Gemcitabine in Sodium Chloride Injection (Infugem®)

NDC CODE(S)

62756-0073-XX INFUGEM 1200MG/120ML Solution (SUN PHARMACEUTICALS)
62756-0008-XX INFUGEM 1300MG/130ML Solution (SUN PHARMACEUTICALS)
62756-0102-XX INFUGEM 1400MG/140ML Solution (SUN PHARMACEUTICALS)
62756-0219-XX INFUGEM 1500MG/150ML Solution (SUN PHARMACEUTICALS)
62756-0321-XX INFUGEM 1600MG/160ML Solution (SUN PHARMACEUTICALS)
62756-0438-XX INFUGEM 1700MG/170ML Solution (SUN PHARMACEUTICALS)
62756-0533-XX INFUGEM 1800MG/180ML Solution (SUN PHARMACEUTICALS)
62756-0614-XX INFUGEM 1900MG/190ML Solution (SUN PHARMACEUTICALS)
62756-0746-XX INFUGEM 2000MG/200ML Solution (SUN PHARMACEUTICALS)
62756-0974-XX INFUGEM 2200MG/220ML Solution (SUN PHARMACEUTICALS)

DESCRIPTION

Gemcitabine, synthetic pyrimidine nucleoside, is a nucleoside metabolic inhibitor or antimetabolite antineoplastic agent. It kills cells undergoing DNA synthesis and blocks cell progression through the G1/S-phase boundary.

Gemcitabine in sodium chloride injection is a single-dose, premixed intravenous infusion bag (10 mg/mL) for intravenous use and does not require any further preparation. Each 100 mL contains 1000 mg of gemcitabine (equivalent to 1138 mg of gemcitabine hydrochloride, USP), 900 mg of sodium chloride, and water for injection. Hydrochloric acid and/or sodium hydroxide may have been added for pH adjustment.

POLICY

- Gemcitabine in Sodium Chloride Injection for the treatment of the following is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
  - Breast Cancer
  - Non-Small Cell Lung Cancer
  - Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer
  - Pancreatic Adenocarcinoma

- Gemcitabine in Sodium Chloride Injection for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

- 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

- 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)

- 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

- 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

- 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.

RENEWAL 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 the Initial Approval Criteria; **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.

DOSAGE/ADMINISTRATION

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/m2 weekly for weeks 1-7, followed by one week of rest then, 1000 mg/m2 on days 1, 8, and 15 of every 28 day cycle

LENGTH OF AUTHORIZATION

Coverage will be provided for six months and may be renewed

DOSING LIMITS

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

- 25 billable units every 7 days

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

1. Infugem [package insert]. Gujarat, India; Sun Pharmaceuticals; January 2020. Accessed April 2021.
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, 2021. 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 2021.
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-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 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
9. Lexicomp Online. (2020, March). AHFS DI. *Gemcitabine.* Retrieved May 14, 2020 from Lexicomp Online with AHFS.
10. MICROMEDEX Healthcare Series. Drugdex Evaluations. (2020, March). *Gemcitabine*. Retrieved May 14, 2020 from MICROMEDEX Healthcare Series.

EFFECTIVE DATE 8/31/2021

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