Medical Policy:

Gemcitabine (Infugem) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.202	April 4, 2025	January 1, 2020

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Gemcitabine kills cells undergoing DNA synthesis and blocks the progression of cells through the G1/S-phase boundary. Gemcitabine is metabolized by nucleoside kinases to diphosphate (dFdCDP) and triphosphate (dFdCTP) nucleosides. Gemcitabine diphosphate inhibits ribonucleotide reductase, an enzyme responsible for catalyzing the reactions that generate deoxynucleoside triphosphates for DNA synthesis, resulting in reductions in deoxynucleotide concentrations, including dCTP. Gemcitabine triphosphate competes with dCTP for incorporation into DNA. The reduction in the intracellular concentration of dCTP by the action of the diphosphate enhances the incorporation of gemcitabine triphosphate into DNA (self-potentiation). After the gemcitabine nucleotide is incorporated into DNA, only one additional nucleotide is added to the growing DNA strands, which eventually results in the initiation of apoptotic cell death. Gemcitabine is only indicated for patients 18 years of age and older.

Length of Authorization

Coverage will be provided for 12 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

25 billable units every 7 days

Guideline

I. Initial Approval Criteria

Gemcitabine *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

1. Ovarian Cancer

A. When used in combination with carboplatin, for the treatment of advanced disease that has relapsed at least six months after completion of platinum-based therapy

2. Metastatic Breast Cancer

A. When used 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

3. Non-Small Cell Lung Cancer

A. When used in combination with cisplatin; **AND**

B. Patient has inoperable, locally advanced (Stage IIIA or IIIB) or metastatic (Stage IV) non-small cell lung cancer (NSCLC).

4. Pancreatic Cancer

A. Patient has locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) disease; **AND**

B. Used as first-line treatment; **AND**

C. Patient has received previous treatment with fluorouracil

Limitations/Exclusions

Gemcitabine is not considered medically necessary for when any of the following selection criteria is met:

1. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. Renewal Criteria

1. Patient continues to meet criteria identified above; **AND**
2. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe myelosuppression, pulmonary toxicity/respiratory failure, hemolytic-uremic syndrome (HUS), hepatotoxicity, exacerbation of radiation therapy toxicity, capillary leak syndrome, posterior reversible encephalopathy syndrome (PRES), etc.

Dosage/Administration

Indication	Dose
Ovarian Cancer	1000mg/m² on Days 1 and 8 of each 21-day cycle
Breast Cancer	1250mg/m² on Days 1 and 8 of each 21-day cycle
Non-Small Cell Lung Cancer	1000mg/m² on Days 1, 8, 15 of each 28-day cycle or 1250mg/m² on Days 1 and 8 of each 21-day cycle
Pancreatic Cancer	1000mg/m² over 30 minutes once weekly for the first 7 weeks, then one-week rest, then 1000 mg/m2 on days 1, 8, and 15 of every 28 day cycle

Applicable Procedure Codes

Code	Description
J9198	Injection, gemcitabine hydrochloride (Infugem), 100mg: 1 billable unit = 100mg
J9196	Injection, gemcitabine hydrochloride (accord), not therapeutically equivalent to j9201, 200 mg

Applicable NDCs

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

ICD-10 Diagnoses

Code	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
C43.52	Malignant melanoma of skin of breast
C44.501	Unspecified malignant neoplasm of skin of breast
C44.511	Basal cell carcinoma of skin of breast
C44.521	Squamous cell carcinoma of skin of breast
C44.591	Other specified malignant neoplasm of skin of breast
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
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
C56.9	Malignant neoplasm of unspecified ovary
C78.89	Secondary malignant neoplasm of other digestive organs
C79.60	Secondary malignant neoplasm of unspecified ovary
C79.61	Secondary malignant neoplasm of right ovary
C79.62	Secondary malignant neoplasm of left ovary
C79.63	Secondary malignant neoplasm of bilateral ovaries
D39.10	Neoplasm of uncertain behavior of unspecified ovary
D39.11	Neoplasm of uncertain behavior of right ovary
D39.12	Neoplasm of uncertain behavior of left ovary

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	04/04/2025	Annual Review: No criteria changes. Updated ICD-10 codes.
EmblemHealth & ConnectiCare	2/27/2024	Annual Review: changed name of Title of policy from INFUGEM™ (gemcitabine) Intravenous to Gemcitabine Intravenous, due to discontinuation of brand name product. Updated dosing limits and dosage. Initial Criteria: NSCLC; added "Patient has inoperable, locally advanced (Stage IIIA or IIIB) or metastatic (Stage IV) non-small cell lung cancer (NSCLC)."
EmblemHealth & ConnectiCare	06/28/2023	Annual Review: Pancreatic Cancer: Initial Criteria: Removed: "When used as a single agent " Added: 1. "Patient has locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) disease; **AND** 2. Used as first-line treatment; **AND** 3. Patient has received previous treatment with fluorouracil"
EmblemHealth & ConnectiCare	05/30/2023	Added JCODE J9196 - Injection, gemcitabine hydrochloride (accord), not therapeutically equivalent to j9201, 200 mg

EmblemHealth & ConnectiCare	07/22/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	06/11/2020	Update for J-Code (J9199): Injection, gemcitabine hydrochloride (Infugem), 200mg: 1 billable unit = 200mg (Deactivation Date: 06/30/2020) Addition of J-Code (J9198): Injection, gemcitabine hydrochloride (Infugem), 100mg: 1 billable unit = 100mg (Effective Date: 07/01/2020)
EmblemHealth & ConnectiCare	01/01/2020	New Medical Policy

References

1. Product Information: Gemcitabine HCl intravenous injection, gemcitabine HCl intravenous injection. Apotex Corp (per DailyMed), Weston, FL, 2015.
2. Product Information: INFUGEM intravenous injection, gemcitabine in sodium chloride intravenous injection. Sun Pharmaceutical Industries Inc (per FDA), Cranbury, NJ, 2018.