Infugem (gemcitabine)
(Intravenous)

Last Review Date: January 1, 2020  Number: MG.MM.PH.202

Medical Guideline Disclaimer

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Definition

Gemcitabine kills cells undergoing DNA synthesis and blocks the progression of cells through the G1/S-phase boundary. Gemcitabine is metabolized by nucleoside kinases to diphosphate (dFdCDP) and triphosphate (dFdCTP) nucleosides. Gemcitabine diphosphate inhibits ribonucleotide reductase, an enzyme responsible for catalyzing the reactions that generate deoxynucleoside triphosphates for DNA synthesis, resulting in reductions in deoxynucleotide concentrations, including dCTP. Gemcitabine triphosphate competes with dCTP for incorporation into DNA. The reduction in the intracellular concentration of dCTP by the action of the diphosphate enhances the incorporation of gemcitabine triphosphate into DNA (self-potentiation). After the gemcitabine nucleotide is incorporated into DNA, only one additional nucleotide is added to the growing DNA strands, which eventually results in the initiation of apoptotic cell death. Gemcitabine is only indicated for patients 18 years of age and older.

Length of Authorization

Coverage will be provided for 12 months and may be renewed.

Dosing Limits

Max Units (per dose and over time) [Medical Benefit]:
- 13 units every 7 days

I. Initial Approval Criteria

Gemcitabine may be considered medically necessary if one of the below conditions are met AND use is consistent with the medical necessity criteria that follows:
Ovarian Cancer  
- When used in combination with carboplatin, for the treatment of advanced disease that has relapsed at least six months after completion of platinum-based therapy

Metastatic Breast Cancer  
- When used in combination with paclitaxel, for first-line treatment of metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated

Non-Small Cell Lung Cancer  
- When used in combination with cisplatin

Pancreatic Cancer  
- When used as a single agent

Limitations/Exclusions  
Gemcitabine is not considered medically necessary for when any of the following selection criteria is met:

1) 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 criteria identified above; AND
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe myelosuppression, pulmonary toxicity/respiratory failure, hemolytic-uremic syndrome (HUS), hepatotoxicity, exacerbation of radiation therapy toxicity, capillary leak syndrome, posterior reversible encephalopathy syndrome (PRES), etc.

Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<tbody>
<tr>
<td>Ovarian Cancer</td>
<td>1000mg/m² on Days 1 and 8 of each 21-day cycle</td>
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<tr>
<td>Breast Cancer</td>
<td>1250mg/m² on Days 1 and 8 of each 21-day cycle</td>
</tr>
<tr>
<td>Non-Small Cell Lung Cancer</td>
<td>1000mg/m² on Days 1, 8, 15 of each 28-day cycle or 1250mg/m² on Days 1 and 8 of each 21-day cycle</td>
</tr>
<tr>
<td>Pancreatic Cancer</td>
<td>1000mg/m² over 30 minutes once weekly for the first 7 weeks, then one-week rest, then once weekly for 3 weeks of each 28-day cycle</td>
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Revision History  
01/01/2020           New Medical Policy (approved in Medical Policy Subcommittee on 02/06/2020)

Applicable Procedure Codes

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<th>Procedure Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J9199</td>
<td>Injection, gemcitabine hydrochloride (Infugem), 200mg: 1 billable unit = 200mg</td>
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<tr>
<td>J9201</td>
<td>Injection, gemcitabine hydrochloride, not otherwise specified, 200mg: 1 billable unit = 200mg</td>
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Applicable NDCs

Generic available from various manufacturers

Applicable Diagnosis Codes

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<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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References