health and Wellness 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 PA.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 PA.CP.PHAR.57 Global Biopharm Policy:
 - a. Invasive breast cancer.

II. Continued Approval

A. Prostate Cancer (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met approval criteria or the [Continuity of Care policy \(PA.LTSS.PHAR.01\)](#) applies.;
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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
2. Refer to PA.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.

| HCPCS Codes | Description |
|-------------|---------------------------|
| J9155 | Injection,degarelix, 1 mg |

| Reviews, Resivions, and Approvals | Date | Approval Date |
|-----------------------------------|------|---------------|
| | | |

References

1. Firmagon prescribing information. Parsipanny, NJ: Ferring Pharmaceuticals Inc.; July 2016. Available at www.ferringusa.com. Accessed December 28, 2016.
2. Degarelix acetate. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed December 29, 2016.
3. Prostate cancer (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed December 29, 2016.