



Docetaxel (Taxotere®)

Revision: 3

Policy Number: M-0012

Last Update: 6/4/2014

Payment will not be made for any use of these drugs outside of the criteria without prior authorization. The member may not be billed unless the member explicitly agrees in writing to be responsible for the charges in accordance with the contract/provider manual. Prior authorization will only be given if the provider demonstrates the intended use meets Medicare coverage guidelines.

When appropriate compendia references the use of one of the chemotherapeutic agents listed in this Article as part of a 'combination therapy', the drug is only approved for use in such 'combinations', and the documentation should reflect, and be specific about, the use of the additional 'combination therapy' drugs.

Coverage Guidelines:

FDA Indications

- Breast Cancer (BC): single agent for locally advanced or metastatic BC after chemotherapy failure; and with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive BC
- Non-Small Cell Lung Cancer (NSCLC): single agent for locally advanced or metastatic NSCLC after platinum therapy failure; and with cisplatin for unresectable, locally advanced or metastatic untreated NSCLC
- Hormone Refractory Prostate Cancer (HRPC): with prednisone in androgen independent (hormone refractory) metastatic prostate cancer
- Gastric Adenocarcinoma (GC): with cisplatin and fluorouracil for untreated, advanced GC, including the gastroesophageal junction
- Squamous Cell Carcinoma of the Head and Neck Cancer (SCCHN): with cisplatin and fluorouracil for induction treatment of locally advanced SCCHN

Off Labeled Indications

- Breast cancer, Locally advanced/metastatic disease, as first-line chemotherapy
- Breast cancer, Neoadjuvant treatment in combination with an anthracycline-containing regimen

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- Carcinoma of bladder
- Carcinoma of esophagus
- Carcinoma of prostate
- Harvesting of peripheral blood stem cells, Mobilization
- Head and neck cancer
- Ovarian cancer, Advanced, previously treated
- Ovarian cancer, First line in combination with carboplatin
- Small cell carcinoma of lung

Coding Information:

HCPCS Code(s)

J9171	INJECTION, DOCETAXEL, 1 MG
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ICD-9 Code(s)

140.0 - 149.9	MALIGNANT NEOPLASM OF UPPER LIP VERMILION BORDER - MALIGNANT NEOPLASM OF ILL-DEFINED SITES WITHIN THE LIP AND ORAL CAVITY
150.0 - 150.9	MALIGNANT NEOPLASM OF CERVICAL ESOPHAGUS - MALIGNANT NEOPLASM OF ESOPHAGUS UNSPECIFIED SITE
151.0 - 151.9	MALIGNANT NEOPLASM OF CARDIA – MALIGNANT NEOPLASM OF STOMACH UNSPECIFIED SITE
158.0	MALIGNANT NEOPLASM OF RETROPERITONEUM
158.8	MALIGNANT NEOPLASM OF SPECIFIED PARTS OF PERITONEUM
158.9	MALIGNANT NEOPLASM OF PERITONEUM UNSPECIFIED
160.0 - 160.9	MALIGNANT NEOPLASM OF NASAL CAVITIES - MALIGNANT NEOPLASM OF ACCESSORY SINUS UNSPECIFIED
161.0 - 161.9	MALIGNANT NEOPLASM OF GLOTTIS – MALIGNANT NEOPLASM OF LARYNX UNSPECIFIED
162.0 - 162.9	MALIGNANT NEOPLASM OF TRACHEA - MALIGNANT NEOPLASM OF BRONCHUS AND LUNG UNSPECIFIED
171.0 - 171.9	MALIGNANT NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE OF HEAD FACE AND NECK - MALIGNANT NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE SITE UNSPECIFIED
173.00 - 173.49	UNSPECIFIED MALIGNANT NEOPLASM OF SKIN OF LIP - OTHER SPECIFIED MALIGNANT NEOPLASM OF SCALP AND SKIN OF NECK
174.0 - 174.9	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF FEMALE BREAST - MALIGNANT NEOPLASM OF BREAST (FEMALE) UNSPECIFIED SITE
175.0 - 175.9	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF MALE BREAST - MALIGNANT NEOPLASM OF OTHER AND UNSPECIFIED SITES OF MALE BREAST

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179	MALIGNANT NEOPLASM OF UTERUS-PART UNS
180.0-	MALIGNANT NEOPLASM OF ENDOCERVIX –
180.9	MALIGNANT NEOPLASM OF CERVIX UTERI UNSPECIFIED SITE
182.0	MALIGNANT NEOPLASM OF CORPUS UTERI EXCEPT ISTHMUS
182.1	MALIGNANT NEOPLASM OF ISTHMUS
182.8	MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF BODY OF UTERUS
183.0	MALIGNANT NEOPLASM OF OVARY
183.2 -	MALIGNANT NEOPLASM OF FALLOPIAN TUBE - MALIGNANT NEOPLASM OF ROUND
183.5	LIGAMENT OF UTERUS
183.8	MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF UTERINE ADNEXA
183.9	MALIGNANT NEOPLASM OF UTERINE ADNEXA UNSPECIFIED SITE
185	MALIGNANT NEOPLASM OF PROSTATE
188.0 -	MALIGNANT NEOPLASM OF TRIGONE OF URINARY BLADDER - MALIGNANT
188.9	NEOPLASM OF BLADDER PART UNSPECIFIED
189.1 -	MALIGNANT NEOPLASM OF RENAL PELVIS - MALIGNANT NEOPLASM OF URETHRA
189.3	
195.0	MALIGNANT NEOPLASM OF HEAD FACE AND NECK
198.82	SECONDARY MALIGNANT NEOPLASM OF GENITAL ORGANS
199.1	OTHER MALIGNANT NEOPLASM OF UNSPECIFIED SITE

Background:

Taxotere is an anti-mitotic chemotherapy medication (that is, it interferes with cell division). It is used mainly for the treatment of breast, ovarian, prostate, and non-small cell lung cancer.

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Black Box Warning:

WARNINGS:

The incidence of treatment-related mortality associated with Taxotere® therapy is increased in patients with abnormal liver function, in patients receiving higher doses, and in patients with non-small cell lung carcinoma and a history of prior treatment with platinum-based chemotherapy who receive Taxotere® as a single agent at a dose of 100 mg/m²

- Taxotere® should not be given to patients with bilirubin >upper limit of normal (ULN), or to patients with AST and/or ALT >1.5 X ULN concomitant with alkaline phosphatase >2.5 X ULN
 - Patients with elevations of bilirubin or abnormalities of transaminase concurrent with alkaline phosphatase are at increased risk for the development of grade 4 neutropenia, febrile neutropenia, infections, severe thrombocytopenia, severe stomatitis, severe skin toxicity, and toxic death
 - Patients with isolated elevations of transaminase >1.5 X ULN also had a higher rate of febrile neutropenia grade 4 but did not have an increased incidence of toxic death
 - Bilirubin, AST or ALT, and alkaline phosphatase values should be obtained prior to each cycle of Taxotere® therapy
- Taxotere® therapy should not be given to patients with neutrophil counts of <1500 cells/mm³
 - In order to monitor the occurrence of neutropenia, which may be severe and result in infection, frequent blood cell counts should be performed on all patients receiving Taxotere®
- Severe hypersensitivity reactions characterized by generalized rash/erythema, hypotension and/or bronchospasm, or very rarely fatal anaphylaxis, have been reported in patients who received the recommended 3-day dexamethasone premedication
 - Hypersensitivity reactions require immediate discontinuation of Taxotere® infusion and administration of appropriate therapy
- Taxotere® must not be given to patients who have a history of severe hypersensitivity reactions to Taxotere® or to other drugs formulated with polysorbate 80
- Severe fluid retention occurred in 6.5% (6/92) of patients despite use of a 3-day dexamethasone premedication regimen. It was characterized by one or more of the following events: poorly tolerated peripheral edema, generalized edema, pleural effusion requiring urgent drainage, dyspnea at rest, cardiac tamponade, or pronounced abdominal distention (due to ascites)

Definitions:

HCPCS Code—Healthcare Common Procedure Coding System - A system of letter and number codes assigned to procedures, medications, supplies and equipment used for pricing and billing.

ICD-9 Code—International Classification of Disease, 9th edition. A standardized classification of disease, injuries, and causes of death, by etiology and anatomic localization and codified into a 6-digit number, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both US and internationally.



Mitotic Inhibitor—a drug that inhibits mitosis, or cell division. These drugs disrupt microtubules, which are structures that pull the cell apart when it divides. Mitotic inhibitors are used in cancer treatment, because cancer cells are able to grow and eventually spread through the body (metastasize) through continuous mitotic division and so are more sensitive to inhibition of mitosis than normal cells. Mitotic inhibitors are also used in cytogenetics (the study of chromosomes), where they stop cell division at a stage where chromosomes can be easily examined.

References:

1. Taxotere [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S., LLC; 2010. Available at: <http://products.sanofi.us/taxotere/taxotere.html>. Accessed May 29, 2012.
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3. Local Coverage Article for Drugs and Biologicals – Chemotherapeutic Agents (A48896) R4. Available at http://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=48896&ver=89&ContrlD=213&ContrVer=1&CntrctrSelected=213*1&Date=01%2f01%2f2013&DocID=A48896&bc=hAAAAAgAEAAAA%3d%3d&. Accessed June 4, 2014.
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Document History:

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