

MEDICAL PRIOR AUTHORIZATION

Gemzar (gemcitabine) gemcitabine (generic)

POLICY

A. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. In combination with carboplatin for the treatment of patients with advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy
2. In combination with paclitaxel for the first-line treatment of patients with metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated
3. In combination with cisplatin for the first-line treatment of patients with inoperable, locally advanced (Stage IIIA or IIIB), or metastatic (Stage IV) non-small cell lung cancer
4. As first-line treatment for patients with locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) adenocarcinoma of the pancreas. Gemcitabine is indicated for patients previously treated with 5-FU.

Compendial Uses

1. Bladder cancer, primary carcinoma of the urethra, upper genitourinary tract tumors, urothelial carcinoma of the prostate
2. Bone cancer
 - Ewing's sarcoma family of tumors
 - osteosarcoma
3. Breast cancer
4. Head and neck cancers
5. Hepatobiliary cancers
 - extrahepatic cholangiocarcinoma
 - gallbladder cancer
 - intrahepatic cholangiocarcinoma
6. Hodgkin lymphoma
7. Kidney cancer
8. Malignant pleural mesothelioma
9. Non-Hodgkin's lymphoma
 - adult T-cell leukemia/lymphoma
 - AIDS-related B-cell lymphoma
 - Burkitt lymphoma
 - diffuse large B-cell lymphoma (DLBCL)
 - extranodal NK/T-cell lymphoma, nasal type
 - follicular lymphoma
 - gastric mucosa-associated lymphoid tissue (MALT) lymphoma

Gemcitabine Medical PA P2017

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- mantle cell lymphoma (MCL)
 - mycosis fungoides (MF)/Sezary syndrome (SS)
 - nongastric MALT lymphoma
 - peripheral T-cell lymphoma (PTCL)
 - primary cutaneous B-cell lymphoma
 - primary cutaneous CD30+ T-cell lymphoproliferative disorders
 - splenic marginal zone lymphoma (MZL)
10. Non-melanoma skin cancer: dermatofibrosarcoma protuberans (DFSP)
 11. Non-small cell lung cancer (NSCLC)
 12. Occult primary
 13. Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer
 14. Pancreatic adenocarcinoma
 15. Small cell lung cancer (SCLC)
 16. Soft tissue sarcoma (STS)
 - angiosarcoma
 - retroperitoneal/intra-abdominal
 - rhabdomyosarcoma
 - STS of the extremity/superficial trunk
 17. Testicular cancer
 18. Thymomas/thymic carcinomas
 19. Uterine sarcoma
 20. Cervical cancer

All other indications are considered experimental/investigational and are not a covered benefit.

B. CRITERIA FOR INITIAL APPROVAL

1. **Pancreatic Adenocarcinoma**
Authorization of 12 months may be granted for the treatment of pancreatic adenocarcinoma.
2. **Breast Cancer**
Authorization of 12 months may be granted for the treatment of recurrent or metastatic breast cancer.
3. **Intrahepatic and Extrahepatic Cholangiocarcinoma and Gallbladder Cancer**
Authorization of 12 months may be granted for the treatment of intrahepatic and extrahepatic cholangiocarcinoma and gallbladder cancer.
4. **Epithelial Ovarian Cancer, Fallopian Tube Cancer, Primary Peritoneal Cancer**
Authorization of 12 months may be granted for the treatment of epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer.
5. **Non-Small Cell Lung Cancer (NSCLC)**
Authorization of 12 months may be granted for the treatment of NSCLC.
6. **Bladder Cancer, Primary Carcinoma of the Urethra, Upper Genitourinary Tract Tumors, Urothelial Carcinoma of the Prostate**
Authorization of 12 months may be granted for the treatment of bladder cancer, primary carcinoma of the urethra, upper genitourinary tract tumors, and urothelial carcinoma of the prostate.
7. **Small Cell Lung Cancer (SCLC)**
Authorization of 12 months may be granted for the treatment of SCLC.
8. **Soft Tissue Sarcoma**
Authorization of 12 months may be granted for the treatment of soft tissue sarcoma.
9. **Bone Cancer**
Authorization of 12 months may be granted for the treatment of Ewing's sarcoma and osteosarcoma.

10. Nasopharyngeal Cancer

Authorization of 12 months may be granted for the treatment of nasopharyngeal cancer.

11. Hodgkin Lymphoma

Authorization of 12 months may be granted for the treatment of Hodgkin lymphoma.

12. Kidney Cancer

Authorization of 12 months may be granted for the treatment of kidney cancer.

13. Malignant Pleural Mesothelioma

Authorization of 12 months may be granted for the treatment of malignant pleural mesothelioma.

14. Non-Hodgkin's Lymphoma (NHL)

Authorization of 12 months may be granted for the treatment of NHL.

15. Dermatofibrosarcoma Protuberans

Authorization of 12 months may be granted for the treatment of dermatofibrosarcoma protuberans.

16. Occult Primary Tumors (cancer of unknown primary)

Authorization of 12 months may be granted for the treatment of occult primary tumors.

17. Testicular Cancer

Authorization of 12 months may be granted for the treatment of testicular cancer.

18. Thymomas and Thymic Carcinomas

Authorization of 12 months may be granted for the treatment of thymomas and thymic carcinomas.

19. Uterine Sarcoma

Authorization of 12 months may be granted for the treatment of uterine sarcoma.

20. Cervical cancer

Authorization of 3 months may be granted for the treatment of cervical cancer.

C. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

D. REFERENCES

1. Gemzar [package insert]. Indianapolis, IN: Eli Lilly and Company; June 2014.
2. Gemcitabine [package insert]. Lake Forest, IL: Hospira, Inc.; April 2016.
3. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. <http://www.nccn.org>. Accessed August 3, 2016.
4. DRUGDEX® System (electronic version). Truven Health Analytics, Ann Arbor, MI. Available at <http://www.micromedexsolutions.com> [available with subscription]. Accessed August 18, 2016.
5. AHFS Drug Information. <http://online.lexi.com/lco>. Accessed August 18, 2016.
6. Clinical Pharmacology [Internet]. Elsevier, Tampa, FL: Elsevier. Available at <http://www.clinicalpharmacology-ip.com>. Accessed August 18, 2016.