Reference number(s)
4469-A

Standard Medicare Part B Management 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
Avgemsi	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[1,2]

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)

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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. Gemcitabine is indicated for patients previously treated with fluorouracil.

Compendial Uses[3-6]

- 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 subtype histology
- Bone cancer
    - Ewing sarcoma
    - Mesenchymal chondrosarcoma
    - Osteosarcoma
    - Dedifferentiated chondrosarcoma
    - High-grade undifferentiated pleomorphic sarcoma (UPS)
- Breast cancer
- Head and neck cancers (including very advanced head and neck cancer, cancer of the nasopharynx, occult primary and salivary gland tumors)
- Hepatocellular carcinoma
- Biliary tract cancers
    - Extrahepatic cholangiocarcinoma
    - Intrahepatic cholangiocarcinoma
    - Gallbladder cancer
- Hodgkin lymphoma
    - Classic Hodgkin lymphoma
    - Nodular lymphocyte-predominant Hodgkin lymphoma
    - Pediatric 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
- Malignant germ cell tumors
- Pancreatic adenocarcinoma
- Small cell lung cancer (SCLC)
- Soft tissue sarcoma
- Testicular cancer
- Thymomas and thymic carcinomas
- Uterine neoplasms (including endometrial carcinoma, uterine sarcoma and uterine leiomyosarcoma)

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- 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
    - Extranodal natural killer (NK)/T-cell lymphoma
    - Hepatosplenic T-cell lymphoma
    - Breast implant-associated anaplastic large cell lymphoma (ALCL)
- Gestational trophoblastic neoplasia
- Non-Hodgkin B-Cell lymphomas
- Small bowel adenocarcinoma
- Cervical cancer
- Vaginal cancer
- Vulvar cancer

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Pancreatic Adenocarcinoma[1-5]

Authorization of 12 months may be granted for treatment of pancreatic adenocarcinoma.

Breast Cancer[1-3]

Authorization of 12 months may be granted for treatment of members with no response to preoperative systemic therapy, recurrent, or metastatic breast cancer.

Hepatocellular Carcinoma[4]

Authorization of 12 months may be granted for treatment of hepatocellular carcinoma.

Biliary Tract Cancer[3-6]

Authorization of 12 months may be granted for treatment of biliary tract cancer (including intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer).

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Ampullary Adenocarcinoma[3,4]

Authorization of 12 months may be granted for treatment of ampullary adenocarcinoma.

Ovarian Cancer, Fallopian Tube Cancer, and Primary Peritoneal Cancer[1-4]

Authorization of 12 months may be granted for treatment of advanced, persistent, relapsed or recurrent disease if the member has one of the following:

- Epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer
- Carcinosarcoma (malignant mixed Mullerian tumors)
- Clear cell carcinoma of the ovary
- Mucinous carcinoma of the ovary
- Grade 1 endometroid carcinoma
- Low-grade serous carcinoma/ovarian borderline epithelial tumors (low malignant potential)
- Malignant germ cell tumors

Non-Small Cell Lung Cancer (NSCLC)[1-4]

Authorization of 12 months may be granted for treatment of NSCLC.

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[3-6]

Authorization of 12 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 subtype histology.

Small Cell Lung Cancer (SCLC)[3,4]

Authorization of 12 months may be granted for treatment of SCLC.

Soft Tissue Sarcoma[3,4]

Authorization of 12 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, dedifferentiated liposarcoma with or without concurrent well-differentiated liposarcoma, epithelioid hemangioendothelioma, and dermatofibrosarcoma protuberans (DFSP) with fibrosarcomatous transformation).

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Bone Cancer[3]

Ewing Sarcoma or Mesenchymal Chondrosarcoma

Authorization of 12 months may be granted for treatment of relapsed, progressive, or metastatic Ewing sarcoma or mesenchymal chondrosarcoma.

Osteosarcoma, Dedifferentiated Chondrosarcoma, or High-Grade Undifferentiated Pleomorphic Sarcoma (UPS)

Authorization of 12 months may be granted for treatment of relapsed/refractory or metastatic osteosarcoma, dedifferentiated chondrosarcoma, or high-grade undifferentiated pleomorphic sarcoma (UPS).

Head and Neck Cancer[3,4]

Authorization of 12 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[3,4]

Hodgkin Lymphoma

Authorization of 12 months may be granted for treatment of Hodgkin lymphoma including classic Hodgkin lymphoma and pediatric Hodgkin lymphoma.

Nodular Lymphocyte-Predominant Hodgkin Lymphoma

Authorization of 12 months may be granted for treatment of progressive, relapsed, or refractory nodular lymphocyte-predominant Hodgkin lymphoma.

Kidney Cancer[3,4]

Authorization of 12 months may be granted for treatment of unresectable, relapsed, or metastatic kidney cancer.

Pleural or Peritoneal Mesothelioma[3]

Authorization of 12 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)[3,4]

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

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Thymomas and Thymic Carcinomas[3]

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

Testicular Cancer[3,4]

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

Uterine Neoplasms[3]

Authorization of 12 months may be granted for treatment of uterine neoplasms (including endometrial carcinoma, uterine sarcoma and uterine leiomyosarcoma).

Kaposi Sarcoma[3,4]

Authorization of 12 months may be granted for treatment of Kaposi sarcoma.

Primary Cutaneous Lymphomas[3]

Authorization of 12 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[3,4]

Authorization of 12 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 [ALCL], and extranodal NK/T-cell lymphoma).

Gestational Trophoblastic Neoplasia[3,4]

Authorization of 12 months may be granted for treatment of gestational trophoblastic neoplasia.

Non-Hodgkin B-Cell Lymphomas[3,4,6]

Authorization of 12 months may be granted for treatment of non-Hodgkin B-cell lymphomas.

Cervical Cancer[3,4]

Authorization of 12 months may be granted for treatment of cervical cancer.

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Vulvar Cancer[3]

Authorization of 12 months may be granted for treatment of vulvar cancer.

Vaginal Cancer[3]

Authorization of 12 months may be granted for treatment of vaginal cancer when used as a single agent.

Small Bowel Adenocarcinoma[3]

Authorization of 12 months may be granted for treatment of small bowel adenocarcinoma.

Malignant Germ Cell Tumor[3,4]

Authorization of 12 months may be granted for treatment of malignant germ cell tumor.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested drug
- The requested drug is being used to treat an indication listed in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen AND
    - No evidence of disease progression while on the current regimen

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Avgemsi and generic gemcitabine.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Hodgkin lymphoma
- NCCN Guideline: Thymomas and thymic carcinomas

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- NCCN Guideline: Small cell lung cancer
- NCCN Guideline: Cervical cancer
- NCCN Guideline: Gestational trophoblastic neoplasia
- NCCN Guideline: Small bowel adenocarcinoma
- NCCN Guideline: Peritoneal mesothelioma
- NCCN Guideline: Pleural mesothelioma
- NCCN Guideline: T-cell lymphomas
- NCCN Guideline: Pediatric Hodgkin lymphoma
- NCCN Guideline: Kaposi sarcoma
- NCCN Guideline: Bone cancer
- NCCN Guideline: Testicular cancer
- NCCN Guideline: Non-small cell lung cancer
- NCCN Guideline: Breast cancer
- NCCN Guideline: Soft tissue sarcoma
- NCCN Guideline: Occult primary
- NCCN Guideline: Biliary tract cancers
- NCCN Guideline: Ampullary adenocarcinoma
- NCCN Guideline: Bladder cancer
- NCCN Guideline: B-cell lymphomas
- NCCN Guideline: Uterine neoplasms
- NCCN Guideline: Primary cutaneous lymphomas
- NCCN Guideline: Ovarian cancer/fallopian tube cancer/primary peritoneal cancer
- NCCN Guideline: Vulvar cancer
- NCCN Guideline: Pancreatic adenocarcinoma
- NCCN Guideline: Head and neck cancers
- NCCN Guideline: Kidney cancer
- NCCN Guideline: Vaginal cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Avgemsi and generic gemcitabine are covered in addition to the following:

- 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 subtype histology
- Bone cancer
    - Ewing sarcoma
    - Mesenchymal chondrosarcoma
    - Osteosarcoma
    - Dedifferentiated chrondrosarcoma
    - High-grade undifferentiated pleomorphic sarcoma (UPS)
- Recurrent breast cancer.

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- Head and neck cancers (including very advanced head and neck cancer, cancer of the nasopharynx, occult primary, and salivary gland tumors)
- Hepatocellular carcinoma
- Hepatobiliary and biliary tract cancers
    - Extrahepatic cholangiocarcinoma
    - Intrahepatic cholangiocarcinoma
    - Gallbladder cancer
- Hodgkin lymphoma
    - Classic Hodgkin lymphoma
    - Nodular lymphocyte-predominant Hodgkin lymphoma
    - Pediatric Hodgkin lymphoma
- Kidney cancer
- Malignant pleural or peritoneal mesothelioma
- Non-small cell lung cancer (NSCLC) other than inoperable locally advanced or metastatic
- Occult primary tumors (cancer of unknown primary)
- Persistent, relapsed, or recurrent ovarian cancer
- Fallopian tube cancer, and primary peritoneal cancer
- Malignant germ cell tumors
- Pancreatic adenocarcinoma
- Small cell lung cancer (SCLC)
- Soft tissue sarcoma
- 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
    - Extranodal natural killer (NK)/T-cell lymphoma
    - Hepatosplenic T-cell lymphoma
    - Breast implant-associated anaplastic large cell lymphoma (ALCL)
- Gestational trophoblastic neoplasia
- Non-Hodgkin B-cell lymphomas
- Cervical cancer
- Vaginal cancer
- Vulvar cancer
- Small bowel adenocarcinoma

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Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for all compendial indications other than hepatocellular carcinoma and can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for hepatocellular carcinoma and non-Hodgkin B-cell lymphoma can be found in the Micromedex DrugDex database. Use of information in the DrugDex database for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

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