

Firmagon® (degarelix) (Subcutaneous)

Document Number: IC-0044

Last Review Date: 10/22/2021

Date of Origin: 01/01/2012

Dates Reviewed: 03/2012, 06/2012, 09/2012, 12/2012, 03/2013, 06/2013, 09/2013, 12/2013, 03/2014, 02/2015, 1/2016, 10/2016, 10/2017, 10/2018, 11/2019, 11/2020, 11/2021

I. Length of Authorization

Coverage will be provided for twelve months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Loading Dose: Firmagon 120 mg vial powder for injection: 2 vials first 28 days
- Maintenance Dose: Firmagon 80 mg powder for injection: 1 vial every 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- Loading Dose
 - 240 units one time
- Maintenance Dose
 - 80 units every 28 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

Advanced Prostate Cancer †

† FDA Approved Indication(s); ☐ Orphan Drug

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the indication-specific relevant criteria identified in section III;
AND
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: prolongation of the QT-interval, severe hypersensitivity reactions, etc.

V. Dosage/Administration

Indication	Dose
Advanced Prostate Cancer	Loading Dose: Administer 240 mg subcutaneously (SQ) x 1 dose Routine Dose: Administer 80 mg subcutaneously (SQ) once every 28 days

VI. Billing Code/Availability Information

HCPCS Code:

- J9155– Injection, degarelix, 1 mg: 1 billable unit = 1 mg

NDC:

- Firmagon 80 mg powder for injection Maintenance Dose Kit: 55566-8303-xx
- Firmagon 120 mg vial (2) powder for injection Starter Dose Kit: 55566-8403-xx

VII. References

1. Firmagon [package insert]. Parsippany, NJ; Ferring Pharmaceuticals, Inc; February 2020. Accessed September 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Degarelix. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed October 2021.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C61	Malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs), and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at:

<https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC