



Gemcitabine (Gemzar®)
Revision: 2

Policy Number: M-0022
Last Update: 6/4/2014

Payment will not be made for any use of these drugs outside of the criteria without prior authorization. The member may not be billed unless the member explicitly agrees in writing to be responsible for the charges in accordance with the contract/provider manual. Prior authorization will only be given if the provider demonstrates the intended use meets Medicare coverage guidelines.

When appropriate compendia references the use of one of the chemotherapeutic agents listed in this Article as part of a 'combination therapy', the drug is only approved for use in such 'combinations', and the documentation should reflect, and be specific about, the use of the additional 'combination therapy' drugs.

Coverage Guidelines:

FDA:

- Carcinoma of pancreas, As first line therapy in locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) disease, or for patients previously treated with 5-fluorouracil
- Metastatic breast cancer, As first-line therapy for patients previously treated with anthracycline-containing adjuvant chemotherapy or in whom anthracyclines are clinically contraindicated
- Non-small cell lung cancer, As first line therapy in combination with cisplatin for patients with inoperable, locally advanced (Stage IIIA or IIIB) or metastatic (Stage IV) disease
- Ovarian cancer, Advanced, In combination with carboplatin for patients who relapsed at least 6 months after platinum-based therapy

Off Label:

- Breast cancer
- Carcinoma of gallbladder
- Carcinoma of pancreas, Adjuvant



- Cervical cancer, Neoadjuvant
- Germ cell tumor
- Germ cell tumor - Testicular cancer
- Head and neck cancer
- Hodgkin's disease, Relapsed or refractory
- Kaposi's sarcoma, Classic
- Malignant tumor of biliary tract, Locally advanced, unresectable, or metastatic
- Malignant tumor of urinary bladder
- Mantle cell lymphoma, Relapsed or refractory, as combination therapy
- Non-Hodgkin's lymphoma
- Non-small cell lung cancer
- Small cell carcinoma of lung, In combination with other chemotherapeutic agents
- Soft tissue sarcoma, Advanced disease, in combination with other chemotherapeutic agents
- Transitional cell carcinoma of the urinary tract, Advanced/metastatic disease, first-line in combination with cisplatin

Coding Information:

HCPCS Code(s)

J9201	INJECTION, GEMCITABINE HYDROCHLORIDE, 200 MG
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ICD-9 Code(s)

149.0	MALIGNANT NEOPLASM OF PHARYNX UNSPECIFIED
149.1	MALIGNANT NEOPLASM OF WALDEYER'S RING
149.9	MALIGNANT NEOPLASM OF ILL-DEFINED SITES WITHIN THE LIP AND ORAL CAVITY
151.9	MALIGNANT NEOPLASM OF STOMACH UNSPECIFIED SITE
155.1	MALIGNANT NEOPLASM OF INTRAHEPATIC BILE DUCTS
156.0-156.9	MALIGNANT NEOPLASM OF GALLBLADDER - MALIGNANT NEOPLASM OF BILIARY TRACT PART UNSPECIFIED SITE
157.0-157.9	MALIGNANT NEOPLASM OF HEAD OF PANCREAS - MALIGNANT NEOPLASM OF PANCREAS PART UNSPECIFIED
158.0-158.9	MALIGNANT NEOPLASM OF RETROPERITONEUM - MALIGNANT NEOPLASM OF PERITONEUM UNSPECIFIED
162.0-	MALIGNANT NEOPLASM OF TRACHEA - MALIGNANT NEOPLASM OF BRONCHUS AND

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162.9	LUNG UNSPECIFIED
164.0	MALIGNANT NEOPLASM OF THYMUS
164.2	MALIGNANT NEOPLASM OF ANTERIOR MEDIASTINUM
164.3	MALIGNANT NEOPLASM OF POSTERIOR MEDIASTINUM
164.8	MALIGNANT NEOPLASM OF OTHER PARTS OF MEDIASTINUM
164.9	MALIGNANT NEOPLASM OF MEDIASTINUM PART UNSPECIFIED
171.0- 171.9	MALIGNANT NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE OF HEAD FACE AND NECK - MALIGNANT NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE SITE UNSPECIFIED
174.0- 175.9	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF FEMALE BREAST - MALIGNANT NEOPLASM OF OTHER AND UNSPECIFIED SITES OF MALE BREAST
179	MALIGNANT NEOPLASM OF UTERUS-PART UNS
180.0	MALIGNANT NEOPLASM OF ENDOCERVIX
181	MALIGNANT NEOPLASM OF PLACENTA
182.0	MALIGNANT NEOPLASM OF CORPUS UTERI EXCEPT ISTHMUS
182.1	MALIGNANT NEOPLASM OF ISTHMUS
182.8	MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF BODY OF UTERUS
183.0	MALIGNANT NEOPLASM OF OVARY
183.2- 183.5	MALIGNANT NEOPLASM OF FALLOPIAN TUBE - MALIGNANT NEOPLASM OF ROUND LIGAMENT OF UTERUS
183.8	MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF UTERINE ADNEXA
183.9	MALIGNANT NEOPLASM OF UTERINE ADNEXA UNSPECIFIED SITE
186.0- 186.9	MALIGNANT NEOPLASM OF UNDESCENDED TESTIS - MALIGNANT NEOPLASM OF OTHER AND UNSPECIFIED TESTIS
188.0- 188.9	MALIGNANT NEOPLASM OF TRIGONE OF URINARY BLADDER - MALIGNANT NEOPLASM OF BLADDER PART UNSPECIFIED
189.1- 189.2	MALIGNANT NEOPLASM OF RENAL PELVIS - MALIGNANT NEOPLASM OF URETER
189.9	MALIGNANT NEOPLASM OF URINARY ORGAN SITE UNSPECIFIED
194.4	MALIGNANT NEOPLASM OF PINEAL GLAND
196.0- 198.82	SECONDARY AND UNSPECIFIED MALIGNANT NEOPLASM OF LYMPH NODES OF HEAD FACE AND NECK - SECONDARY MALIGNANT NEOPLASM OF GENITAL ORGANS
199.1	OTHER MALIGNANT NEOPLASM OF UNSPECIFIED SITE
200.00- 202.98	RETICULOSARCOMA UNSPECIFIED SITE - OTHER AND UNSPECIFIED MALIGNANT NEOPLASMS OF LYMPHOID AND HISTIOCYTIC TISSUE INVOLVING LYMPH NODES OF

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	MULTIPLE SITES
V10.43	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF OVARY

Background:

Gemcitabine is a nucleoside analogue that exhibits antitumor activity which is cell phase-specific for the S-phase and for the G1/S-phase boundary of cell division. It is metabolized intracellularly by nucleoside kinases to the active diphosphate (dFdCDP) and triphosphate (dFdCTP) nucleosides. Cytotoxic effect of gemcitabine is due to a combination of 2 actions of the dFdCDP and dFdCTP nucleosides, which leads to inhibition of DNA synthesis.

Definitions:

HCPCS Code—Healthcare Common Procedure Coding System - A system of letter and number codes assigned to procedures, medications, supplies and equipment used for pricing and billing.

ICD-9 Code—International Classification of Disease, 9th edition. A standardized classification of disease, injuries, and causes of death, by etiology and anatomic localization and codified into a 6-digit number, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both US and internationally.

References:

1. Gemzar [package insert]. Indianapolis, IN: Eli Lilly and Company; February 2011. Available at: <http://pi.lilly.com/us/gemzar.pdf>. June 7, 2012.
2. The NCCN Drugs & Biologics Compendium™ © 2010 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed May 23, 2012.
3. Local Coverage Article for Drugs and Biologicals – Chemotherapeutic Agents (A48896) (R4). Available at: http://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=48896&ver=89&ContrlId=213&ContrVer=1&CtrctrSelected=213*1&Date=01%2f01%2f2013&DocID=A48896&bc=hAAAAAgAEAAAAA%3d%3d&. Accessed June 4, 2014.
4. Micromedex® 2.0 Gemzar. Available at: http://www.thomsonhc.com/micromedex2/librarian/ND_T/evidencexpert/ND_PR/evidencexpert/CS/8C2F34/ND_AppProduct/evidencexpert/DUPLICATIONSHIELDSYNC/B39AFC/ND_PG/evidencexpert/ND_B/evidencexpert/ND_P/evidencexpert/PFActionId/evidencexpert.DisplayDrugpointDocument?docId=923608&contentSetId=100&title=Gemcitabine+Hydrochloride&servicesTitle=Gemcitabine+Hydrochloride&topicId=dosingAndIndicationsSection&subtopicId=nonfdaSection. Accessed June 7, 2012.



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