

Infugem™ (gemcitabine) (Intravenous)

Document Number: IC-0423

Last Review Date: 05/02/2022

Date of Origin: 09/01/2010

Dates Reviewed: 12/2010, 03/2011, 06/2011, 09/2011, 12/2011, 03/2012, 06/2012, 09/2012, 12/2012, 03/2013, 06/2013, 09/2013, 12/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 05/2015, 11/2015, 02/2016, 05/2016, 08/2016, 11/2016, 02/2017, 05/2017, 04/2018, 01/2019, 05/2019, 12/2019, 05/2020, 05/2021, 05/2022

I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Infugem single-dose premixed infusion bags (available in 1200 mg, 1300 mg, 1400 mg, 1500 mg, 1600 mg, 1700 mg, 1800 mg, 1900 mg, 2000mg, and 2200mg): 4 bags every 21 days

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

- 25 billable units every 7 days

III. Initial Approval Criteria

Coverage 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 unresectable, 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

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

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

Coverage can be renewed based upon the following criteria:

- Patient continues to meet 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, 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/Administration¹

| 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

1. Infugem [package insert]. Gujarat, India; Sun Pharmaceuticals; January 2020. Accessed March 2022.
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, 2022. 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 March 2022.
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*, 26 (24), 3950-7; 2008 Aug 20. PMID: 18711184. DOI: 10.1200/JCO.2007.11.9362

6. Sandler AB, Nemunaitis J, von Pawel J, 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*, 18 (1), 122-30; Jan 2000. PMID: 10623702. DOI: 10.1200/JCO.2000.18.1.122
7. Cardenal F, Lopez-Cabrero 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 3rd HA, 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*, 15 (6), 2403-13; Jun 1997. PMID: 9196156. DOI: 10.1200/JCO.1997.15.6.2403

Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|--------|---|
| C24.1 | Malignant neoplasm of ampulla of Vater |
| 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 |

| ICD-10 | ICD-10 Description |
|---------|---|
| 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 |
| 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 |

| ICD-10 | ICD-10 Description |
|---------|---|
| 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 |
| C56.3 | 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 |

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

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

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered 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, LLC |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA, LLC |
| 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 |