



MLN Matters



Information for Medicare Fee-for-Service Health Care Professionals

Related Change Request (CR) #: 3775

MLN Matters Number: MM3775

Related CR Release Date: July 22, 2005

Related CR Transmittal #: 612

Effective Date: March 15, 2005

Implementation Date: May 25, 2005

Abarelix for the Treatment of Prostate Cancer

Note: This article was revised to contain Web addresses that conform to the new CMS website and to show they are now MLN Matters articles. All other information remains the same.

Provider Types Affected

Providers who care for Medicare beneficiaries with prostate cancer

Provider Action Needed



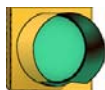
STOP – Impact to You

Effective March 15, 2005, you may bill for the use of abarelix (Plenaxis™) for certain patients with advanced, symptomatic prostate cancer.



CAUTION – What You Need to Know

Effective March 15, 2005, CMS is extending national coverage for the use of abarelix (Plenaxis™) as a palliative treatment, for the indications described below, in patients with advanced, symptomatic prostate cancer.



GO – What You Need to Do

Make sure that your billing staff is aware of this new coverage.

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

Background

Treatment Options for Prostate Cancer

Treatment options for prostate cancer vary depending on patient age, cancer stage, and individual medical conditions. Surgery (e.g., radical prostatectomy) or radiation is typically used for early-stage disease, whereas hormonal therapy, chemotherapy, and radiation (or combinations of these treatments) are used for more advanced disease.

Hormonal therapy for prostate cancer has evolved from orchiectomy and estrogens to the use, in recent years, of synthetic drugs known as gonadotropin-releasing hormone (GnRH) agonists, such as leuprolide (Lupron™) and goserelin (Zoladex™).

Abarelix

More recently, newer GnRH receptor antagonist compounds, such as abarelix (Plenaxis™), are, in contrast, thought to be devoid of agonist activity and to lack an initial androgen-stimulating effect. Abarelix (Plenaxis™) has been proposed as a substitute for GnRH agonists (with and without antiandrogens) in the treatment of patients with advanced prostate cancer, for whom a surge in androgen blood levels may pose a risk of “clinical flare.” For this indication, abarelix is the first GnRH receptor antagonist that the Food and Drug Administration (FDA) has approved.

CMS determines that the evidence is adequate to conclude that abarelix (Plenaxis™) is reasonable and necessary as a palliative treatment in patients with advanced symptomatic prostate cancer who: (1) decline surgical castration; (2) when GnRH agonist therapy is not appropriate, and (3) 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.

Please note that the following additional conditions for coverage must be met, in accordance with the Food and Drug Administration (FDA) labeling requirements, to ensure that abarelix (Plenaxis™) is used only in patients for whom the drug is indicated:

In evaluating this prostate cancer patient, the physician must attest to, and accept the following qualifications and responsibilities, and must have enrolled in the post-marketing risk management program that the drug manufacturer has established.

The physician must attest willingness and ability to:

- 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™);

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- 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.

Finally, be aware that CMS has also determined that the evidence is not adequate to conclude that abarelix (Plenaxis™) is reasonable and necessary for indications other than those specified above. Therefore, all other uses of abarelix (Plenaxis™) are not covered. Further, in light of the concern regarding safety risks of abarelix (Plenaxis™), off-label uses that may appear in listed statutory drug compendia on which Medicare and its contractors rely to make coverage determinations will remain non-covered until CMS completes a reconsideration of this National Coverage Determination.

Additional Information

The following claims processing points should be noted:

- Use HCPCS code J0128 for claims when billing Medicare for abarelix used for treatment of prostate cancer patients in accordance with the requirements specified by the NCD.
- Medicare fiscal intermediaries will accept abarelix claims on types of bill 11X, 13X, 18X, 83X, and 85X. Also, use revenue code 0636 on outpatient claims and revenue code 0250 on inpatient claims to reflect a drug requiring detailed coding.
- Medicare carriers and intermediaries will pay separately for abarelix chemotherapy injections when billed using an appropriate chemotherapy administration procedure code in addition to the visit furnished on the same day.
- For services performed on or after March 15, 2005, Medicare will deny claims for uses of abarelix that are not covered under the NCD, (NCD Manual Section 110.18). An appropriate remittance advice code will be sent to reflect the denial using MSN 6.5 (*Medicare cannot pay for this in injection because one or more requirements for coverage were not met, reason code 47 (this, these) diagnosis(es) is (are) not covered, missing, or are invalid*), and remark code M76 -- *missing/incomplete invalid diagnosis or condition*.

You 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 CMS website.

You 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.

Finally, if you have any questions, please contact your 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.

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