Abarelix for Treatment of Prostate Cancer (NCD 110.19)

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<th>Policy Number</th>
<th>Approved By</th>
<th>Current Approval Date</th>
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<tr>
<td>110.19</td>
<td>UnitedHealthcare Medicare Reimbursement Policy Committee</td>
<td>08/14/2013</td>
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IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

This policy is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare reimbursement policies use Current Procedural Terminology (CPT®*), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT or other sources are for definitional purposes only and do not imply any right to reimbursement.

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450). Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy. This information is intended to serve only as a general resource regarding UnitedHealthcare’s reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the physician or other provider contracts, and/or the enrollee’s benefit coverage documents. Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare due to programming or other constraints; however, UnitedHealthcare strives to minimize these variations.

UnitedHealthcare may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

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Application

This reimbursement policy applies to services reported using the Health Insurance Claim Form CMS-1500 or its electronic equivalent or its successor form, and services reported using facility claim form CMS-1450 or its electronic equivalent or its successor form. This policy applies to all products, all network and non-network physicians, and other health care professionals.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing UnitedHealthcare. It is not enough to link the procedure code to a correct, payable

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ICD-9-CM diagnosis code. The diagnosis must be present for the procedure to be paid. Compliance with the provisions in this policy is subject to monitoring by pre-payment review and/or post-payment data analysis and subsequent medical review. The effective date of changes/additions/deletions to this policy is the committee meeting date unless otherwise indicated. CPT codes and descriptions are copyright 2010 American Medical Association (or such other date of publication of CPT). All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS restrictions apply to Government use. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Current Dental Terminology (CDT), including procedure codes, nomenclature, descriptors, and other data contained therein, is copyright by the American Dental Association, 2002, 2004. All rights reserved. CDT is a registered trademark of the American Dental Association. Applicable FARS/DFARS apply.

Summary

Overview

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 TM) and goserelin (Zoladex TM). In contrast with GnRH agonists, newer compounds such as abarelix (Plenaxis TM) 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.”)

Covered for use as palliative treatment in patients with advanced symptomatic prostate cancer.

Reimbursement Guidelines

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;
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- 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.

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.

CPT/HCPCS Codes

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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>J0128</td>
<td>Injection, abarelix, 10 mg (Expired effective 12/31/2010 – no code replacement)</td>
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References Included (but not limited to):

CMS National Coverage Determinations (NCDs)
NCD 110.19 Abarelix for Treatment of Prostate Cancer

CMS Transmittals
CMS Transmittal 612

UnitedHealthcare Medicare Advantage Coverage Summaries
Chemotherapy, and Associated Drugs and Treatments

Next Review Date
August 2014, unless issues arise.

History

<table>
<thead>
<tr>
<th>Date</th>
<th>Revisions</th>
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| 08/14/2013| • Re-review presented to MRPC for approval; no changes  
            • Approved                                             |
| 08/22/2012| • Re-review presented to MRPC for approval       
            • Approved                                             |
| 03/09/2011| • Re-review presented to MRPC for approval       
            • Approved                                             |