MEDICAL PRIOR AUTHORIZATION

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 and malignant sex cord-stromal tumors
10. Prostate cancer
11. Small cell lung cancer
12. Soft tissue sarcoma (STS): angiosarcoma, rhabdomyosarcoma, retroperitoneal/intra-abdominal STS and STS of the extremity/superficial trunk, head/neck
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 when docetaxel is used as single-agent, second-line therapy for locally advanced, post cystectomy-recurrent, or metastatic disease.

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 primary carcinoma of the urethra, upper genitourinary tract tumors, or urothelial carcinoma of the prostate when docetaxel is used as single-agent, second-line therapy for recurrent or metastatic disease.

B. Bone Cancer

1. Ewing's Sarcoma

Authorization of 12 months may be granted for treatment of Ewing's sarcoma when docetaxel is prescribed for relapsed or progressive disease, or as second-line therapy for metastatic disease.

2. Osteosarcoma

Authorization of 12 months may be granted for treatment of osteosarcoma when docetaxel is prescribed as second-line therapy for relapsed/refractory or metastatic disease.

C. Breast Cancer

1. Authorization of 6 months may be granted for treatment of breast cancer when docetaxel is prescribed for preoperative/neoadjuvant or adjuvant chemotherapy.
2. Authorization of 12 months may be granted for treatment of breast cancer when docetaxel is prescribed for recurrent or metastatic disease.

D. Esophageal and Esophagogastric Junction Cancers

1. Authorization of 3 months may be granted for treatment of esophageal or esophagogastric junction cancer when the member has a locoregional disease and docetaxel is prescribed for use as chemoradiation.
2. Authorization of 12 months may be granted for treatment of esophageal or esophagogastric junction cancer when docetaxel is prescribed for palliative therapy (e.g., unresectable/medically inoperable locally advanced, locally recurrent or metastatic disease).

E. Gastric Cancer

1. Authorization of 3 months may be granted for treatment of gastric cancer in members with locoregional disease who are prescribed docetaxel for use as chemoradiation.
2. Authorization of 12 months may be granted for treatment of gastric cancer in members who are prescribed docetaxel for palliative therapy (e.g., unresectable/medically inoperable locally advanced, locally recurrent or metastatic disease).

F. Head and Neck Cancer

1. Authorization of 3 months may be granted for use as induction therapy for locally advanced non-nasopharyngeal cancer (e.g., glottic larynx, hypopharynx, supraglottic larynx).

2. Authorization of 12 months may be granted for use as primary chemotherapy for metastatic nasopharyngeal cancer.
3. Authorization of 12 months may granted for treatment of very advanced local disease, recurrent/persistent disease, unresectable/inoperable disease or metastatic disease.

G. Non-Small Cell Lung Cancer (NSCLC)

1. Authorization of 6 months may be granted for members who are prescribed docetaxel for use in any of the following settings:
   a. Neoadjuvant or induction chemotherapy
   b. Adjuvant chemotherapy
2. Authorization of 12 months may be granted for members with recurrent, locally advanced or metastatic disease who are prescribed docetaxel for use as systemic chemotherapy in any of the following settings:
   a. First-line therapy
   b. Subsequent therapy for progression following first-line cytotoxic therapy or for further progression on a systemic immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab) or other systemic therapy
   c. Subsequent therapy following prior epidermal growth factor receptor (EGFR) inhibitor therapy (e.g., erlotinib, afatinib, or gefitinib) in members with sensitizing EGFR mutation-positive tumors
   d. Subsequent therapy following prior anaplastic lymphoma kinase (ALK) inhibitor therapy (e.g., crizotinib) in members with ALK-positive tumors

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

a. Authorization of 6 months may be granted for members who are prescribed docetaxel in combination with carboplatin for neoadjuvant therapy, primary treatment or primary adjuvant treatment.
b. Authorization of 12 months may be granted for members who are prescribed docetaxel in combination with carboplatin for clinical relapse or biochemical recurrence (i.e., rising CA-125 levels) in members who have not received previous chemotherapy.
c. Authorization of 12 months may be granted for members who are prescribed docetaxel as a single agent (if platinum-resistant) or in combination with carboplatin (if platinum-sensitive) for persistent or recurrent disease.

2. Malignant Germ Cell Tumors

Authorization of 12 months may be granted for members with residual disease after primary treatment who are prescribed docetaxel in combination with carboplatin.

3. Malignant Sex-Cord Stromal Tumors

Authorization of 12 months may be granted for members who are prescribed docetaxel as a single agent for clinical relapse.

J. Prostate Cancer

1. Authorization of 12 months may be granted for members who are prescribed docetaxel for clinically localized, high-risk disease or locally advanced, very high risk disease.
2. Authorization of 12 months may be granted for members who are prescribed docetaxel for metastatic disease.

K. Small Cell Lung Cancer (SCLC)

Authorization of 12 months may be granted for members who are prescribed docetaxel for subsequent chemotherapy as a single agent.

L. Soft Tissue Sarcoma (STS)

1. Angiosarcoma

Authorization of 12 months may be granted for treatment of angiosarcoma.

2. Retroperitoneal or Intra-abdominal STS
Authorization of 12 months may be granted for treatment of retroperitoneal or intra-abdominal STS.

3. Rhabdomyosarcoma
Authorization of 12 months may be granted for treatment of pleomorphic rhabdomyosarcoma.

4. STS of the Extremity, Superficial Trunk, Head and Neck
Authorization of 12 months may be granted for treatment of STS of the extremity, superficial trunk or head and neck.

M. Thyroid Carcinoma – Anaplastic Carcinoma
Authorization of 12 months may be granted for treatment of locoregional or metastatic disease.

N. Uterine Neoplasms

1. Endometrial Carcinoma
Authorization of 12 months may be granted for members in whom paclitaxel is contraindicated and docetaxel is prescribed in combination with carboplatin.

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

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