

PA Criteria	Criteria Details						
<b>Covered Uses (FDA approved indication)</b>	<p>Infugem is a nucleoside metabolic inhibitor indicated for multiple cancers including:</p> <ol style="list-style-type: none"> <li>in combination with carboplatin, for the treatment of advanced ovarian cancer that has relapsed at least 6 months after completion of platinum- based therapy,</li> <li>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,</li> <li>in combination with cisplatin for the treatment of non-small cell lung cancer, and</li> <li>as a single agent for the treatment of pancreatic cancer.</li> </ol>						
<b>Exclusion Criteria</b>	None.						
<b>Required Medical Information</b>	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.						
<b>Other Criteria</b>	<p>Must follow LCD (L37205) for Chemotherapy Drugs and their Adjuncts.  <a href="https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdld=37205&amp;ver=15">https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdld=37205&amp;ver=15</a></p>						
<b>Age Restriction</b>	None.						
<b>Prescriber Restrictions</b>	None.						
<b>Coverage Duration</b>	Up to one year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.						
<b>Other Criteria/Information</b>	<p>Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.</p> <table border="1"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>J9198</td> <td>Infugem (gemcitabine HCl)</td> <td> <p><b>Billing unit: 100 mg</b></p> <p>1200 mg/120 mL, 1300 mg/130 mL, 1400 mg/140 mL, 1500 mg/150 mL, 1600 mg/160 mL, 1700 mg/170 mL, 1800 mg/180 mL, 1900 mg/190 mL, 2000 mg/200 mL, 2200 mg/220 mL single dose infusion bag</p> </td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	J9198	Infugem (gemcitabine HCl)	<p><b>Billing unit: 100 mg</b></p> <p>1200 mg/120 mL, 1300 mg/130 mL, 1400 mg/140 mL, 1500 mg/150 mL, 1600 mg/160 mL, 1700 mg/170 mL, 1800 mg/180 mL, 1900 mg/190 mL, 2000 mg/200 mL, 2200 mg/220 mL single dose infusion bag</p>
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STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	5/15/2025	Pharmacy & Therapeutics (P&T) Committee	5/15/2025