Infugem (gemcitabine) (Intravenous)

Last Review Date: June 11, 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>
</tr>
</thead>
<tbody>
<tr>
<td>Ovarian Cancer</td>
<td>1000mg/m² on Days 1 and 8 of each 21-day cycle</td>
</tr>
<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>
</tr>
</tbody>
</table>

Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J9199</td>
<td>Injection, gemcitabine hydrochloride (Infugem), 200mg: 1 billable unit = 200mg (Deactivation Date: 06/30/2020)</td>
</tr>
<tr>
<td>J9198</td>
<td>Injection, gemcitabine hydrochloride (Infugem), 100mg: 1 billable unit = 100mg (Effective Date: 07/01/2020)</td>
</tr>
</tbody>
</table>
Applicable NDC

<table>
<thead>
<tr>
<th>Infugem 10 mg/mL concentration in 0.9% sodium chloride injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>- 1200 mg in 120 mL: 62756-0073-xx</td>
</tr>
<tr>
<td>- 1300 mg in 130 mL: 62756-0008-xx</td>
</tr>
<tr>
<td>- 1400 mg in 140 mL: 62756-0102-xx</td>
</tr>
<tr>
<td>- 1500 mg in 150 mL: 62756-0219-xx</td>
</tr>
<tr>
<td>- 1600 mg in 160 mL: 62756-0321-xx</td>
</tr>
<tr>
<td>- 1700 mg in 170 mL: 62756-0438-xx</td>
</tr>
<tr>
<td>- 1800 mg in 180 mL: 62756-0533-xx</td>
</tr>
<tr>
<td>- 1900 mg in 190 mL: 62756-0614-xx</td>
</tr>
<tr>
<td>- 2000 mg in 200 mL: 62756-0746-xx</td>
</tr>
<tr>
<td>- 2200 mg in 220 mL: 62756-0974-xx</td>
</tr>
</tbody>
</table>

Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10 Code and Description</th>
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</thead>
<tbody>
<tr>
<td><strong>Malignant neoplasm of head of pancreas</strong></td>
</tr>
<tr>
<td>C25.1 Malignant neoplasm of body of the pancreas</td>
</tr>
<tr>
<td>C25.2 Malignant neoplasm of tail of pancreas</td>
</tr>
<tr>
<td>C25.3 Malignant neoplasm of pancreatic duct</td>
</tr>
<tr>
<td>C25.7 Malignant neoplasm of other parts of pancreas</td>
</tr>
<tr>
<td>C25.8 Malignant neoplasm of overlapping sites of pancreas</td>
</tr>
<tr>
<td>C25.9 Malignant neoplasm of pancreas, unspecified</td>
</tr>
<tr>
<td>C33 Malignant neoplasm of trachea</td>
</tr>
<tr>
<td>C34.00 Malignant neoplasm of unspecified main bronchus</td>
</tr>
<tr>
<td>C34.01 Malignant neoplasm of right main bronchus</td>
</tr>
<tr>
<td>C34.02 Malignant neoplasm of left main bronchus</td>
</tr>
<tr>
<td>C34.10 Malignant neoplasm of upper lobe, unspecified bronchus or lung</td>
</tr>
<tr>
<td>C34.11 Malignant neoplasm of upper lobe, right bronchus or lung</td>
</tr>
<tr>
<td>C34.12 Malignant neoplasm of upper lobe, left bronchus or lung</td>
</tr>
<tr>
<td>C34.2 Malignant neoplasm of middle lobe, bronchus or lung</td>
</tr>
<tr>
<td>C34.30 Malignant neoplasm of lower lobe, unspecified bronchus or lung</td>
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<tr>
<td>C34.31 Malignant neoplasm of lower lobe, right bronchus or lung</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Malignant neoplasm of lower lobe, left bronchus or lung</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>C34.80 Malignant neoplasm of overlapping sites of unspecified bronchus or lung</td>
</tr>
<tr>
<td>C34.81 Malignant neoplasm of overlapping sites of right bronchus and lung</td>
</tr>
<tr>
<td>C34.82 Malignant neoplasm of overlapping sites of left bronchus and lung</td>
</tr>
<tr>
<td>C34.90 Malignant neoplasm of unspecified part of unspecified bronchus or lung</td>
</tr>
<tr>
<td>C34.91 Malignant neoplasm of unspecified part of right bronchus or lung</td>
</tr>
<tr>
<td>C34.92 Malignant neoplasm of unspecified part of left bronchus or lung</td>
</tr>
<tr>
<td>C48.1 Malignant neoplasm of specified parts of peritoneum</td>
</tr>
<tr>
<td>C48.2 Malignant neoplasm of peritoneum, unspecified</td>
</tr>
<tr>
<td>C48.8 Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum</td>
</tr>
<tr>
<td>C50.011 Malignant neoplasm of nipple and areola, right female breast</td>
</tr>
<tr>
<td>C50.012 Malignant neoplasm of nipple and areola, left female breast</td>
</tr>
<tr>
<td>C50.019 Malignant neoplasm of nipple and areola, unspecified female breast</td>
</tr>
<tr>
<td>C50.021 Malignant neoplasm of nipple and areola, right male breast</td>
</tr>
<tr>
<td>C50.022 Malignant neoplasm of nipple and areola, left male breast</td>
</tr>
<tr>
<td>C50.029 Malignant neoplasm of nipple and areola, unspecified male breast</td>
</tr>
</tbody>
</table>
C50.111 Malignant neoplasm of central portion of right female breast
C50.112 Malignant neoplasm of central portion of left female breast
C50.119 Malignant neoplasm of central portion of unspecified female breast
C50.121 Malignant neoplasm of central portion of right male breast
C50.122 Malignant neoplasm of central portion of left male breast
C50.129 Malignant neoplasm of central portion of unspecified male breast
C50.211 Malignant neoplasm of upper-inner quadrant of right female breast
C50.212 Malignant neoplasm of upper-inner quadrant of left female breast
C50.219 Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221 Malignant neoplasm of upper-inner quadrant of right male breast
C50.222 Malignant neoplasm of upper-inner quadrant of left male breast
C50.229 Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311 Malignant neoplasm of lower-inner quadrant of right female breast
C50.312 Malignant neoplasm of lower-inner quadrant of left female breast
C50.319 Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321 Malignant neoplasm of lower-inner quadrant of right male breast
C50.322 Malignant neoplasm of lower-inner quadrant of left male breast
C50.329 Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411 Malignant neoplasm of upper-outer quadrant of right female breast
C50.412 Malignant neoplasm of upper-outer quadrant of left female breast
C50.421 Malignant neoplasm of upper-outer quadrant of right male breast
C50.422 Malignant neoplasm of upper-outer quadrant of left male breast
C50.429 Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511 Malignant neoplasm of lower-outer quadrant of right female breast
C50.512 Malignant neoplasm of lower-outer quadrant of left female breast
C50.519 Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521 Malignant neoplasm of lower-outer quadrant of right male breast
C50.522 Malignant neoplasm of lower-outer quadrant of left male breast
C50.529 Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611 Malignant neoplasm of axillary tail of right female breast
C50.612 Malignant neoplasm of axillary tail of left female breast
C50.619 Malignant neoplasm of axillary tail of unspecified female breast
C50.621 Malignant neoplasm of axillary tail of right male breast
C50.622 Malignant neoplasm of axillary tail of left male breast
C50.629 Malignant neoplasm of axillary tail of unspecified male breast
C50.811 Malignant neoplasm of overlapping sites of right female breast
C50.812 Malignant neoplasm of overlapping sites of left female breast
C50.819 Malignant neoplasm of overlapping sites of unspecified female breast
C50.821 Malignant neoplasm of overlapping sites of right male breast
C50.822 Malignant neoplasm of overlapping sites of left male breast
C50.829 Malignant neoplasm of overlapping sites of unspecified male breast
C50.911 Malignant neoplasm of unspecified site of right female breast
C50.912 Malignant neoplasm of unspecified site of left female breast
C50.919 Malignant neoplasm of unspecified site of unspecified female breast
C50.921 Malignant neoplasm of unspecified site of right male breast
C50.922 Malignant neoplasm of unspecified site of left male breast
C50.929 Malignant neoplasm of unspecified site of unspecified male breast
C56.1 Malignant neoplasm of right ovary
C56.2 Malignant neoplasm of left ovary
C56.9 Malignant neoplasm of unspecified ovary
C57.00 Malignant neoplasm of unspecified fallopian tube
C57.01 Malignant neoplasm of right fallopian tube

Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421 Malignant neoplasm of upper-outer quadrant of right male breast
C50.422 Malignant neoplasm of upper-outer quadrant of left male breast
C50.429 Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511 Malignant neoplasm of lower-outer quadrant of right female breast
C50.512 Malignant neoplasm of lower-outer quadrant of left female breast
C50.519 Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521 Malignant neoplasm of lower-outer quadrant of right male breast
C50.522 Malignant neoplasm of lower-outer quadrant of left male breast
C50.529 Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611 Malignant neoplasm of axillary tail of right female breast
C50.612 Malignant neoplasm of axillary tail of left female breast
C50.619 Malignant neoplasm of axillary tail of unspecified female breast
C50.621 Malignant neoplasm of axillary tail of right male breast
C50.622 Malignant neoplasm of axillary tail of left male breast
C50.629 Malignant neoplasm of axillary tail of unspecified male breast
C50.811 Malignant neoplasm of overlapping sites of right female breast
C50.812 Malignant neoplasm of overlapping sites of left female breast
C50.819 Malignant neoplasm of overlapping sites of unspecified female breast
C50.821 Malignant neoplasm of overlapping sites of right male breast
C50.822 Malignant neoplasm of overlapping sites of left male breast
C50.829 Malignant neoplasm of overlapping sites of unspecified male breast
C50.911 Malignant neoplasm of unspecified site of right female breast
C50.912 Malignant neoplasm of unspecified site of left female breast
C50.919 Malignant neoplasm of unspecified site of unspecified female breast
C50.921 Malignant neoplasm of unspecified site of right male breast
C50.922 Malignant neoplasm of unspecified site of left male breast
C50.929 Malignant neoplasm of unspecified site of unspecified male breast
C56.1 Malignant neoplasm of right ovary
C56.2 Malignant neoplasm of left ovary
C56.9 Malignant neoplasm of unspecified ovary
C57.00 Malignant neoplasm of unspecified fallopian tube
C57.01 Malignant neoplasm of right fallopian tube
C57.02 Malignant neoplasm of left fallopian tube
C57.10 Malignant neoplasm of unspecified broad ligament
C57.11 Malignant neoplasm of right broad ligament
C57.12 Malignant neoplasm of left broad ligament
C57.20 Malignant neoplasm of unspecified round ligament
C57.21 Malignant neoplasm of right round ligament
C57.22 Malignant neoplasm of left round ligament
C57.3 Malignant neoplasm of parametrium
C57.4 Malignant neoplasm of uterine adnexa, unspecified
C57.7 Malignant neoplasm of other specified female genital organs
C57.8 Malignant neoplasm of overlapping sites of female genital organs
C57.9 Malignant neoplasm of female genital organ, unspecified
Z85.07 Personal history of malignant neoplasm of pancreas
Z85.118 Personal history of other malignant neoplasm of bronchus and lung
Z85.3 Personal history of malignant neoplasm of breast
Z85.43 Personal history of malignant neoplasm of ovary

Revision History

06/11/2020 Update for J-Code (J9199): Injection, gemcitabine hydrochloride (Infugem), 200mg: 1 billable unit = 200mg  (Deactivation Date: 06/30/2020)

Addition of J-Code (J9198): Injection, gemcitabine hydrochloride (Infugem), 100mg: 1 billable unit = 100mg  (Effective Date: 07/01/2020)

01/01/2020 New Medical Policy

References