

Infugem™ (gemcitabine) (Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 6 months.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 25 billable units every 7 days

III. Initial Approval Criteria ¹

Prior authorization validity is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria

- Gemcitabine is not obtainable (in any dosage strength) as confirmed by the FDA Drug shortage website located at: <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>; **AND**

Breast Cancer † ^{1,3,5}

- Patient has metastatic disease; **AND**
- Used in combination with paclitaxel as first-line treatment; **AND**
- Patient has previous failure on an anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated

Non-Small Cell Lung Cancer (NSCLC) † ^{1,3,6,7}

- Patient has inoperable, locally advanced (Stage IIIA or IIIB), or metastatic (Stage IV) disease; **AND**
- Used in combination with cisplatin as first-line treatment

Ovarian Cancer † Φ^{1,3,4}

- Patient has advanced disease that has relapsed at least 6 months after completion of a platinum-based regimen; **AND**
- Used in combination with carboplatin in patients who are platinum-sensitive

Pancreatic Adenocarcinoma † Φ^{1,3,8}

- Patient has locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) disease; **AND**
- Used as first-line treatment; **AND**
- Patient has received previous treatment with fluorouracil

Infugem is a ready-to-use formulation of gemcitabine approved via 505(b)(2) NDA referencing the lyophilized formulation (Gemzar). This product is nearly identical to the listed product, Gemzar, when the listed product is reconstituted and diluted for administration. No new clinical or nonclinical data were provided with this submission, as no studies were conducted for this 505(b)(2) application.²

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication; Φ Orphan Drug

IV. Renewal Criteria^{1,4-8}

Prior authorization validity may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **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, severe cutaneous adverse reactions (e.g., Stevens-Johnson syndrome [SJS], toxic epidermal necrolysis [TEN], drug reaction with eosinophilia and systemic symptoms [DRESS], and acute generalized exanthematous pustulosis [AGEP], etc.), pulmonary toxicity/respiratory failure (e.g., interstitial pneumonitis, pulmonary fibrosis, pulmonary edema, and adult respiratory distress syndrome [ARDS], etc.), hemolytic-uremic syndrome (HUS), hepatotoxicity, exacerbation of radiation therapy toxicity, capillary leak syndrome (CLS), posterior reversible encephalopathy syndrome (PRES), etc.

V. Dosage/Administration ¹

Indication	Dose
Breast Cancer	1250 mg/m ² on days 1 and 8 of every 21 day cycle
Ovarian Cancer	1000 mg/m ² on days 1 and 8 of every 21 day cycle
NSCLC	1000 mg/m ² on days 1, 8 and 15 of every 28 day cycle OR 1250 mg/m ² on days 1 and 8 of every 21 day cycle
Pancreatic Cancer	1000 mg/m ² weekly for weeks 1-7, followed by one week of rest then, 1000 mg/m ² on days 1, 8 and 15 of every 28 day cycle

VI. Billing Code/Availability Information

HCPCS Code

- J9198 – Injection, gemcitabine hydrochloride, (infugem), 100 mg; 1 billable unit = 100 mg

NDC

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

VII. References (STANDARD)

1. Infugem [package insert]. Gujarat, India; Sun Pharmaceuticals; September 2024. Accessed September 2025.
2. Center for Drug Evaluation and Research. APPLICATION NUMBER: 208313Orig1s000. Summary Review. U. S. Food and Drug Administration. Washington, DC.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for gemcitabine. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National

Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2023.

4. Pfisterer J, Plante M, Vergote I, et al. Gemcitabine Plus Carboplatin Compared With Carboplatin in Patients With Platinum-Sensitive Recurrent Ovarian Cancer: An Intergroup Trial of the AGO-OVAR, the NCIC CTG, and the EORTC GCG. *J Clin Oncol*, 24 (29), 4699-707; 2006 Oct 10. PMID: 16966687. DOI: 10.1200/JCO.2006.06.0913
5. Albain KS, Nag SM, Calderillo-Ruiz G, et al. Gemcitabine plus Paclitaxel versus Paclitaxel monotherapy in patients with metastatic breast cancer and prior anthracycline treatment. *J Clin Oncol*. 2008;26(24):3950-3957. doi:10.1200/JCO.2007.11.9362.
6. Sandler AB, Nemunaitis J, Denham C, et al. Phase III trial of gemcitabine plus cisplatin versus cisplatin alone in patients with locally advanced or metastatic non-small-cell lung cancer. *J Clin Oncol*. 2000;18(1):122-130. doi:10.1200/JCO.2000.18.1.122
7. Cardenal F, Lopez-Cabrerizo MP, Anton A, et al. Randomized Phase III Study of Gemcitabine-Cisplatin Versus Etoposide-Cisplatin in the Treatment of Locally Advanced or Metastatic Non-Small-Cell Lung Cancer. *J Clin Oncol*, 17 (1), 12-12; Jan 1999. PMID: 10458212. DOI: 10.1200/JCO.1999.17.1.12
8. Burris HA 3rd, Moore MJ, Andersen J, et al. Improvements in survival and clinical benefit with gemcitabine as first-line therapy for patients with advanced pancreas cancer: a randomized trial. *J Clin Oncol*. 1997;15(6):2403-2413. doi:10.1200/JCO.1997.15.6.2403.

VIII. References (ENHANCED)

- 1e. Prime Therapeutics Management. Infugem Clinical Literature Review Analysis. Last updated September 2025. Accessed September 2025.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of the pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast

ICD-10	ICD-10 Description
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
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
C50.419	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

ICD-10	ICD-10 Description
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
C56.3	Malignant neoplasm of parametrium
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

ICD-10	ICD-10 Description
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
Z85.43	Personal history of malignant neoplasm of ovary

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC