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

LCD Database ID Number
L33723

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
Etoposide (Etopophos®, Toposar®, Vepesid®, VP-16)

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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
Etoposide (Etopophos®, Toposar®, Vepesid®, VP-16) Part A/B

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

10/01/2016

Revision Ending Date

09/30/2016

Indications and Limitations of Coverage and/or Medical Necessity

ETOPOSIDE (ETOOPHOS®, TOPOSAR®, VEPESID®, VP-16)-J9181

Etoposide is a podophyllotoxin which inhibits DNA synthesis prior to mitosis by blocking topoisomerase II.

Etoposide is FDA approved for the following indications:

- Management of refractory testicular tumors, in combination with other approved chemotherapeutic agents.
- In combination with other approved chemotherapeutic agents as first-line treatment in patients with small cell lung cancer.

Etoposide will be covered when provided for its FDA approved uses, as well as for the treatment of the following off-labeled indications:

- Primary peritoneal carcinoma
- Fallopian tube carcinoma
- Gastric carcinoma
- Hepatoblastoma
- Neuroblastoma
- Non-small cell lung carcinoma
- Testicular cancer
- Thymoma
- Osteosarcoma
- Ewing’s sarcoma
- Soft tissue sarcomas
- Cutaneous T cell lymphomas
- Breast carcinoma
- AIDS associated Kaposi’s sarcoma
- Endometrial carcinoma
- Ovarian germ cell tumors
- Bladder carcinoma
- Wilms’ Tumor
- Retinoblastoma
- Adrenocortical carcinoma
- Acute lymphocytic leukemia
- Acute nonlymphocytic leukemia
- Chronic myelocytic leukemia
- Hodgkin’s lymphoma
- Non-Hodgkin’s lymphoma
- Multiple myeloma
- Primary brain tumor
- Gestational trophoblastic tumor
- Cancer of Unknown Primary site (CUPs)
- Trophoblastic neoplasm
- Myelodysplastic syndromes (MDS)
- Neuroendocrine tumors (malignant poorly differentiated)
- For Merkel cell carcinoma in combination with carboplatin or cisplatin as a consideration for adjuvant treatment with or without radiation therapy for N+ disease
- For Merkel cell carcinoma in combination with carboplatin or cisplatin as treatment for distant metastatic disease or disseminated recurrence with or without surgery or radiation therapy

**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**

- J9181 Injection, etoposide, 10 mg

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

- C16.0-C16.9 Malignant neoplasm of stomach
- C22.0-C22.9 Malignant neoplasm of liver and intraheptic ducts
- C30.0-C30.1 Malignant neoplasm of nasal cavity and middle ear
- C31.0-C31.9 Malignant neoplasm of accessory sinuses
- C32.0-C32.9 Malignant neoplasm of larynx
- C33 Malignant neoplasm of trachea
- C34.00-C34.92 Malignant neoplasm of bronchus and lung
- C37 Malignant neoplasm of thymus
- C38.0-C38.8 Malignant neoplasm of heart, mediastinum and pleura
- C40.00-C40.92 Malignant neoplasm of the bone and articular cartilage of limbs
- C41.0-C41.9 Malignant neoplasm of bone and articular cartilage of other and unspecified
- C43.0-C43.9 Malignant melanoma of skin
- C4A.0 Merkel cell carcinoma of lip
- C4A.10 Merkel cell carcinoma of unspecified eyelid, including canthus
Etoposide (Etopophos®, Toposar®, Vepesid®, VP-16)  Part A/B

C4A.11  Merkel cell carcinoma of right eyelid, including canthus
C4A.12  Merkel cell carcinoma of left eyelid, including canthus
C4A.20  Merkel cell carcinoma of unspecified ear and external auricular canal
C4A.21  Merkel cell carcinoma of right ear and external auricular canal
C4A.22  Merkel cell carcinoma of left ear and external auricular canal
C4A.30  Merkel cell carcinoma of unspecified part of face
C4A.31  Merkel cell carcinoma of nose
C4A.32  Merkel cell carcinoma of skin of scalp and neck
C4A.51  Merkel cell carcinoma of anal skin
C4A.52  Merkel cell carcinoma of skin of breast
C4A.59  Merkel cell carcinoma of other part of trunk
C4A.60  Merkel cell carcinoma of unspecified upper limb, including shoulder
C4A.61  Merkel cell carcinoma of right upper limb, including shoulder
C4A.62  Merkel cell carcinoma of left upper limb, including shoulder
C4A.70  Merkel cell carcinoma of unspecified lower limb, including hip
C4A.71  Merkel cell carcinoma of right lower limb, including hip
C4A.72  Merkel cell carcinoma of left lower limb, including hip
C4A.8  Merkel cell carcinoma of overlapping sites
C4A.9  Merkel cell carcinoma, unspecified
C44.00-C44.99  Other and unspecified malignant neoplasm of skin
C46.0-C46.9  Kaposi’s sarcoma
C47.0-C47.9  Malignant neoplasm of peripheral nerves and autonomic nervous system
C48.1-C48.8  Malignant neoplasm of retroperitoneum and peritoneum
C49.10-C49.9  Malignant neoplasm of other connective and soft tissue
C49.40-C49.9  Gastrointestinal stromal tumor, unspecified site - Gastrointestinal stromal tumor of other sites
C50.01-C50.929  Malignant neoplasm of breast
C53.0-C53.9  Malignant neoplasm of cervix uteri
C54.0-C54.9  Malignant neoplasm of corpus uteri
C56.1-C56.9  Malignant neoplasm of ovary
C57.00-C57.9  Malignant neoplasm of other and unspecified female genital organs
C58  Malignant neoplasm of placenta
C62.00-C62.92  Malignant neoplasm of testis
C64.1-C64.9  Malignant neoplasm of kidney, except renal pelvis
C67.0-C67.9  Malignant neoplasm of bladder
C69.20-C69.22  Malignant neoplasm of retina
C71.0-C71.9  Malignant neoplasm of brain
C74.00-C74.92  Malignant neoplasm of adrenal glands
C7A.1  Malignant poorly differentiated neuroendocrine tumors
C78.6  Secondary malignant neoplasm or retoperitoneum and peritoneum
C79.51-.C79.52  Secondary malignant neoplasm of bone and bone marrow
C80.0  Disseminated malignant neoplasm, unspecified
C80.1  Malignant (primary) neoplasm, unspecified
C81.00-C81.99  Hodgkin lymphoma
C82.00-C82.99  Follicular lymphoma
C83.00-C83.09  Small cell b-lymphoma
C83.10-C83.19  Mantle cell lymphoma
C83.30-.C83.39  Diffuse large b-cell lymphoma
C83.50-C83.59  Lymphoblastic (diffuse) lymphoma
C83.70-C83.79  Burkitt lymphoma
C83.80-C83.89  Other non-follicular, unspecified
C84.00-C84.99  Mature t/nk cell lymphoma
C90.00-C90.32  Multiple myeloma and malignant plasma cell neoplasm
C91.00-C91.92  Lymphoid leukemia
C92.00-C92.22  Myeloid leukemia
C93.00-C93.92  Monocytic leukemia
C94.00-C94.82  Other leukemias of unspecified type
C96.0-C96.9  Other and unspecified malignant neoplasm of lymphoid hematopoietic and related tissue
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 etoposide 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. 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

FCSO reference LCD number(s) – L28870, L29169, L29423


Etoposide (Etopophos®, Toposar®, Vepesid®, VP-16) Part A/B

Food and Drug Administration (FDA) product label for Etoposide. Revised 2010.


Other Medicare contractor’s LCDs


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

**Start Date of Comment Period**

N/A

**End Date of Comment Period**

N/A

**Start Date of Notice Period**

04/01/2014

**Revision History**

**Revision History Number: R2**

Revision Number: 2
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. The effective date of this revision is based on date of service.

**Revision History Number: R1**

Revision Number: 1
Publication: April 2016 Connection
LCR A/B2016-058

Explanation of Revision: Based on LCD reconsideration requests, this LCD was revised to add ICD-10 codes C7A.1 and C80.1 to the “ICD-10 Codes that Support Medical Necessity” section of the LCD. The effective date of this revision is for claims processed on or after 04/06/2016, for dates of service on or after 10/01/2015.
**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