Onivyde® (irinotecan liposome)

Last Review Date: July 15, 2019

Number: MG.MM.PH.158

Medical Guideline Disclaimer

C All rights reserved. The treating physician or primary care provider must submit to EmblemHealth the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request for prior authorization. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary. If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid programs, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid programs. All coding and web site links are accurate at time of publication. EmblemHealth Services Company LLC, (“EmblemHealth”) has adopted the herein policy in providing management, administrative and other services to HIP Health Plan of New York, HIP Insurance Company of New York, Group Health Incorporated and GHI HMO Select, related to health benefit plans offered by these entities. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definition

Onivyde (irinotecan liposome) is irinotecan, a topoisomerase inhibitor, encapsulated in lipid bilayer vesicle or liposome. The lipid bilayer vesicle allows higher concentrations in the body with lower doses compared to irinotecan HCL (non liposomal formulation).

Irinotecan and its active metabolite SN-38 bind reversibly to the topoisomerase 1-DNA complex and prevent re- ligation of the single strand breaks, leading to exposure time-dependent double-strand DNA damage and cell death.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits

Max Units (per dose and over time) [Medical Benefit]:
- 172 billable units per 14 days

I. INITIAL APPROVAL CRITERIA

Onivyde may be considered medically necessary if one of the below conditions are met AND use is consistent with the medical necessity criteria that follows:

1. Metastatic Adenocarcinoma of the pancreas
   a. Onivyde (irinotecan liposome) must be used in combination with fluorouracil and leucovorin; AND
   b. Member must have progressed on prior treatment of a gemcitabine-based therapy; AND
   c. Member must not have failed prior therapy with irinotecan HCL (non liposomal formulation).
Limitations/Exclusions
Onivyde (irinotecan liposome) is not considered medically necessary when any of the following selection criteria is met:

1. Disease progression while taking Onivyde (irinotecan liposome)
2. Disease progression while taking irinotecan HCL (non liposomal formulation)
3. Dosing exceeds single dose limit of Onivyde (irinotecan liposome)
   a. 70 mg/m²
4. Member with absolute neutrophil count below 1500/mm² or neutropenic fever
5. Member with bowel obstruction
6. Member with diarrhea of Grade 2-4 severity
7. Onivyde (irinotecan liposome) **CANNOT** be substituted for irinotecan HCL (non liposomal formulation)
8. Member with hypersensitivity to Onivyde (irinotecan liposome) or irinotecan HCL (non liposomal formulation)
9. Member with interstitial lung disease
   a. Withhold Onivyde (irinotecan liposome) in member with new or progressive dyspnea, cough, and fever, pending diagnostic evaluation
10. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. **RENEWAL CRITERIA**

Patient continues to meet initial approval criteria and tumor response with stabilization of disease or decrease in tumor spread or size.

Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatic Cancer</td>
<td>- 70 mg/m² intravenously every 14 days</td>
</tr>
<tr>
<td></td>
<td>- 50 mg/m² intravenously every 14 days for member with homozygous</td>
</tr>
<tr>
<td></td>
<td>liposomal for UGT1A1*28 allele.</td>
</tr>
</tbody>
</table>

Applicable Procedure Codes

| J9205            | Injection, irinotecan liposome, 1 mg, 1 billable unit = 1 mg         |

Applicable NDCs

| 69171-0398-xx    | Onivyde 43 mg/10 ml single dose vial                                |

Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C25.0</td>
<td>Malignant neoplasm of head of pancreas</td>
</tr>
</tbody>
</table>
### References

4. UpToDate, Waltham, MA. (Accessed on January 19, 2016.)