Reference number(s)
2040-A

SPECIALTY GUIDELINE MANAGEMENT

GEMZAR (gemcitabine)
gemcitabine

POLICY

I. 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.

A. FDA-Approved Indications
1. 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
2. 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
3. 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)
4. 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 or gemcitabine is indicated for patients previously treated with fluorouracil.

B. Compendial Uses
1. 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
2. Bone cancer
   a. Ewing's sarcoma
   b. Osteosarcoma
3. Breast cancer
4. Head and neck cancers (including very advanced head and neck cancer and cancer of the nasopharynx)
5. Hepatobiliary and biliary tract cancer
   a. Extrahepatic cholangiocarcinoma
   b. Intrahepatic cholangiocarcinoma
   c. Gallbladder cancer
   d. Ampullary cancer
6. Hodgkin lymphoma
   a. Classic Hodgkin lymphoma
   b. Nodular lymphocyte-predominant Hodgkin lymphoma

7. Kidney cancer
8. Malignant pleural mesothelioma
9. Non-small cell lung cancer (NSCLC)
10. Occult primary tumors (cancer of unknown primary)
11. Ovarian cancer, fallopian tube cancer, and primary peritoneal cancer: epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer
12. Pancreatic adenocarcinoma
13. Small cell lung cancer (SCLC)
14. Soft tissue sarcoma
    a. Angiosarcoma
    b. Extremity/Body wall, head/neck
    c. Retroperitoneal/intra-abdominal
    d. Rhabdomyosarcoma
    e. Solitary fibrous tumor
    f. Undifferentiated pleomorphic sarcoma (UPS)
15. Testicular cancer
16. Thymomas and thymic carcinomas
17. Uterine neoplasms (including uterine sarcoma and uterine leiomyosarcoma)
18. Kaposi Sarcoma
19. Primary cutaneous lymphomas
    a. Mycosis fungoides/Sezary syndrome
    b. Primary cutaneous CD30+ T-Cell lymphoproliferative disorders
20. T-Cell lymphomas
    a. Peripheral T-Cell lymphomas
    b. Adult T-Cell leukemia/lymphoma
    c. Extranodal NK/T-Cell lymphoma, nasal type
    d. Hepatosplenic T-Cell lymphoma
21. Gestational trophoblastic neoplasia
22. B-Cell lymphomas
    a. Follicular lymphoma (grade 1-2)
    b. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-Cell lymphoma
    c. Mantle cell lymphoma
    d. Diffuse large B-Cell lymphoma
    e. High-Grade B-Cell lymphomas
    f. Burkitt lymphoma
    g. AIDS-Related B-Cell lymphomas
    h. Post-Transplant lymphoproliferative disorders
23. Small bowel adenocarcinoma
24. Malignant germ cell tumor

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

II. CRITERIA FOR INITIAL APPROVAL

A. Pancreatic Adenocarcinoma

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

B. Breast Cancer

Authorization of 6 months may be granted for treatment of recurrent or metastatic breast cancer.

C. Hepatobiliary and Biliary Tract Cancer
Authorization of 6 months may be granted for treatment of hepatobiliary and biliary tract cancer (including intrahepatic and extrahepatic cholangiocarcinoma, gallbladder cancer, and ampullary cancer).

D. Ovarian Cancer, Fallopian Tube Cancer, and Primary Peritoneal Cancer

Epithelial 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, and primary peritoneal cancer.

E. Non-Small Cell Lung Cancer (NSCLC)
Authorization of 6 months may be granted for treatment of NSCLC.

F. 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.

G. Small Cell Lung Cancer (SCLC)
Authorization of 6 months may be granted for treatment of SCLC.

H. 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, and undifferentiated pleomorphic sarcoma [UPS]).

I. Bone Cancer

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

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

J. 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 and cancer of the nasopharynx).

K. Hodgkin Lymphoma

1. Classic Hodgkin Lymphoma
Authorization of 6 months may be granted for treatment of classic Hodgkin lymphoma.

2. Nodular Lymphocyte-Predominant Hodgkin Lymphoma
Authorization of 6 months may be granted for treatment of progressive, relapsed, or refractory

nodular lymphocyte-predominant Hodgkin lymphoma.

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

M. Malignant Pleural Mesothelioma
Authorization of 6 months may be granted for treatment of malignant pleural mesothelioma.

N. Occult Primary Tumors (cancer of unknown primary)
Authorization of 6 months may be granted for treatment of occult primary tumors.

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

P. Thymomas and Thymic Carcinomas
Authorization of 6 months may be granted for treatment of thymomas and thymic carcinomas.

Q. Uterine Neoplasms
Authorization of 6 months may be granted for treatment of uterine neoplasms (including uterine sarcoma and uterine leiomyosarcoma).

R. Kaposi Sarcoma
Authorization of 6 months may be granted for treatment of Kaposi Sarcoma.

S. 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. 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, and extranodal NKT/T-Cell lymphoma, nasal type).

U. Gestational Trophoblastic Neoplasia
Authorization of 6 months may be granted for treatment of gestational trophoblastic neoplasia.

V. B-Cell Lymphomas
Authorization of 6 months may be granted for treatment of B-Cell lymphomas (including follicular lymphoma [grade 1-2], histologic transformation of nodal marginal zone lymphoma to diffuse large B-Cell lymphoma, mantle cell lymphoma, diffuse large B-Cell lymphoma, high-grade B-Cell lymphomas, Burkitt lymphoma, AIDS-Related B-Cell lymphomas, and post-transplant lymphoproliferative disorders).

W. Small Bowel Adenocarcinoma
Authorization of 6 months may be granted for treatment of small bowel adenocarcinoma.

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

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

1. Gemzar [package insert]. Indianapolis, IN: Lilly USA, LLC; May 2019.
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