Reference number(s)
4455- A

Standard Medicare Part B Management Firmagon

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Firmagon	degarelix

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.

FDA-approved Indication[1]

Firmagon is indicated for the treatment of patients with advanced prostate cancer.

Compendial Use[2]

Prostate cancer

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Prostate cancer[1,2]

Authorization of 12 months may be granted for treatment of prostate cancer.

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Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat an indication in the coverage criteria section
- The member is receiving benefit from therapy (e.g., serum testosterone less than 50 ng/dL) and has not experienced an unacceptable toxicity.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Firmagon.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Prostate cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Firmagon are covered in addition to prostate cancer in other clinical settings.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for prostate cancer outside the setting of advanced disease can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Firmagon [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; February 2020.

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2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 4, 2025.

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