FIRST COAST SERVICE OPTIONS
MAC - PART A/B
LOCAL COVERAGE DETERMINATION

LCD Database ID Number
L33989

Contractor Name
First Coast Service Options, Inc.

Contractor Number
09101 - Florida
09201 – Puerto Rico/Virgin Islands
09102 – Florida
09202 – Puerto Rico
09302 – Virgin Islands

Contractor Type
MAC – Part A and B

LCD Title
Docetaxel (Taxotere®)

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CMS National Coverage Policy
Language quoted from CMS National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

CMS Manual System, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 1, Section 30-30.1
CMS Manual System, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 50
CMS Manual System, Pub. 100-04, Medicare Claims Processing Manual, Chapter 17, Sections 10, 20 and 40
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CMS Manual System, Pub. 100-08, Medicare Program Integrity Manual, Chapter 13, Section 13.1.3

Primary Geographic Jurisdiction

Florida
Puerto Rico/Virgin Islands

Oversight Region

Region I

Original Determination Effective Date

10/01/2015

Original Determination Ending Date

N/A

Revision Effective Date

10/01/2016

Revision Ending Date

09/30/2016

Indications and Limitations of Coverage and/or Medical Necessity

DOCETAXEL (TAXOTERE®)-J9171

Docetaxel, an antineoplastic agent belonging to the taxoid family, acts by disrupting cell replication. It is a derivative of 10-deacetyl-baccatin 111, a compound extracted from the needles of the European yew tree. Docetaxel acts by disrupting the microtubular network in cells, an essential component of vital mitotic and interphase cellular functions.

Taxotere is FDA approved for the following indications:

- For treatment of locally advanced or metastatic breast cancer after failure of prior chemotherapy.
- Docetaxel in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with operable node-positive breast cancer.
- Docetaxel as a single agent for treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of platinum-based chemotherapy.
- Docetaxel in combination with cisplatin is indicated for the treatment of patients with unresectable, locally advanced or metastatic non-small cell lung cancer who have not previously received chemotherapy for this condition.
- Docetaxel in combination with prednisone is indicated for the treatment of patients with androgen independent (hormone refractory) metastatic prostate cancer.
- Docetaxel in combination with cisplatin and fluorouracil is indicated for the treatment of patients with advanced gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for advanced disease.
- Docetaxel in combination with cisplatin and fluorouracil is indicated for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck.
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Taxotere will be covered for its FDA approved uses, as well as for the treatment of the following off-labeled indications:

- Fallopian tube carcinoma
- Endometrial carcinoma
- Primary peritoneal carcinoma
- Small-cell lung carcinoma after first-line chemotherapy has failed
- Bladder carcinoma, alone or in combination with other chemotherapeutic agents
- Ovarian carcinoma, after platinum-based therapy has failed, or as first-line treatment in combination with carboplatin
- Melanoma
- Breast carcinoma, first-line therapy for locally advanced or metastatic
- Non-small cell lung (NSCLC) carcinoma, first-line
- Esophageal carcinoma, alone or in combination with other agents, for the treatment of advanced and/or metastatic esophageal carcinomas, including adenocarcinomas and squamous cell carcinomas
- Gastric carcinomas, alone or in combination for the treatment of advanced and/or metastatic esophageal, gastric, and/or gastroesophageal (GE) junction carcinomas which includes adenocarcinomas and squamous cell carcinomas
- Pancreatic carcinoma
- Soft tissue sarcomas
- Bone and articular cartilage
- Second-line treatment of AIDS-related Kaposi’s sarcoma

**Type of Bill Code**

Hospital - 13x  
Skilled Nursing Facility - 21x, 22x, 23x  
Critical Access Hospital – 85x

**Revenue Codes**

636       Drugs Requiring Detailed Coding

**CPT/HCPCS Codes**

J9171     Injection, Docetaxel, 1 mg

**ICD-10 Codes that Support Medical Necessity**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C00.0-C14.8</td>
<td>Neoplasms</td>
</tr>
<tr>
<td>C15.3-C15.9</td>
<td>Malignant neoplasm of esophagus</td>
</tr>
<tr>
<td>C16.0-C16.9</td>
<td>Malignant neoplasm of stomach</td>
</tr>
<tr>
<td>C25.0-C25.9</td>
<td>Malignant neoplasm of pancreas</td>
</tr>
<tr>
<td>C30.0-C30.1</td>
<td>Malignant neoplasms nasal cavity and middle ear</td>
</tr>
<tr>
<td>C31.0-C31.9</td>
<td>Malignant neoplasm of accessory sinuses</td>
</tr>
<tr>
<td>C32.0-C32.9</td>
<td>Malignant neoplasm of larynx</td>
</tr>
<tr>
<td>C33</td>
<td>Malignant neoplasm of trachea</td>
</tr>
<tr>
<td>C34.00-C34.92</td>
<td>Malignant neoplasm of main bronchus</td>
</tr>
<tr>
<td>C40.00-C41.9</td>
<td>Neoplasms</td>
</tr>
<tr>
<td>C43.0-C43.9</td>
<td>Malignant melanoma of skin</td>
</tr>
<tr>
<td>C44.00</td>
<td>Unspecified malignant neoplasm of skin of lip</td>
</tr>
<tr>
<td>C44.01</td>
<td>Basal cell carcinoma of skin of lip</td>
</tr>
<tr>
<td>C44.02</td>
<td>Squamous cell carcinoma of skin of lip</td>
</tr>
<tr>
<td>C44.09</td>
<td>Other specified malignant neoplasm of skin of lip</td>
</tr>
</tbody>
</table>
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C44.101-C44.199 Other and unspecified malignant neoplasm of skin of eyelid, including canthus
C44.201-C44.299 Other and unspecified malignant neoplasm of skin of ear and external auricular canal
C44.300-C44.399 Other and unspecified malignant neoplasm of skin of other and unspecified parts of face
C44.40-C44.49 Other and unspecified malignant neoplasm of skin of scalp and neck
C45.1 Mesothelioma of peritoneum
C46.0-C46.9 Kaposi's sarcoma
C48.1 Malignant neoplasm of specified parts of peritoneum
C48.2 Malignant neoplasm of peritoneum, unspecified
C48.8 Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C49.0-C49.9 Malignant neoplasm of other connective and soft tissue
C49.A0 - C49.A9 Gastrointestinal stromal tumor, unspecified site - Gastrointestinal stromal tumor of other sites
C50.011-C50.019 Malignant neoplasm of nipple and areola, female
C50.111-C50.119 Malignant neoplasm of central portion of breast, female
C50.211-C50.219 Malignant neoplasm of upper-inner quadrant of breast, female
C50.311-C50.319 Malignant neoplasm of lower-inner quadrant of breast, female
C50.411-C50.419 Malignant neoplasm of upper-outer quadrant of breast, female
C50.511-C50.519 Malignant neoplasm of lower-outer quadrant of breast, female
C50.611-C50.619 Malignant neoplasm of axillary tail of breast, female
C50.811-C50.819 Malignant neoplasm of overlapping sites of breast, female
C50.911-C50.919 Malignant neoplasm of breast of unspecified site, female
C50.021-C50.029 Malignant neoplasm of nipple and areola, male
C50.121-C50.129 Malignant neoplasm of central portion of breast, male
C50.221-C50.229 Malignant neoplasm of upper-inner quadrant of breast, male
C50.321-C50.329 Malignant neoplasm of lower-inner quadrant of breast, male
C50.421-C50.429 Malignant neoplasm of upper-outer quadrant of breast, male
C50.521-C50.529 Malignant neoplasm of lower-outer quadrant of breast, male
C50.621-C50.629 Malignant neoplasm of axillary tail of breast, male
C50.821-C50.829 Malignant neoplasm of overlapping sites of breast, male
C50.921-C50.929 Malignant neoplasm of breast of unspecified site, male
C54.1-C54.3 Malignant neoplasm of corpus uteri
C54.9 Malignant neoplasm of corpus uteri, unspecified
C56.1-C57.4 Neoplasms
C61 Malignant neoplasm of prostate
C67.0-C67.9 Malignant neoplasm of bladder
C76.0 Malignant neoplasm of head, face and neck
C78.6 Secondary malignant neoplasm of retroperitoneum and peritoneum

**Diagnoses that Support Medical Necessity**

See ICD-10 Codes that Support Medical Necessity
ICD-10 Codes that DO NOT Support Medical Necessity

All other diagnosis codes not listed as covered in the “ICD-10 Codes that Support Medical Necessity” section of this LCD.

Diagnoses that DO NOT Support Medical Necessity

All other diagnoses not listed as covered in the “ICD-10 Codes that Support Medical Necessity” section of this LCD.

Associated Information

Documentation Requirements

Medical record documentation maintained by the ordering/referring physician must substantiate the medical need for the use of these chemotherapy drugs by clearly indicating the condition for which these drugs are being used. This might include the type of cancer, staging, if applicable, prior therapy and the patient’s response to that therapy. This documentation is usually found in the history and physical or in the office/progress notes.

If the provider of the service is other than the ordering/referring physician, that provider must maintain copies of the ordering/referring physician’s order for the chemotherapy drug. The physician must state the clinical indication/medical need for using the chemotherapy drug in the order.

Utilization Guidelines

It is expected that these services would be performed as indicated by current medical literature and/or standards of practice. When services are performed in excess of established parameters, they may be subject to review for medical necessity.

Sources of Information and Basis for Decision

FCSO reference LCD number(s) – L28858, L29155, L29417


Taxotere® (Docetaxel) injection concentrate prescribing information, sanofi-aventis


U.S. Food and Drug Administration, Department of Health and Human Services, CDER web site updates, February 2008.

Start Date of Comment Period

N/A

End Date of Comment Period

N/A
Docetaxel (Taxotere®) AB

Start Date of Notice Period

04/01/2015

Revision History

Revision History Number: R1

Revision Number: 1
Publication: October 2016 Connection
LCR A/B2016-097

Explanation of Revision: Based on CR 9677 (Annual 2017 ICD-10-CM Update) the LCD was revised to add ICD-10-CM diagnosis code range C49.A0-C49.A9 to the “ICD-10 Codes that Support Medical Necessity” section of this LCD. The effective date of this revision is based on date of service.

Revision Number: Original

This LCD replaces all previous LCD versions (refer to “Sources of Information and Basis for Decision” section of the LCD) and publications on this subject to comply with ICD-10-CM based on Change Request 8112. The effective date of this LCD is based on date of service.

Related Documents

N/A

LCD Attachments

N/A

Document formatted: 09/08/2016 (TG/et)