

## **SPECIALTY GUIDELINE MANAGEMENT**

### **Firmagon (degarelix)**

#### **POLICY**

##### **I. INDICATIONS**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

###### **A. FDA-Approved Indication**

Firmagon is indicated for the treatment of advanced prostate cancer.

###### **B. Compendial Uses**

Prostate cancer:

1. Adjuvant therapy for lymph node-positive disease found during pelvic lymph node dissection (PLND)
2. Initial androgen deprivation therapy (ADT) for:
  - a. Intermediate risk group
  - b. High or very high risk group
  - c. Regional disease
  - d. Metastatic disease
3. Recurrent disease in patients who experience biochemical failure after previous therapy
4. Progressive castration-naïve disease

All other indications are considered experimental/investigational and are not a covered benefit.

##### **II. EXCLUSION**

Coverage will not be provided when Firmagon is used as neoadjuvant therapy prior to radical prostatectomy

##### **III. CRITERIA FOR INITIAL APPROVAL**

###### **A. Prostate Cancer**

1. Authorization of 12 months may be granted for treatment of lymph node-positive disease found during pelvic lymph node dissection (PLND) when Firmagon is used as adjuvant therapy.
2. Authorization of 12 months may be granted for treatment of prostate cancer with intermediate, high or very high risk stratification when Firmagon is used as initial androgen deprivation therapy (ADT).
3. Authorization of 12 months may be granted for treatment of regional or metastatic prostate cancer when Firmagon is used as initial androgen deprivation therapy (ADT).
4. Authorization of 12 months may be granted for treatment of recurrent prostate cancer in members who experience biochemical failure after previous therapy.
5. Authorization of 12 months may be granted for treatment of progressive castration-naïve prostate cancer.

##### **IV. CONTINUATION OF THERAPY**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

**I. REFERENCES**

1. Firmagon [package insert]. Parsippany, NJ: Ferring Pharmaceuticals; July 2016.
2. The NCCN Drugs & Biologics Compendium® © 2016 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed November 14, 2016.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer. Version 3.2016. [http://www.nccn.org/professionals/physician\\_gls/pdf/prostate.pdf](http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf). Accessed November 9, 2016.