Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2020**
Policy Number: PA.CP.PHAR.170	**Effective Date: 01/2018** **Revision Date: 10/2020**
Policy Name: Degarelix Acetate (Firmagon)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

4Q 2020 annual review: for prostate cancer, added urologist specialist option; in continuation criteria clarified quantity limit of one injection; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Degarelix Acetate (Firmagon)

Reference Number: PA.CP.PHAR.170
Effective Date: 01/18
Last Review Date: 10/2020 Revision Log

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

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 or urologist;
3. Age ≥ 18 years;
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 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

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 as a single injection per 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 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

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 policies – PA.CP.PMN.53

IV. Appendices/General Information

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
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Prostate cancer	Starting dose: 240 mg SC given as two 120 mg injections Maintenance dose: 80 mg SC given as one injection per 28 days	See regimen

VI. Product Availability

Vial: 80 mg (20 mg/mL), 120 mg (40 mg/mL)

VII. References

1. Firmagon Prescribing Information. Parsipanny, NJ: Ferring Pharmaceuticals Inc.; February 2020. Available at www.ferringusa.com. Accessed July 8, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Degarelix acetate. Available at nccn.org. Accessed July 8, 2020.
3. National Comprehensive Cancer Network. Prostate cancer (Version 2.2020). Available at https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 8, 2020.

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
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	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/30/19	
4Q 2020 annual review: for prostate cancer, added urologist specialist option; in continuation criteria clarified quantity limit of one injection; references reviewed and updated.	10/2020	