Gemcitabine in Sodium Chloride Injection

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.)**
  - AIDS-Related Kaposi Sarcoma
  - B-Cell Lymphomas
  - Bladder Cancer
  - Bone Cancer
  - Breast Cancer
  - Gestational Trophoblastic Neoplasia
  - Head and Neck Cancers
  - Hepatobiliary Cancers
  - Kidney Cancer
  - Malignant Pleural Mesothelioma
  - Non-Small Cell Lung Cancer
  - Occult Primary
  - Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer
  - Pancreatic Adenocarcinoma
  - Primary Cutaneous Lymphomas
  - Small Bowel Adenocarcinoma
  - Small Cell Lung Cancer
  - Soft Tissue Sarcoma
  - T-Cell Lymphomas
  - Testicular Cancer
  - Thymomas and Thymic Carcinomas
  - Uterine Sarcoma
  - Vulvar Cancer if Squamous Cell Carcinoma

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

MEDICAL APPROPRIATENESS

INITIAL APPROVAL

- Gemcitabine in Sodium Chloride Injection is considered **medically appropriate** if **ALL** of the following criteria are met:
  - **BCBST requirement**: Prior trial and failure of gemcitabine **UNLESS** gemcitabine is **NOT** obtainable in any dosage strength as confirmed by the FDA Drug Shortage website http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
  - Diagnosis of **ANY ONE** of the following:
    - AIDS-Related Kaposi Sarcoma
    - B-Cell Lymphomas if **ANY ONE** of the following:
      - Follicular Lymphoma (grade 1-2)
      - Histologic Transformation of Marginal Zone Lymphoma to Diffuse Large B-Cell Lymphoma
      - Mantle Cell Lymphoma
      - Diffuse Large B-Cell Lymphoma
      - High-Grade B-Cell Lymphomas
      - Burkitt Lymphoma
      - AIDS-Related B-Cell Lymphomas
      - Post-Transplant Lymphoproliferative Disorders
    - Bladder Cancer if **ANY ONE** of the following:
      - Bladder Cancer
      - Non-Urothelial and Urothelial with Variant Histology
      - Upper GU Tract Tumors
      - Urothelial Carcinoma of the Prostate
      - Primary Carcinoma of the Urethra
    - Bone Cancer if **ANY ONE** of the following:
      - Ewing Sarcoma
      - Osteosarcoma
    - Breast Cancer if Invasive Breast Cancer
    - Gestational Trophoblastic Neoplasia
    - Head and Neck Cancers if **ANY ONE** of the following:
      - Cancer of the Nasopharynx
      - Very Advanced Head and Neck Cancer
    - Hepatobiliary Cancers if **ANY ONE** of the following:
      - Gallbladder Cancer
      - Intrahepatic Cholangiocarcinoma
      - Extrahepatic Cholangiocarcinoma
    - Hodgkin Lymphoma if **ANY ONE** of the following:
      - Classic Hodgkin Lymphoma
      - Nodular Lymphocyte-Predominant Hodgkin Lymphoma
    - Kidney Cancer
    - Malignant Pleural Mesothelioma
    - Non-Small Cell Lung Cancer
    - Occult Primary
    - Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer if **ANY ONE** of the following:
      - Epithelial Ovarian Cancer /Fallopian Tube Cancer/Primary Peritoneal Cancer

    - Malignant Germ Cell Tumors
  - Pancreatic Adenocarcinoma
  - Primary Cutaneous Lymphomas if **ANY ONE** of the following:
    - Mycosis Fungoides/Sézary Syndrome
    - Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders
  - Small Bowel Adenocarcinoma
  - Small Cell Lung Cancer
  - Soft Tissue Sarcoma if **ANY ONE** of the following:
    - Extremity/Body Wall ~~Superficial Trunk~~, Head/Neck
    - Retroperitoneal/Intra-Abdominal
    - Angiosarcoma
    - Rhabdomyosarcoma
    - Solitary Fibrous Tumor
    - Undifferentiated Pleomorphic Sarcoma
  - T-Cell Lymphomas if **ANY ONE** of the following:
    - Peripheral T-Cell Lymphomas
    - Adult T-Cell Leukemia/Lymphoma
    - Extranodal NK/T-Cell Lymphoma, nasal type
    - Hepatosplenic Gamma-Delta T-Cell Lymphoma
  - Testicular Cancer
  - Thymomas and Thymic Carcinomas
  - Uterine Sarcoma
  - Vulvar Cancer if Squamous Cell Carcinoma

RENEWAL CRITERIA

- Gemcitabine in Sodium Chloride Injection is considered **medically appropriate** for renewal if **ALL** of the following criteria are met:
  - Individual continues to meet initial approval criteria, not including prerequisite therapy
  - Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread
  - Absence of unacceptable toxicity from the drug including 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.

INDICATION(S)	DOSAGE & ADMINISTRATION
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

LENGTH OF AUTHORIZATION

Coverage will be provided for six months and may be renewed

Refer to **DOSAGE LIMITS** below

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

Lexicomp Online. (2020, March). AHFS DI. *Gemcitabine.* Retrieved May 14, 2020 from Lexicomp Online with AHFS.

MICROMEDEX Healthcare Series. Drugdex Evaluations. (2020, March). *Gemcitabine*. Retrieved May 14, 2020 from MICROMEDEX Healthcare Series.

National Comprehensive Cancer Network. (2020). NCCN Drugs & Biologics Compendium®. *Gemcitabine.* Retrieved May 27, 2020 from the National Comprehensive Cancer Network.

U. S. Food and Drug Administration. (2020, January). Center for Drug Evaluation and Research. *INFUGEM (gemcitabine in sodium chloride injection), for intravenous use.* Retrieved May 14, 2020 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/208313s002lbl.pdf.

EFFECTIVE DATE 4/2/21

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