CMS Manual System

Pub 100-03 Medicare National Coverage Determinations

Transmittal 34

Department of Health & Human Services
Center for Medicare and & Medicaid Services
Date: APRIL 25, 2005
Change Request 3775

SUBJECT: Abarelix for the Treatment of Prostate Cancer

I. SUMMARY OF CHANGES: Effective March 15, 2005, the Centers for Medicare & Medicaid Services (CMS) is extending national coverage for the use of abarelix/(Plenaxis™) as a palliative treatment in patients with advanced symptomatic prostate cancer:

(1) in whom gonadotropin-releasing hormone (GnRH) therapy is not appropriate; (2) who decline surgical castration; and, (3) who present with one of the following: (a) risk of neurological compromise due to metastases; (b) ureteral or bladder outlet obstruction due to local encroachment or metastatic disease; or, (c) severe bone pain from skeletal metastases persisting on narcotic analgesia.

This addition of section 110.19 to Pub. 100-03 is a national coverage determination (NCD) made under section 1862(a)(1) of the Social Security Act. NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, the Medicare Appeals Council, and administrative law judges (see 42 CFR section 405.732, 405.860). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an administrative law judge may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.

NEW/REVISED MATERIAL :
EFFECTIVE DATE : March 15, 2005
IMPLEMENTATION DATE : May 25, 2005

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:
R = REVISED, N = NEW, D = DELETED

R	1/Table of Contents

N	1/110.19/Abarelix for Treatment of Prostate Cancer (Effective

III. FUNDING:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2005 operating budgets.

IV. ATTACHMENTS:

Manual Instruction

Unless otherwise specified, the effective date is the date of service.

Medicare National Coverage Determinations Manual

Chapter 1, Part 2 (Sections 90 – 160.25)

Coverage Determinations

Table of Contents

(Rev. 34, 04-25-05)

110.19 – Abarelix for the Treatment of Prostate Cancer (Effective March 15, 2005)

(Rev. 34, Issued: 04-25-05; Effective: 03-15-05; Implementation: 05-25-05)

A. General

An estimated 230,000 new cases of prostate cancer occurred in the United States during 2004. Treatment options vary once the disease is diagnosed depending on age, stage of the cancer, and other individual medical conditions. Surgery (e.g., radical prostatectomy) or radiation is typically used for early-stage disease. Hormonal therapy, chemotherapy, and radiation (or combinations of these treatments) are used for more advanced disease. Prostate cancer is androgen-dependent. In recent years, hormonal therapy has evolved from orchiectomy and estrogens to the use of synthetic drugs known as gonadotropin-releasing hormone (GnRH) agonists or analogues. GnRH agonists include drugs such as leuprolide (Lupron™) and goserelin (Zoladex™). In contrast with GnRH agonists, newer compounds such as abarelix (Plenaxis™) are thought to be devoid of agonist activity and to lack an initial androgen-stimulating effect and are thus considered GnRH receptor antagonists. Abarelix has been proposed as a substitute for GnRH agonists with and without anti-androgens in the treatment of patients with advanced prostate cancer for whom a surge in androgen blood levels may pose a risk of worsening symptoms ("clinical flare.")

B. Nationally Covered Indications

Effective for services performed on or after March 15, 2005, the Centers for Medicare & Medicaid Services (CMS) make the following determinations regarding the use of abarelix in the treatment of patients with prostate cancer:

The evidence is adequate to conclude that abarelix is reasonable and necessary as a palliative treatment in patients with advanced symptomatic prostate cancer: (1) in whom GnRH agonist therapy is not appropriate; (2) who decline surgical castration; and (3) who present with one of the following:

- *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.*

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

- *The patient has been evaluated by, and the drug has been prescribed by, a physician who has attested to the following qualifications and accepted the following responsibilities, and on that basis, has enrolled in the post-marketing risk management program established by the drug manufacturer.*
- *Physicians have attested 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;*
- *Understand the risks and benefits of palliative treatment with abarelix;*
- *Educate patients on the risks and benefits of palliative treatment with abarelix; and,*
- *Report serious adverse events as soon as possible to the manufacturer and/or the FDA.*

C. Nationally Noncovered Indications

Effective March 15, 2005, CMS determines that the evidence is not adequate to conclude that abarelix is reasonable and necessary for indications other than that specified above. All other uses of abarelix are not covered. In light of the concern regarding safety risks of abarelix, 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 unless CMS extends coverage through a reconsideration of this National Coverage Determination.

D. Other

N/A

(This NCD last reviewed April 2005.)