Reference number(s)
1901-A

SPECIALTY GUIDELINE MANAGEMENT

TAXOTERE (docetaxel)
DOCEFREZ(docetaxel)
docetaxel (generic)

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
      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 androgen independent (hormone refractory) metastatic prostate cancer.

   4. Gastric Adenocarcinoma
      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 (5FU) 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, 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

7. Non-small cell lung cancer
8. Occult primary
9. Ovarian 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, mucinous carcinoma, low-grade serious/grade 1 endometrioid epithelial carcinoma.
10. Prostate cancer
11. Small cell lung cancer
12. Soft tissue sarcoma (STS)
13. Thyroid carcinoma: anaplastic carcinoma
14. Uterine neoplasms: endometrial carcinoma and uterine sarcoma

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

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

1. Bladder Cancer
Authorization of 12 months may be granted for treatment of bladder cancer.

2. Primary Carcinoma of the Urethra, Upper Genitourinary Tract Tumors, or Urothelial Carcinoma of the Prostate
Authorization of 12 months may be granted for treatment of recurrent or metastatic primary carcinoma of the urethra, upper genitourinary tract tumors, or urothelial carcinoma of the prostate.

B. Bone Cancer

1. Ewing's Sarcoma
Authorization of 12 months may be granted for treatment of relapsed, progressive or metastatic Ewing's sarcoma.

2. Osteosarcoma
Authorization of 12 months may be granted for treatment of relapsed/refractory or metastatic osteosarcoma.

C. Breast Cancer
Authorization of 12 months may be granted for treatment of breast cancer.

D. Esophageal and Esophagogastric Junction Cancers
Authorization of 12 months may be granted for treatment of esophageal or esophagogastric junction cancer.

E. Gastric Cancer
Authorization of 12 months may be granted for treatment of gastric cancer.

F. Head and Neck Cancer
Authorization of 12 months may granted for treatment of head and neck cancer.

G. Non-Small Cell Lung Cancer (NSCLC)
Authorization of 12 months may be granted for treatment of non-small cell lung cancer.

H. Occult Primary
Authorization of 12 months may be granted for treatment of occult primary cancer.

I. Ovarian Cancer

1. Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer
Authorization of 12 months may be granted for treatment of epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer.

2. Malignant Germ Cell Tumors
Authorization of 12 months may be granted for treatment of malignant germ cell tumors.

3. Malignant Sex-Cord Stromal Tumors
Authorization of 12 months may be granted for treatment of malignant sex-cord stromal tumors.

4. Carcinosarcoma (Malignant Mixed Müllerian Tumors)
Authorization of 12 months may be granted for treatment of malignant mixed Müllerian tumors.

5. Clear Cell Carcinoma
Authorization of 12 months may be granted for treatment of clear cell carcinoma.

6. Mucinous Carcinoma
Authorization of 12 months may be granted for treatment of mucinous carcinoma.

7. Low-Grade Serous/Grade 1 Endometrioid Epithelial Carcinoma
Authorization of 12 months may be granted for treatment of low-grade serous/grade 1 endometrioid epithelial carcinoma.

J. Prostate Cancer
Authorization of 12 months may be granted for treatment of prostate cancer.

K. Small Cell Lung Cancer (SCLC)
Authorization of 12 months may be granted for treatment of small cell lung cancer.

L. Soft Tissue Sarcoma (STS)
Authorization of 12 months may be granted for treatment of soft tissue sarcoma.

M. Thyroid Carcinoma – Anaplastic Carcinoma
Authorization of 12 months may be granted for treatment of thyroid carcinoma-anaplastic carcinoma.

N. Uterine Neoplasms

1. Endometrial Carcinoma
Authorization of 12 months may be granted for treatment of endometrial carcinoma.

2. Uterine Sarcoma
Authorization for 12 months may be granted for treatment of uterine sarcoma.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

V. REFERENCES

1. Taxotere [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; December 2015.
2. Docefrez [package insert]. Gujarat, India: Sun Pharmaceuticals; October 2014.
3. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. July 23, 2018.