Local Coverage Determination (LCD): Irinotecan (L33727)

Contractor Information

<table>
<thead>
<tr>
<th>Contractor Name</th>
<th>Contract Type</th>
<th>Contract Number</th>
<th>Jurisdiction</th>
<th>State(s)</th>
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<tr>
<td>First Coast Service Options, Inc.</td>
<td>A and B MAC</td>
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LCD Information

Document Information

**LCD ID**
L33727

**Original ICD-9 LCD ID**
L28897

**LCD Title**
Irinotecan

**Proposed LCD in Comment Period**
N/A

**Source Proposed LCD**
N/A

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IRINOTECAN HCL (CAMPTOSAR®)-J9206

Irinotecan HCL, also known as CPT-11, is an analog of camptothecin, a plant alkaloid. It inhibits the enzyme, topoisomerase I, which is necessary for DNA replication.

Irinotecan HCL is FDA approved for the following indications:

- As a component of first-line therapy in combination with 5-fluorouracil and leucovorin for patients with metastatic carcinoma of the colon or rectum.
- For patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following initial fluorouracil-based therapy.

Irinotecan HCL will be covered for its FDA approved use, as well as, for the treatment of the following off-labeled indications:

- Carcinoma of small intestine
- Non small-cell lung carcinoma (alone or in combination for the treatment of locally advanced and/or metastatic stage IIIB or IV NSCLC)
- Small-cell lung carcinoma, extensive-stage small-cell lung cancer, first line treatment, in combination with cisplatin
- Cervical carcinoma
- Pancreatic carcinoma
- Advanced esophageal carcinoma
- Metastatic gastric carcinoma
- Primary brain tumor
- Epithelial ovarian cancer for platinum-resistant or platinum-refractory patients
Metastatic breast cancer, refractory

IRINOTECAN LIPOSOME INJECTION (ONIVYDE®)-J9205

Irinotecan liposome injection is a topoisomerase inhibitor indicated, and is FDA approved in combination with fluorouracil and leucovorin, for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy.

Irinotecan liposome injection is not indicated as a single agent for the treatment of patients with metastatic adenocarcinoma of the pancreas.

Irinotecan liposome injection will be covered for its FDA approved use, as well as, for the treatment of the following off-labeled indication: second-line therapy in combination with fluorouracil and leucovorin for patients with progressive metastatic disease and good performance status who have received prior gemcitabine-based therapy.

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

013x Hospital Outpatient
022x Skilled Nursing - Inpatient (Medicare Part B only)
023x Skilled Nursing - Outpatient
085x Critical Access Hospital

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

0636 Pharmacy - Drugs Requiring Detailed Coding

CPT/HCPCS Codes

Group 1 Paragraph: N/A

Group 1 Codes:
J9205 INJECTION, IRINOTECAN LIPOSOME, 1 MG
J9206 INJECTION, IRINOTECAN, 20 MG

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph: For: J9205

Group 1 Codes:

<table>
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<th>ICD-10 Code</th>
<th>DESCRIPTION</th>
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<tr>
<td>C25.0 - C25.9</td>
<td>Malignant neoplasm of head of pancreas - Malignant neoplasm of pancreas, unspecified</td>
</tr>
<tr>
<td>C79.89</td>
<td>Secondary malignant neoplasm of other specified sites</td>
</tr>
<tr>
<td>C79.9</td>
<td>Secondary malignant neoplasm of unspecified site</td>
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### ICD-10 Codes that DO NOT Support Medical Necessity

#### Additional ICD-10 Information
N/A

### General Information

#### 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.

The amount of drug, route and timing of administration, and any reaction to 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. In no circumstances can multiple patients be billed for the entire contents of a single vial when the patients each received a portion of the drug from the same vial. With appropriate procedures, it is safe to reenter 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 wasted drug. The hospital pharmacy record should have documentation on drug discarded for single use vials that is 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) – L28919, L29208, L29443


FDA prescribing information: ONIVYDE® (irinotecan liposome injection), revised 10/2015.


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

Revision History Information

<table>
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<tr>
<th>Revision History Date</th>
<th>Revision History Number</th>
<th>Revision History Explanation</th>
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<tr>
<td>01/01/2017</td>
<td>R1</td>
<td>Revision Number: 1</td>
<td>• Revisions Due To CPT/HCPCS Code Changes</td>
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<td></td>
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<td>Publication: December 2016 Connection</td>
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Explanation of Revision: Annual 2017 HCPCS Update (CR9752). HCPCS code J9205 was added to the CPT/HCPCS section of the LCD, and FDA and off-labeled indications were added to the “Indications and Limitations of Coverage and/or Medical Necessity” section of the LCD for J9205. Additionally, the title of this LCD was revised to remove Camptosar. Also, to
distinguish between J9205 Irinotecan liposome injection and J9206 Irinotecan, HCL was added to J9206 in the “Indications and Limitations of Coverage and/or Medical Necessity” section of the LCD. The “ICD-10 Codes that Support Medical Necessity” section of the LCD was revised to categorize J9205 and J9206 into Groups 1 and 2. The following ICD-10-CM diagnosis codes were added to Group 1 for HCPCS code J9205: C25.0-C25.9, C79.89, and C79.9. Furthermore, the “Sources of Information and Basis for Decision” section of the LCD was updated. The effective date of this revision is based on date of service.

**Associated Documents**

Attachments
N/A

Related Local Coverage Documents
N/A

Related National Coverage Documents
N/A

**Keywords**

N/A