Reference number(s)
1901-A

SPECIALTY GUIDELINE MANAGEMENT

TAXOTERE (docetaxel)
docetaxel

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. Breast Cancer (BC)
   a. Docetaxel is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy.
   b. Docetaxel in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with operable node-positive breast cancer.
2. Non-Small Cell Lung Cancer (NSCLC)
   a. Docetaxel as a single agent is indicated for the treatment of patients with locally advanced or metastatic NSCLC after failure of prior platinum-based chemotherapy.
   b. Docetaxel in combination with cisplatin is indicated for the treatment of patients with unresectable, locally advanced or metastatic NSCLC who have not previously received chemotherapy for this condition.
3. Prostate Cancer
   Docetaxel in combination with prednisone is indicated for the treatment of patients with metastatic castration-resistant prostate cancer.
4. Gastric Adenocarcinoma (GC)
   Docetaxel in combination with cisplatin and fluorouracil is indicated for the treatment of patients with advanced gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for advanced disease.
5. Head and Neck Cancer
   Docetaxel in combination with cisplatin and fluorouracil is indicated for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN).

B. Compendial Uses
1. Anal cancer
2. Bladder cancer, primary carcinoma of the urethra, upper genitourinary (GU) tract tumors, and urothelial carcinoma of the prostate
3. Bone cancer: Ewing's sarcoma and osteosarcoma
4. Breast cancer
5. Cervical cancer
6. Esophageal and esophagogastric junction cancers
7. Gastric cancer
8. Head and neck cancer (including very advanced head and neck cancer and cancers of the lip (mucosa), oral cavity, salivary gland, oropharynx, hypopharynx, nasopharynx, glottic larynx, or supraglottic larynx)
9. Non-small cell lung cancer
10. Occult primary tumors (cancer of unknown primary)

11. Ovarian cancer/fallopian tube cancer/primary peritoneal cancer: epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, malignant germ cell tumors, malignant sex cord-stromal tumors, carcinosarcoma (malignant mixed Müllerian tumors), clear cell carcinoma of the ovary, mucinous carcinoma of the ovary, low-grade serious carcinoma/ovarian borderline epithelial tumor (low malignant potential), and grade 1 endometrioid carcinoma.
12. Prostate cancer
13. Small cell lung cancer
14. Soft tissue sarcoma (including angiosarcoma, extremity/body wall, head/neck, retroperitoneal/intra-abdominal, pleomorphic rhabdomyosarcoma, dermatofibrosarcoma protuberans (DFSP) with fibrosarcomatous transformation, dedifferentiated chordoma, and solitary fibrous tumor)
15. Thyroid carcinoma: anaplastic carcinoma
16. Uterine neoplasms: endometrial carcinoma and uterine sarcoma
17. Small bowel adenocarcinoma

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

II. CRITERIA FOR INITIAL APPROVAL

A. Anal Cancer

Authorization of 6 months may be granted for treatment of metastatic or unresectable locally recurrent anal squamous cell carcinoma.

B. Bladder Cancer, Primary Carcinoma of the Urethra, Upper Genitourinary Tract Tumors, and Urothelial Carcinoma of the Prostate

1. Bladder Cancer

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

2. Primary Carcinoma of the Urethra

Authorization of 6 months may be granted for treatment of recurrent or metastatic primary carcinoma of the urethra.

3. Upper Genitourinary Tract Tumors and Urothelial Carcinoma of the Prostate

Authorization of 6 months may be granted for treatment of metastatic upper genitourinary tract tumors or urothelial carcinoma of the prostate.

C. 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.

D. Breast Cancer

Authorization of 6 months may be granted for treatment of breast cancer in members when any of the following criteria are met:

1. Member has human epidermal growth factor receptor 2 (HER2)-negative recurrent unresectable or metastatic disease or no response to preoperative systemic therapy, as a single agent or in combination with capecitabine.
2. Member has human epidermal growth factor receptor 2 (HER2)-positive recurrent unresectable or metastatic disease or no response to preoperative systemic therapy, and the requested medication will be used in one of the following regimens (with or without endocrine therapy):
   a. In combination with pertuzumab and trastuzumab.
   b. In combination with trastuzumab.
3. The requested medication will be used as adjuvant therapy.
4. The requested medication will be used as preoperative therapy.
5. The requested medication will be used as a substitute for other taxanes (e.g., paclitaxel or albumin-bound paclitaxel) in select patients due to medical necessity.

E. Cervical Cancer
Authorization of 6 months may be granted for subsequent treatment of persistent, recurrent, or metastatic cervical cancer as a single agent.

F. Esophageal and Esophagogastric Junction Cancers
Authorization of 6 months may be granted for treatment of esophageal or esophagogastric junction cancer.

G. Gastric Cancer
Authorization of 6 months may be granted for treatment of gastric cancer.

H. 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, cancers of the lip (mucosa), oral cavity, salivary gland, oropharynx, hypopharynx, nasopharynx, glottic larynx, and supraglottic larynx).

I. Non-Small Cell Lung Cancer (NSCLC)
Authorization of 6 months may be granted for treatment of non-small cell lung cancer.

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

K. Ovarian Cancer, Fallopian Tube Cancer, and Primary Peritoneal Cancer
Authorization of 6 months may be granted for treatment of 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 tumor (low malignant potential), mucinous carcinoma of the ovary, malignant sex-cord stromal tumors, or malignant germ cell tumor residual disease.

L. Prostate Cancer
Authorization of 6 months may be granted for treatment of prostate cancer.

M. Small Cell Lung Cancer (SCLC)
Authorization of 6 months may be granted for treatment of small cell lung cancer.

N. 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, pleomorphic rhabdomyosarcoma, dermatofibrosarcoma protuberans (DFSP) with fibrosarcomatous transformation, dedifferentiated chordoma, and solitary fibrous tumor.

O. Thyroid Carcinoma – Anaplastic Carcinoma
Authorization of 6 months may be granted for treatment of thyroid carcinoma-anaplastic carcinoma.

P. Uterine Neoplasms
Authorization of 6 months may be granted for treatment of uterine neoplasms (including endometrial carcinoma and uterine sarcoma).

Q. Small Bowel Adenocarcinoma
Authorization of 6 months may be granted for treatment of advanced or metastatic small bowel adenocarcinoma.

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

1. Taxotere [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; January 2023.
2. Docetaxel [package insert]. Gujarat, India: Sun Pharmaceutical Ind. Ltd; February 2021.
3. Lexicomp [database online]. Hudson, OH: Lexi-Comp, Inc.; https://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed July 13, 2023.
4. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed July 12, 2023.