| Reference number(s) |
| --- |
| 2040-A |

# Medical Prior Authorization
# gemcitabine

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Gemzar | gemcitabine |
| Infugem | gemcitabine |
| gemcitabine (all other brands) | gemcitabine |

## 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

#### Ovarian Cancer

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

#### Breast Cancer

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

#### Non-Small Cell Lung Cancer

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 (NSCLC)

## Pancreatic Cancer

As first-line treatment for patients with locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) adenocarcinoma of the pancreas. Gemzar, Infugem or gemcitabine is indicated for patients previously treated with fluorouracil.

# Compendial Uses

- Ampullary adenocarcinoma
- Bladder cancer, primary carcinoma of the urethra, upper genitourinary tract tumors, transitional cell carcinoma of the urinary tract, urothelial carcinoma of the prostate, non-urothelial and urothelial cancer with variant histology
- Bone cancer
    - Ewing sarcoma
    - Osteosarcoma
- Breast cancer
- Cervical cancer
- Head and neck cancers (including very advanced head and neck cancer, cancer of the nasopharynx, occult primary and salivary gland tumors)
- Biliary tract cancer
    - Extrahepatic cholangiocarcinoma
    - Intrahepatic cholangiocarcinoma
    - Gallbladder cancer
- Hodgkin lymphoma
    - Classic Hodgkin lymphoma
    - Nodular lymphocyte-predominant Hodgkin lymphoma
- Kidney cancer
- Pleural or peritoneal mesothelioma
- Non-small cell lung cancer (NSCLC)
- Occult primary tumors (cancer of unknown primary)
- Ovarian cancer, fallopian tube cancer, and primary peritoneal cancer: epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer
- Pancreatic adenocarcinoma
- Small cell lung cancer (SCLC)
- Soft tissue sarcoma
    - Angiosarcoma
    - Extremity/Body wall, head/neck
    - Retroperitoneal/intra-abdominal
    - Rhabdomyosarcoma
    - Solitary fibrous tumor
    - Dedifferentiated chordoma
    - Dermatofibrosarcoma protuberans (DFSP) with fibrosarcomatous transformation
- Testicular cancer
- Thymomas and thymic carcinomas
- Uterine neoplasms (including endometrial carcinoma, uterine sarcoma and uterine leiomyosarcoma)

- Kaposi sarcoma
- Primary cutaneous lymphomas
    - Mycosis fungoides/Sezary syndrome
    - Primary cutaneous CD30+ T-Cell lymphoproliferative disorders
- T-Cell lymphomas
    - Peripheral T-Cell lymphomas
    - Adult T-Cell leukemia/lymphoma
    - Breast implant-associated anaplastic large cell lymphoma
    - Extranodal natural killer (NK)/T-Cell lymphoma
    - Hepatosplenic T-Cell lymphoma
- Gestational trophoblastic neoplasia
- B-Cell lymphomas
    - Histologic transformation of indolent lymphomas to diffuse large B-Cell lymphoma
    - Mantle cell lymphoma
    - Diffuse large B-Cell lymphoma
    - High-Grade B-Cell lymphomas
    - Burkitt lymphoma
    - Human immunodeficiency virus (HIV)-Related B-Cell lymphomas
    - Post-Transplant lymphoproliferative disorders
- Small bowel adenocarcinoma
- Malignant germ cell tumor
- Vaginal cancer
- Vulvar cancer

All other indications are considered experimental/investigational and not medically necessary.

# Coverage Criteria

## Pancreatic Adenocarcinoma

Authorization of 6 months may be granted for treatment of pancreatic adenocarcinoma.

## Breast Cancer

Authorization of 6 months may be granted for treatment of members with no response to preoperative systemic therapy, recurrent, or metastatic breast cancer.

## Biliary Tract Cancer

Authorization of 6 months may be granted for treatment of biliary tract cancer (including intrahepatic and extrahepatic cholangiocarcinoma, and gallbladder cancer).

## Ampullary Adenocarcinoma

Authorization of 6 months may be granted for treatment of ampullary adenocarcinoma.

## Ovarian Cancer, Fallopian Tube Cancer, and Primary Peritoneal Cancer

Authorization of 6 months may be granted for treatment of advanced, persistent, or recurrent epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma of the ovary, grade 1 endometrioid carcinoma, low-grade serous carcinoma/ovarian borderline epithelial tumors (low malignant potential), mucinous carcinoma of the ovary, or malignant germ cell tumor residual disease.

## Non-Small Cell Lung Cancer (NSCLC)

Authorization of 6 months may be granted for treatment of NSCLC.

## Cervical Cancer

Authorization of 6 months may be granted for treatment of cervical cancer.

## -Bladder Cancer, Primary Carcinoma of the Urethra, Upper Genitourinary Tract Tumors, Transitional Cell Carcinoma of the Urinary Tract, Urothelial Carcinoma of the Prostate, and Non-Urothelial and Urothelial Cancer with Variant Histology

Authorization of 6 months may be granted for treatment of bladder cancer, primary carcinoma of the urethra, upper genitourinary tract tumors, transitional cell carcinoma of the urinary tract, urothelial carcinoma of the prostate, and non-urothelial and urothelial cancer with variant histology.

## Small Cell Lung Cancer (SCLC)

Authorization of 6 months may be granted for treatment of SCLC.

## Soft Tissue Sarcoma

Authorization of 6 months may be granted for treatment of soft tissue sarcoma (including angiosarcoma, extremity/body wall, head/neck, retroperitoneal/intra-abdominal, rhabdomyosarcoma, solitary fibrous tumor, dedifferentiated chordoma, and dermatofibrosarcoma protuberans (DFSP) with fibrosarcomatous transformation).

## Bone Cancer

### Ewing Sarcoma

Authorization of 6 months may be granted for treatment of relapsed, progressive, or metastatic Ewing sarcoma.

### Osteosarcoma

Authorization of 6 months may be granted for treatment of relapsed/refractory or metastatic osteosarcoma.

## Head and Neck Cancer

Authorization of 6 months may be granted for treatment of head and neck cancer (including very advanced head and neck cancer, cancer of the nasopharynx, occult primary, and salivary gland tumors).

## Hodgkin Lymphoma

### Hodgkin Lymphoma

Authorization of 6 months may be granted for treatment of Hodgkin lymphoma including classic Hodgkin lymphoma and pediatric Hodgkin lymphoma.

### Nodular Lymphocyte-Predominant Hodgkin Lymphoma

Authorization of 6 months may be granted for treatment of progressive, relapsed, or refractory

nodular lymphocyte-predominant Hodgkin lymphoma.

## Kidney Cancer

Authorization of 6 months may be granted for treatment of relapsed or metastatic kidney cancer.

## Pleural or Peritoneal Mesothelioma

Authorization of 6 months may be granted for treatment of pleural or peritoneal mesothelioma, including pericardial mesothelioma and tunica vaginalis testis mesothelioma.

## Occult Primary Tumors (cancer of unknown primary)

Authorization of 6 months may be granted for treatment of occult primary tumors.

## Testicular Cancer

Authorization of 6 months may be granted for treatment of testicular cancer.

## Thymomas and Thymic Carcinomas

Authorization of 6 months may be granted for treatment of thymomas and thymic carcinomas.

## Uterine Neoplasms

Authorization of 6 months may be granted for treatment of uterine neoplasms (including endometrial carcinoma, uterine sarcoma and uterine leiomyosarcoma).

## Kaposi Sarcoma

Authorization of 6 months may be granted for treatment of Kaposi sarcoma.

## Primary Cutaneous Lymphomas

Authorization of 6 months may be granted for treatment of primary cutaneous lymphomas (including mycosis fungoides/Sezary syndrome and primary cutaneous CD30+ T-Cell lymphoproliferative disorders).

## T-Cell Lymphomas

Authorization of 6 months may be granted for treatment of T-Cell lymphomas (including peripheral T-Cell lymphomas, adult T-Cell leukemia/lymphoma, hepatosplenic T-Cell lymphoma, breast implant-associated anaplastic large cell lymphoma, and extranodal NK/T-Cell lymphoma).

## Gestational Trophoblastic Neoplasia

Authorization of 6 months may be granted for treatment of gestational trophoblastic neoplasia.

## B-Cell Lymphomas

Authorization of 6 months may be granted for treatment of B-Cell lymphomas (including histologic transformation of indolent lymphomas to diffuse large B-Cell lymphoma, mantle cell lymphoma, diffuse large B-Cell lymphoma, high-grade B-Cell lymphomas, Burkitt lymphoma, HIV-Related B-Cell lymphomas, and post-transplant lymphoproliferative disorders).

## Small Bowel Adenocarcinoma

Authorization of 6 months may be granted for treatment of small bowel adenocarcinoma.

## Malignant Germ Cell Tumor

Authorization of 6 months may be granted for treatment of malignant germ cell tumor.

## Vaginal Cancer

Authorization of 6 months may be granted for treatment of vaginal cancer when used as a single agent.

## Vulvar Cancer

Authorization of 6 months may be granted for treatment of vulvar cancer as concurrent chemoradiation as a single agent if cisplatin or carboplatin are unavailable.

# Continuation of Therapy

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

# References

1. Gemzar [package insert]. Indianapolis, IN: Lilly USA, LLC; May 2019.
2. Infugem [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; January 2020.
3. Gemcitabine [package insert]. Chicago, IL: Meitheal Pharmaceuticals Inc.; October 2023.
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6. Clinical Pharmacology [database online]. Tampa, FL: Elsevier; https://www.clinicalkey.com/pharmacology [available with subscription]. Accessed July 1, 2024.
7. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed July 1, 2024.