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

LCD Database ID Number
L33730

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
Paclitaxel (Taxol®)

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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
Paclitaxel (Taxol®) AB

CMS Manual System, Pub. 100-08, Medicare Program Integrity Manual, Chapter 13, Section 13.1.3
Social Security Act, Section 1861 (t)(2)(B)

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

03/09/2017

Revision Ending Date

03/08/2017

Indications and Limitations of Coverage and/or Medical Necessity

PACLITAXEL (TAXOL®) J9267)

Paclitaxel is an antimicrotubule agent. It interferes with the normal cellular microtubule function that is required for interphase and mitosis.

Paclitaxel is FDA approved for treatment of the following indications:

• adjuvant treatment of node-positive breast cancer when administered sequentially to standard doxorubicin-containing combination chemotherapy;
• metastatic breast carcinoma after failure of combination chemotherapy or at relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated;
• advanced carcinoma of ovary - first-line therapy in combination with cisplatin, and subsequent therapy;
• as a second-line treatment for AIDS-associated Kaposi’s sarcoma; and
• non-small cell lung carcinoma in combination with Cisplatin as a first-line treatment for patients who are not candidates for radiation therapy or potentially curative surgery.

Paclitaxel will be covered when provided for its FDA approved uses, as well as for the treatment of the following off-labeled indications:
Paclitaxel (Taxol®) AB

- First line therapy for treatment of metastatic breast cancer - as a single agent or in combination with other chemotherapy agents
- Bladder carcinoma
- Cervical carcinoma
- Endometrial carcinoma
- Esophageal carcinoma
- Head & neck carcinoma
- Small cell and non-small cell lung carcinoma
- Prostatic carcinoma
- Advanced gastric carcinoma - in combination therapy
- Malignant pleural effusion
- Cancer of Unknown Primary site (CUPs)
- Fallopian and peritoneal carcinomas of ovarian origin when used in combination with Carboplatin or Cisplatin
- Testicular germ cell carcinoma
- Soft tissue sarcomas
- Used in combination with carboplatin for the treatment of malignant melanoma
- Thymic carcinoma
- Anaplastic thyroid carcinoma
- Malignant neoplasm of vulva

Type of Bill Code

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

Revenue Codes

636 Drugs Requiring Detailed Coding

CPT/HCPCS Codes

J9267 Injection, paclitaxel, 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 of lip, oral cavity, and pharynx</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>C30.0-C37</td>
<td>Malignant neoplasms of respiratory and intrathoracic organs</td>
</tr>
<tr>
<td>C43.0-C43.9</td>
<td>Malignant melanoma of skin</td>
</tr>
<tr>
<td>C45.1</td>
<td>Mesothelioma of peritoneum</td>
</tr>
<tr>
<td>C45.9</td>
<td>Mesothelioma, unspecified</td>
</tr>
<tr>
<td>C46.0-C46.9</td>
<td>Kaposi's sarcoma</td>
</tr>
<tr>
<td>C47.0-C47.9</td>
<td>Malignant neoplasm of peripheral nerves and autonomic nervous system</td>
</tr>
<tr>
<td>C48.1</td>
<td>Malignant neoplasm of specified parts of peritoneum</td>
</tr>
<tr>
<td>C48.2</td>
<td>Malignant neoplasm of peritoneum, unspecified</td>
</tr>
<tr>
<td>C48.8</td>
<td>Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum</td>
</tr>
<tr>
<td>C49.0-C49.9</td>
<td>Malignant neoplasm of other connective and soft tissue</td>
</tr>
<tr>
<td>C50.011-C50.929</td>
<td>Malignant neoplasm of breast</td>
</tr>
<tr>
<td>C51.8</td>
<td>Malignant neoplasm of overlapping sites of vulva</td>
</tr>
<tr>
<td>C51.9</td>
<td>Malignant neoplasm of vulva, unspecified</td>
</tr>
<tr>
<td>C53.0-C57.4</td>
<td>Malignant neoplasm of female genital organs</td>
</tr>
</tbody>
</table>
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C61 Malignant neoplasm of prostate
C62.00-C62.92 Malignant neoplasm of testis
C67.0-C67.9 Malignant neoplasm of bladder
C73 Malignant neoplasm of thyroid gland
C76.0 Malignant neoplasm of head, face and neck
C78.6 Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.2 Secondary malignant neoplasm of pleura (malignant pleural effusion)
C80.0-C80.2 Malignant neoplasm without specification of site
D03.0-D03.9 Melanoma in situ

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.

Documentation in the medical record must support paclitaxel was given for an indication specified in this Local Coverage Determination (LCD). The amount of drug, route & timing of administration, and any reaction of the patient should be documented in the medical record. In general, a facility should bill what is administered to the patient with attention to the code descriptor and quantity billed (see coding guidelines if applicable). In the event that only one patient needs a portion of the contents in the single-use vial, then the remainder can be discarded. In such a situation, the entire contents of the vial can be billed. Under no circumstances can multiple patients be billed for the entire contents of a single vial when the each patient received a portion of the drug from the same vial. With appropriate procedures, it is safe to re-enter a medication vial labeled as single use. CMS issued a procedure, developed with the approval of the Centers for Disease Control, for safe re-entry into “single-use” vials. This procedure is expected to be used whenever feasible for efficient use of medications and minimal drug wastage. The hospital pharmacy record should have documentation on drugs discarded from single-use vials that are subsequently billed to a patient.

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
Paclitaxel (Taxol®) AB

FCSO reference LCD number(s) – L28964, L29249, L29460


Smallridge, R., Ain, K., Asa, S., Bible, K., Brierley, J., Burman, K., et al. (2012). American Thyroid Association Guidelines for Management of Patients with Anaplastic Thyroid Cancer. Thyroid, Volume 22, # 11.


U.S. Food and Drug Administration, Department of Health and Human Services, CDER web site updates, March 2007.


Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

04/01/2015

Revision History
Revision History Number: R1

Revision Number: 1
Publication: February 2017 Connection
LCR A/B2017-005

Explanation of revision: This LCD was revised to add ICD-10 diagnosis codes C51.8 and C51.9 as an off-label indication, resulting from an LCD reconsideration request. 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: 01/24/2017 (TG/et)