

## Firmagon<sup>®</sup> (degarelix) (Subcutaneous)

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### I. Length of Authorization

Coverage will be provided for 12 months and may be renewed.

### II. Dosing Limits

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

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

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

- Starting Dose
  - 240 billable units one time
- Maintenance Dose
  - 80 billable units every 28 days

### III. Initial Approval Criteria <sup>1</sup>

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

**Advanced Prostate Cancer † ‡ <sup>1,2</sup>**

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); ☐ Orphan Drug

### IV. Renewal Criteria <sup>1</sup>

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: QT interval prolongation, severe hypersensitivity reactions, etc.

## V. Dosage/Administration <sup>1</sup>

| Indication               | Dose  |
|--------------------------|---|
| Advanced Prostate Cancer | <p><b>Starting Dose:</b> Administer 240 mg (given as two 120 mg subcutaneous injections) for 1 dose</p> <p><b>Maintenance Dose:</b> Administer 80 mg subcutaneously 28 days after the Starting Dose, and then once every 28 days thereafter</p> |

## VI. Billing Code/Availability Information

### HCPCS Code:

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

### NDC:

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

## VII. References

1. Firmagon [package insert]. Parsippany, NJ; Ferring Pharmaceuticals, Inc; February 2020. Accessed October 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Degarelix. National Comprehensive Cancer Network, 2023. 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 2023.

## 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                           |