Clinical Policy: Degarelix Acetate (Firmagon)

Reference Number: ERX.SPA.16
Effective Date: 07.01.16
Last Review Date: 11.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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

FDA Approved Indication(s)
Firmagon is indicated for the treatment of advanced prostate cancer.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Prostate Cancer (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Firmagon for prostate cancer and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

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

Vials: 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 15, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Degarelix acetate. Available at nccn.org. Accessed July 15, 2021.
3. National Comprehensive Cancer Network. Prostate cancer (Version 2.2021). Available at https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 15, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2018 annual review: no significant changes; for prostate cancer, summarized NCCN and FDA-approved uses for improved clarity (limited to diagnosis) and added specialist involvement in care; references reviewed and updated.	08.07.18	11.18
4Q 2019 annual review: for prostate cancer added urologist specialist option; references reviewed and updated.	07.29.19	11.19
4Q 2020 annual review: no significant changes; in continuation criteria clarified quantity limit of one injection; references reviewed and updated.	07.08.20	11.20
4Q 2021 annual review: no significant changes; references reviewed and updated.	07.19.21	11.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.