

Clinical Policy: Degarelix Acetate (Firmagon)

Reference Number: PA.CP.PHAR.170

Effective Date: 01/18

Last Review Date: 10/18

[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®).

FDA Approved Indication(s)

Firmagon is indicated for treatment of advanced prostate cancer.

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. Prescribed by or in consultation with an oncologist;
3. 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 per 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: Refer to PA.CP.PMN.53

1. The following NCCN recommended uses for Firmagon, meeting NCCN categories 1, 2a, or 2b, are approved per the PA.CP.PMN.53:

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. If request is for a dose increase, request meets one of the following:
 - a. New dose does not exceed 80 mg per 28 days (maintenance dose);
 - 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 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.PMN.53

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)

Appendices

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

GnRH: gonadotropin-releasing hormone

NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives

Not applicable.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Previous hypersensitivity reactions to degarelix
 - Pregnancy
- Boxed warning(s): None reported

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.

HCPSC Codes	Description
J9155	Injection,degarelix, 1 mg

Reviews, Resivions, and Approvals	Date	Approval Date
4Q 2018 annual review: no significant changes, for oncology, summarized NCCN and FDA-approved uses for improved clarity (limited to diagnosis); specialist involvement in care and continuation of care added; references reviewed and updated.	08/18	

References

1. Firmagon Prescribing Information. Parsipanny, NJ: Ferring Pharmaceuticals Inc.; July 2016. Available at www.ferringusa.com. Accessed July 30, 2018.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Degarelix acetate. Available at nccn.org. Accessed July 30, 2018.
3. National Comprehensive Cancer Network. Prostate cancer (Version 3.2018). Available at nccn.org. Accessed July 30, 2018.