



Related MLN Matters Article #: MM3775

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## *Abarelix for the Treatment of Prostate Cancer*

### Key Words

Abarelix, Prostate, Cancer, Treatment, Options, Palliative, MM3775, CR3775, Qualifications, Coverage, Plenaxis™ Determination, Indications, Conditions

### Provider Types Affected

Providers who care for Medicare beneficiaries with prostate cancer

### Key Points

- The effective date of the instruction is March 15, 2005.
- The implementation date is May 25, 2005.
- CR3775 was revised on July 26, 2005, to clarify that GnRH therapy is GnRH agonist therapy.
- CR3775 extends national coverage for the use of abarelix (Plenaxis™) as a palliative treatment in patients with advanced symptomatic prostate cancer.
- Abarelix (Plenaxis™) is reasonable and necessary as a palliative treatment in patients with advanced symptomatic prostate cancer:
  - Who decline surgical castration;
  - When GnRH agonist therapy is not appropriate; and
  - Who present with one of the following indications:
    - Risk of neurological compromise due to metastases;
    - Ureteral or bladder outlet obstruction due to local encroachment or metastatic disease; or
    - Severe bone pain from skeletal metastases persisting on narcotic analgesia.
- Additional conditions for coverage that must be met to ensure that abarelix (Plenaxis™) is used only in patients for whom the drug is indicated are as follows:
  - The physician must attest to and accept the following qualifications and responsibilities:
    - Diagnose and manage advanced symptomatic prostate cancer;

- Diagnose and treat allergic reactions, including anaphylaxis;
  - Have access to medication and equipment necessary to treat allergic reactions, including anaphylaxis;
  - Have patients observed for development of allergic reactions for 30 minutes following each administration of abarelix (Plenaxis™);
  - Understand the risks and benefits of palliative treatment with abarelix (Plenaxis™);
  - Educate patients on the risks and benefits of palliative treatment with abarelix (Plenaxis™); and
  - Report serious adverse events as soon as possible to the manufacturer and/or the FDA.
- The physician must have enrolled in the post-marketing risk management program that the drug manufacturer has established.
  - Providers billing Medicare intermediaries for the use of abarelix should note that revenue code 0250 should be used on inpatient claims.

### Important Links

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3775.pdf>

Affected providers can find more information about abarelix for the Treatment of Prostate Cancer by going to <http://www.cms.hhs.gov/Transmittals/downloads/R612CP.pdf> on the Centers for Medicare and Medicaid Services (CMS) website.

Providers might also want to look at Chapter 1, Part 2, Section 110.18 of the Medicare National Coverage Determinations Manual that is an attachment to CR 3775.

For questions, affected providers should contact their carrier/intermediary at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.