Clinical Policy Title:	degarelix acetate
Policy Number:	RxA.129
Drug(s) Applied:	Firmagon®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Degarelix acetate (Firmagon®) is a gonadotropin-releasing hormone (GnRH) receptor antagonist. It is indicated for treatment of advanced prostate cancer.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
degarelix acetate (Firmagon®)	Advanced prostate cancer	Starting dose: 240 mg SC given as two 120 mg (40mg/mL) injections Maintenance dose: 80 mg SC given as one 80mg (20mg/mL) injection every 28 days after starting dose	See regimen

Dosage Forms

- Vial: 80 mg (20 mg/mL) as one single-dose vial, 240mg as two 120 mg (40 mg/mL) single-dose vials

Clinical Policy

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

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 given 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
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance, 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. New dose does not exceed 80 mg 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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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):
  - Patients with history of severe hypersensitivity reactions to degarelix or to any of the product components.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Females and males of reproductive potential: Firmagon® may impair fertility.
- Patients with severe liver or kidney dysfunction have not been studied and caution is therefore warranted.

References

1. Firmagon® Prescribing Information. Parsipanny, NJ: Ferring Pharmaceuticals Inc.; February 2020. . Available at www.ferringusa.com. Accessed January 22, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Degarelix acetate. Available at nccn.org. Accessed January 22, 2020.
3. National Comprehensive Cancer Network. Prostate cancer (Version 3.2020). Updated November 17, 2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed January 22, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. References updated.	04/2020	05/06/2020
Policy was reviewed: 1. Policy title table updated. 2. Indication in dosing table updated to align with background section. 3. Approval duration section updated to specify commercial and Medicaid plans. 4. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 5. Appendix D information added. 6. References updated.	01/22/2021	03/09/2021