Reference number(s)
2040-A

SPECIALTY GUIDELINE MANAGEMENT

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, non-urothelial and urothelial cancer with variant histology
2. Bone cancer
   - Ewing's sarcoma family of tumors
   - osteosarcoma
3. Breast cancer
4. Head and neck cancers
   - nasopharyngeal cancer
5. Hepatobiliary cancers
   - extrahepatic cholangiocarcinoma
   - gallbladder cancer
   - intrahepatic cholangiocarcinoma
6. Hodgkin lymphoma
7. Kidney cancer
8. Malignant pleural mesothelioma
9. Non-Hodgkin's lymphoma
10. Non-small cell lung cancer (NSCLC)
11. Occult primary
12. Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer
13. Pancreatic adenocarcinoma
14. Small cell lung cancer (SCLC)
15. Soft tissue sarcoma (STS)
16. Testicular cancer

17. Thymomas/thymic carcinomas
18. Uterine sarcoma
19. AIDS-Related Kaposi Sarcoma

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, Non-Urothelial and Urothelial cancer with Variant Histology**
   Authorization of 12 months may be granted for the treatment of bladder cancer, primary carcinoma of the urethra, upper genitourinary tract tumors, urothelial carcinoma of the prostate, and non-urothelial and urothelial cancer with variant histology.

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. **Occult Primary Tumors (cancer of unknown primary)**
    Authorization of 12 months may be granted for the treatment of occult primary tumors.

16. **Testicular Cancer**
    Authorization of 12 months may be granted for the treatment of testicular cancer.

17. **Thymomas and Thymic Carcinomas**
    Authorization of 12 months may be granted for the treatment of thymomas and thymic carcinomas.

18. **Uterine Sarcoma**
    Authorization of 12 months may be granted for the treatment of uterine sarcoma.

19. **AIDS-Related Kaposi Sarcoma**
    Authorization of 12 months may be granted for the treatment of AIDS-Related Kaposi Sarcoma.

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; May 2018.
2. Gemcitabine [package insert]. Lake Forest, IL: Hospira, Inc.; February 2018.
3. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 24, 2018.