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Contractor Name

CareFirst of Maryland INC., Medicare Part A

Contractor Number

00190

Contractor Type

Fiscal Intermediary

LCD Database ID Number

L20393

LCD Title

Docetaxel

Contractor's Determination Number

05-01

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CMS National Coverage Policy

- Establishment of national policy supersedes all previous contractor policy statements, including Local Medical Policy coverage guidelines
- Title XVIII of the Social Security Act, section 1862 (a) (7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, section 1862 (a) (1) (A). This section

allows coverage and payment for only those services that are considered to be medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

- Title XVIII of the Social Security Act, Section 1833(e). This section prohibits Medicare payment for any claim that lacks the necessary information to process the claim.

Primary Geographic Jurisdiction

Maryland

Washington, DC

Secondary Geographic Jurisdiction

Alabama, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Wisconsin, Washington state, and Wyoming

Oversight Region

Region III

CMS Consortium

Northeast

DMERC Region LCD Covers

N/A

Original Determination Effective Date

June 28, 2005

Revision Effective Date

Indications and Limitations of Coverage and/or Medical Necessity

Docetaxel (Taxotere®) is an antineoplastic agent of the taxoid family prepared from yew plants which exerts its therapeutic effect by disrupting the microtubular network in cells, thus inhibiting mitosis.

Indications:

Docetaxel is indicated for the treatment of patients with malignant neoplasia of the head and neck; esophagus; stomach; lung; breast; and gynecologic and urogenital systems. Usually it is used as a second-line therapy, but may be used first-line in certain tumors, such as when used with cisplatin in non-small cell lung cancer. It is often used in combination with other agents.

Limitations

Docetaxel is generally given at a dosage of 75mg/meter squared (range 60 to 100 mg/meter squared) given over one hour every three weeks. Pretreatment with corticosteroids is recommended.

Coverage Topics

Chemotherapy (Outpatient), Chemotherapy (Inpatient)

Bill Type Codes

13X, 21X, 83X, 85X

Revenue Codes

636

CPT/HCPCS Codes

The AMA and CMS require the use of short descriptors for policies published on the Web. Refer to the CPT book for the long description of the following codes:

J9170 Doxetaxel, 20 mg

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Does the "CPT 30% Coding Rule" Apply?

NA

ICD-9 Codes that Support Medical Necessity

ICD-9-CM code listings may cover a range and include truncated codes. It is the provider's responsibility to avoid truncated codes by selecting a code(s) carried out to the highest level of specificity and selected from the ICD-9-CM book appropriate to the year in which the claim is submitted.

It is not enough to link the procedure code to a correct, payable ICD-9-CM code. The diagnosis or clinical suspicion must be present for the procedure to be paid.

Medicare is establishing the following limited coverage for docetaxel:

Covered for:

140.0-
140.1 Malignant neoplasm of lip
140.3-
140.6 Malignant neoplasm of lip
140.8-
140.9 Malignant neoplasm of lip
141.0-
141.6 Malignant neoplasm of tongue
141.8-
141.9 Malignant neoplasm of tongue
143.0-
143.1 Malignant neoplasm of gum
143.8-
143.9 Malignant neoplasm of gum
144.0-
144.1 Malignant neoplasm of floor of mouth
144.8-
144.9 Malignant neoplasm of floor of mouth
145.0-
145.6 Malignant neoplasm of other and unspecified parts of mouth
145.8-
145.9 Malignant neoplasm of other and unspecified part of mouth
146.0-
146.9 Malignant neoplasm of oropharynx
147.0-
147.3 Malignant neoplasm of nasopharynx
147.8-
147.9 Malignant neoplasm of nasopharynx
148.0-
148.3 Malignant neoplasm of hypopharynx
148.8-
148.9 Malignant neoplasm of hypopharynx
150.0-
150.5 Malignant neoplasm of esophagus
150.8-
150.9 Malignant neoplasm of esophagus
151.0-
151.6 Malignant neoplasm of stomach, cardia
151.8 Malignant neoplasm of stomach, other unspecified sites
158.0 Malignant neoplasm of retroperitoneum
158.8-
158.9 Malignant neoplasm of peritoneum
161.0-
161.3 Malignant neoplasm of larynx
161.8- Malignant neoplasm of larynx
161.9
162.0 Malignant neoplasm of trachea
162.2 Malignant neoplasm of main bronchus
162.3 Malignant neoplasm of upper lobe, bronchus or lung
162.4 Malignant neoplasm of middle lobe, bronchus or lung
162.5 Malignant neoplasm of lower lobe, bronchus or lung
162.8 Malignant neoplasm of other parts of bronchus or lung
162.9 Malignant neoplasm of bronchus and lung, unspecified
174.0-
174.6 Malignant neoplasm of female breast
174.8-

174.9 Malignant neoplasm of female breast
175.0 Malignant neoplasm of male breast, nipple and areola
175.9 Malignant neoplasm of male breast, other and unspecified sites of male breast
176.0-
176.5 Kaposi sarcoma
176.8-
176.9 Kaposi sarcoma
180.0-
180.1 Malignant neoplasm of cervix uteri
180.8-
180.9 Malignant neoplasm of cervix uteri
182.0 Malignant neoplasm of corpus uteri, except isthmus
182.1 Malignant neoplasm of isthmus
182.8 Malignant neoplasm of other specified sites of body of uterus
183.0 Malignant neoplasm of ovary and other uterine adnexa, ovary
183.2-
183.5 Malignant neoplasm of ovary and other uterine adnexa
183.8-
183.9 Malignant neoplasm of ovary and other uterine adnexa
185 Malignant neoplasm of prostate
188.0-
188.9 Malignant neoplasm of bladder
189.0-
189.3 Malignant neoplasm of kidney and other and unspecified urinary organs
197.0-
197.2 Secondary malignant neoplasm of respiratory and digestive system
197.7 Secondary malignant neoplasm of respiratory and digestive system, liver specified as secondary
198.2-
198.3 Secondary malignant neoplasm of other specified sites
198.5-
198.6 Secondary malignant neoplasm of other specified sites
198.81 Secondary malignant neoplasm of other specified sites
198.82 Secondary malignant neoplasm of other specified sites
198.89 Secondary malignant neoplasm of other specified sites, other
199.0- Malignant neoplasm of without specification of site
199.1
233.3 Carcinoma in situ of other and unspecified female genital organs
V10.03 Personal history of malignant neoplasm, gastrointestinal tract
V10.04 Personal history of malignant neoplasm, gastrointestinal tract
V10.11 Personal history of malignant neoplasm, bronchus and lung
V10.21 Personal history of malignant neoplasm, larynx
V10.3 Personal history of malignant neoplasm, breast
V10.43 Personal history of malignant neoplasm, ovary
V10.46 Personal history of malignant neoplasm, prostate
V10.51 Personal history of malignant neoplasm, bladder

Diagnoses that Support Medical Necessity

N/A

ICD-9 Codes that DO NOT Support Medical Necessity

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Documentation Requirements

- Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and available to Medicare upon request.
- ICD-9-CM diagnosis codes supporting medical necessity must be submitted with each claim. Claims submitted without such evidence will be denied as not medically necessary.

Utilization Guidelines

Medicare will monitor the utilization of this procedure through the Medical Review process.

Sources of Information and Basis for Decision

Taxotere® prescribing information.

TrailBlazer Health Enterprises, LLC, Maryland Part B Policy - Drugs and Biologicals - Chemotherapeutic Drugs

Articles/Abstracts:

Bamias, A., et al. (2004) "Neoadjuvant chemotherapy with docetaxel and cisplatin in patients with high-risk resectable bladder carcinoma: long term results." *Eur Urol.*, 46(3):344-50.

Berkenblit, A., et al. (2004) "A phase II trial of weekly docetaxel in patients with platinum-resistant epithelial ovarian, primary peritoneal serous cancer, or fallopian tube cancer." *Gynecol Oncol.* 95(3): 624-31.

Dagher, R., et al. (2004) "Approval summary: Docetaxel in combination with prednisone: the treatment of androgen-independent hormone-refractory prostate cancer." *Clin Cancer Res.* 10(24):8147-51.

Genet, D., et al. (2004) "Docetaxel plus 5-fluorouracil in locally recurrent and/or metastatic squamous cell carcinoma of the head and neck: a phase II multicenter study." *Am J Clin Oncol.* 27(5): 472-6.

Gomez-Bernal a., et al. (2005) "Biweekly docetaxel and vinorelbine with granulocyte colony-stimulating factor support for patients with anthracycline-resistant metastatic breast cancer." *Anticancer Drugs* 16(1): 77-82.

Hensley, M.L., et al. (2002) "Gemcitabine and docetaxel in patients with unresectable leiomyosarcoma: results of a phase II trial." *J Clin Oncol.* 20(12): 2824-31.

Ishikawa, T., et al. (2004) "A Multicenter Phase II Study of Docetaxel 60mg/m² as First-Line Chemotherapy in Patients with Advanced or Recurrent Breast Cancer." *Breast Cancer* 11(4): 374-9.

Jatoi, A., et al. (2002) "A phase II trial of docetaxel and CPT-11 in patients with metastatic adenocarcinoma of the esophagus, gastroesophageal junction, and gastric cardia." *Int J Gastrointest Cancer* 32(2-3): 115-23.

Malhotra, V. et al. (2004) "Neoadjuvant and adjuvant chemotherapy with doxorubicin and docetaxel in locally advanced breast cancer." *Clin Breast Cancer* 5(5): 377-84.

Muro, K. et al. (2004) "A phase II study of single-agent docetaxel in patients with metastatic esophageal cancer." *Ann Oncol.* 15(6): 955-9.

Neubauer, M.A., et al. (2005) "Results of a phase II multicenter trial of weekly docetaxel and gemcitabine as first-line therapy for patients with advanced non small cell lung cancer." *Lung Cancer* 47(1): 121-7.

Park, S.H., et al. (2004) "Docetaxel plus cisplatin as second-line therapy in metastatic or recurrent advanced gastric cancer progressing on 5-fluorouracil-based regimen." *Am J Clin Oncol.* 27(5): 477-80.

Takahashi, S., et al. "Combination Chemotherapy of Docetaxel, Ifosfamide and Cisplatin (DIP) in Patients with Metastatic Urothelial Cancer: a Preliminary Report." *Jpn J Clin Oncol.* 35(2): 79-83.

Thuss-Patience, P.C., et al. (2005) "Docetaxel and Continuous-Infusion Fluorouracil Versus Epirubicin, Cisplatin, and Fluorouracil for Advanced Gastric Adenocarcinoma: A Randomized Phase II Study." *J Clin Oncol.* 23(3): 494-501.

Vasey, P.A., et al. (2004) "Phase II randomized trial of docetaxel-carboplatin versus paclitaxel-carboplatin as first-line chemotherapy for ovarian carcinoma." *J Natl Cancer Inst.* 96(22):1682-91.

Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from the appropriate specialty (ies).

Start Date of Comment Period

March 18, 2005

End Date of Comment Period

May 2, 2005

Start Date of Notice Period

May 14, 2005

Revision History Number

Revision History

Revision

Number Revision History Explanation

Does this LCD contain a "Least Costly Alternative" provision?

No

THIS BULLETIN SHOULD BE SHARED WITH ALL HEALTH CARE PRACTITIONERS AND MANAGERIAL MEMBERS OF THE PROVIDER/SUPPLIER STAFF. BULLETINS ISSUED AFTER OCTOBER 1, 1999 ARE AVAILABLE FROM OUR WEBSITE AT www.marylandmedicare.com

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