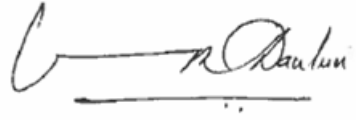


## Prior Authorization Review Panel

### 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.

<b>Plan: PA Health &amp; Wellness</b>	<b>Submission Date: 11/01/2022</b>
<b>Policy Number: PA.CP.PHAR.170</b>	<b>Effective Date: 01/2018</b> <b>Revision Date: 10/2022</b>
<b>Policy Name: Degarelix Acetate (Firmagon)</b>	
<p><b>Type of Submission – <u>Check all that apply</u>:</b></p> <p> <input type="checkbox"/> New Policy  <input checked="" type="checkbox"/> Revised Policy*  <input type="checkbox"/> Annual Review - No Revisions  <input type="checkbox"/> <b>Statewide PDL</b> - <i>Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.</i> </p>	
<p><b>*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.</b></p> <p><b>Please provide any changes or clarifying information for the policy below:</b></p> <p>4Q 2022 annual review: no significant changes; references reviewed and updated.</p>	
<b>Name of Authorized Individual (Please type or print):</b>  <b>Venkateswara R. Davuluri, MD</b>	<b>Signature of Authorized Individual:</b> 

## Clinical Policy: Degarelix Acetate (Firmagon)

Reference Number: PA.CP.PHAR.170

Effective Date: 01/2018

Last Review Date: 10/2022

[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 PA Health & 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  $\geq$  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 PA Health & 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 PA Health & 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 <https://firmagon.com/>. Accessed July 26, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Degarelix acetate. Available at nccn.org. Accessed July 26, 2022.
3. National Comprehensive Cancer Network. Prostate cancer (Version 4.2022). Available at [https://www.nccn.org/professionals/physician\\_gls/pdf/prostate.pdf](https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf). Accessed July 26, 2022.

**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

## CLINICAL POLICY

### Degarelix Acetate



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.	08/2018	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/2019	
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	
4Q 2021 annual review: no significant changes; references reviewed and updated.	10/2021	
4Q 2022 annual review: no significant changes; references reviewed and updated.	10/2022	