

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. Bladder cancer, primary carcinoma of the urethra, upper genitourinary (GU) tract tumors, and urothelial carcinoma of the prostate
2. Bone cancer: Ewing's sarcoma and osteosarcoma
3. Breast cancer
4. Esophageal and esophagogastric junction cancers
5. Gastric cancer
6. 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)
7. Non-small cell lung cancer
8. Occult primary tumors (cancer of unknown primary)
9. 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

Docetaxel 1901-A SGM P2021.docx

© 2021 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Reference number(s)
1901-A

tumors, carcinosarcoma (malignant mixed Müllerian tumors), clear cell carcinoma, mucinous carcinoma, low-grade serious carcinoma/ovarian borderline epithelial tumors (low malignant potential) with invasive implants, and grade 1 endometrioid carcinoma.

10. Prostate cancer
11. Small cell lung cancer
12. Soft tissue sarcoma (including angiosarcoma, extremity/body wall, head/neck, retroperitoneal/intra-abdominal, pleomorphic rhabdomyosarcoma, and solitary fibrous tumor)
13. Thyroid carcinoma: anaplastic carcinoma
14. Uterine neoplasms: endometrial carcinoma and uterine sarcoma
15. Small bowel adenocarcinoma

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

II. CRITERIA FOR INITIAL APPROVAL

A. 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.

B. 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.

C. 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, 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 and docetaxel will be used in one of the following regimens:
 - a. In combination with pertuzumab and trastuzumab.
 - b. In combination with trastuzumab.
3. Docetaxel will be used as adjuvant therapy.
4. Docetaxel will be used as preoperative therapy.

Reference number(s)
1901-A

- Docetaxel will be used as a substitute for other taxanes (e.g., paclitaxel or albumin-bound paclitaxel) in select patients due to medical necessity.

D. Esophageal and Esophagogastric Junction Cancers

Authorization of 6 months may be granted for treatment of esophageal or esophagogastric junction cancer.

E. Gastric Cancer

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

F. Head and Neck Cancer

Authorization of 6 months may 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).

G. Non-Small Cell Lung Cancer (NSCLC)

Authorization of 6 months may be granted for treatment of non-small cell lung cancer.

H. Occult Primary Tumors (cancer of unknown primary)

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

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

1. Epithelial 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, and primary peritoneal cancer.

2. Malignant Germ Cell Tumors

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

3. Malignant Sex-Cord Stromal Tumors

Authorization of 6 months may be granted for treatment of malignant sex-cord stromal tumors.

4. Carcinosarcoma (Malignant Mixed Müllerian Tumors)

Authorization of 6 months may be granted for treatment of carcinosarcoma (malignant mixed Müllerian tumors).

5. Clear Cell Carcinoma

Authorization of 6 months may be granted for treatment of clear cell carcinoma.

6. Mucinous Carcinoma

Authorization of 6 months may be granted for treatment of mucinous carcinoma.

7. Low-Grade Serous Carcinoma and Ovarian Borderline Epithelial Tumors (Low Malignant Potential) with Invasive Implants

Authorization of 6 months may be granted for treatment of low-grade serous carcinoma and ovarian borderline epithelial tumors (low malignant potential) with invasive implants.

8. Grade 1 Endometrioid Carcinoma

Authorization of 6 months may be granted for treatment of grade 1 endometrioid carcinoma.

J. Prostate Cancer

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

Reference number(s)
1901-A

K. Small Cell Lung Cancer (SCLC)

Authorization of 6 months may be granted for treatment of small cell lung cancer.

L. 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, and solitary fibrous tumor).

M. Thyroid Carcinoma – Anaplastic Carcinoma

Authorization of 6 months may be granted for treatment of thyroid carcinoma-anaplastic carcinoma.

N. Uterine Neoplasms

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

O. Small Bowel Adenocarcinoma

Authorization of 6 months may be granted for treatment of advanced or metastatic small bowel adenocarcinoma, including advanced ampullary cancer.

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; May 2021.
2. Docetaxel [package insert]. Gujarat, India: Sun Pharmaceutical Ind. Ltd; February 2021.
3. The NCCN Drugs & Biologics Compendium 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed July 14, 2021.
4. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed July 14, 2021.