

Docetaxel (Taxotere®)	
<input checked="" type="checkbox"/> Original	Original Committee Approval: 12/3/08
<input type="checkbox"/> Revised	Last Committee Approval: 12/3/08
	Last Review: October, 2008

Background

Docetaxel (Taxotere®, Sanofi-aventis) belongs, with a related drug Paclitaxel (Taxol®, Bristol-Myers Squibb, Princeton, NJ) to an important new class of anticancer agents known as the taxanes. These drugs are derived from compounds found in the bark and needles of the European yew tree (*Taxus baccata*), and display potent antineoplastic properties. Docetaxel disrupts the microtubular network in cells, which is essential for mitotic and interphase cellular functions. It does so by causing the production of microtubule bundles without healthy function and the subsequent stabilization of these microtubules. This results in the inhibition of mitosis in cells.

Taxanes are now considered to be among the standard options for adjuvant (post-operative) treatment of breast cancer. Docetaxel was first approved by the FDA in May 1996 for the treatment of patients with locally advanced or metastatic breast cancer who have progressed during anthracycline-based (e.g., doxorubicin) therapy or have relapsed during anthracycline-based adjuvant therapy. Subsequent to this, Docetaxel has been approved by the FDA and has received recommendations from the National Cancer Care Network (NCCN) for the additional indications as specified below.

Indications/Criteria

Docetaxel is considered medically necessary for the following indications:

Breast Cancer

- Treatment for locally advanced or metastatic breast cancer after failure of prior chemotherapy.
- In combination with doxorubicin and cyclophosphamide for the adjuvant (post-operative) treatment of operable node-positive breast cancer

Non-Small Cell Lung Cancer

- As a single agent for the treatment of locally advanced or metastatic disease after failure of prior platinum-based chemotherapy
- In combination with cisplatin for the treatment of unresectable, locally advanced or metastatic disease not previously treated with chemotherapy

Prostate Cancer

- In combination with prednisone for the treatment of androgen independent (hormone refractory) metastatic disease

Gastric Adenocarcinoma

- In combination with cisplatin and fluorouracil in the treatment of advanced disease (including adenocarcinoma of the gastroesophageal junction) not previously treated with chemotherapy

Head and Neck Cancer

- In combination with cisplatin and fluorouracil for the induction (high-dose, pre-operative) treatment of patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN)

Ovarian Cancer:

- In combination with cisplatin as first-line therapy for Stage IIB-IV disease

CHP considers Docetaxel experimental and investigational, alone or in combination with other chemotherapeutic agents, for the following indications:

- Neoadjuvant (pre-operative) use in primary breast cancer which is node positive
- Small cell lung cancer
- Urothelial/bladder cancer
- Esophageal cancer
- Soft tissue sarcoma

Special Considerations

Hepatic function impairment:

Docetaxel therapy requires frequent monitoring of hepatic function. Patients with elevations of bilirubin or with abnormalities of transaminases and alkaline phosphatase are at increased risk for the development of significant neutropenia, febrile neutropenia, infections, severe thrombocytopenia, severe stomatitis, severe skin toxicity, and toxic death.

Neutropenia:

Docetaxel is contraindicated in patients with neutrophil counts of less than $1,500/\text{mm}^3$. Frequent blood count monitoring is required in order to avoid the occurrence of neutropenia, which may be severe and result in serious infection.

Limitations/Exclusions

Healthy Options:	None; pre-authorization required.
Basic Health Plan:	None; pre-authorization required.
GAU:	None; pre-authorization required.
Medicare Advantage:	None; pre-authorization required.

Required Review and Approvals:

Docetaxel (Taxotere®) infusions require prior authorization by the CHP Medical Director or his/her designee. Each authorization period will be for six months.

All requests for this IV medication also require referral to CHP Case Management.

References:

- National Cancer Institute (www.cancer.gov)
- Federal Drug Administration (www.fda.gov)
- Facts and Comparisons 4.0 (<http://online.factsandcomparisons.com>)
- Hayes, Inc., 2008 (www.hayesinc.com)
- National Comprehensive Cancer Network, Clinical Practice Guidelines in Oncology™ (www.nccn.org)
- UpToDate Online, 16.2 (www.uptodate.com)