09-J0000-95

Original Effective Date: 04/15/09

Reviewed: 05/14/25

Revised: 07/01/25

Subject: Docetaxel Products

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Docetaxel (Taxotere) is a semisynthetic antineoplastic that is similar to paclitaxel (Taxol) in structure, mechanism of action, and spectrum of anti-tumor activity. Docetaxel was isolated in 1986 as a result of the National Cancer Institute (NCI) screening program for natural cytotoxic products. It is synthesized from a substance extracted from the needles of the European yew tree (Taxus baccata). Docetaxel exerts is anti-cancer effects by disrupting the function of microtubules, which are essential for cell survival. It also antagonizes the anti-apoptotic gene Bc12 and encourages expression of p27, a cell-cycle inhibitor. Ultimately, docetaxel prevents new cells from forming, causes existing cells to undergo apoptosis, and stops other cells from maturing and replicating.

Docetaxel was initially approved by the US Food and Drug Administration (FDA) in May 1996 for the treatment of refractory, locally advanced or metastatic breast cancer; in August 2004, docetaxel in combination with doxorubicin (Adriamycin) and cyclophosphamide (Cytoxan) was approved as adjuvant therapy in persons with breast cancer that was lymph node positive. Additional indications for the use of docetaxel have been approved by the FDA, including the treatment of advanced or metastatic non-small cell lung cancer after failure of platinum containing chemotherapy (December 1999), the treatment of metastatic, hormone-refractory prostate cancer in combination with prednisone (May 2004), the treatment of advanced gastric cancer in combination with cisplatin (Platinol) and 5-fluorouracil (Adrucil) (March 2006), and the treatment of locally advanced, squamous cell head and neck cancer in combination with cisplatin and 5-fluorouracil (October 2006).

In addition to its position as a treatment of choice within its licensed indications, the use of docetaxel for the treatment of a variety of off-label indications is supported by National Comprehensive Cancer Network guidelines and other standard reference compendia.

POSITION STATEMENT:

Docetaxel (Taxotere, Beizray, Docivyx) IV **meets the definition of medical necessity** when **ALL** of the following are met:

administered for any of the following indications and dosage does not exceed 100 mg/meter squared:

1. Indication for use is one of the following;
    a. Anaplastic thyroid carcinoma
    b. Bladder cancer
    c. Bone cancer
    d. Breast cancer
    e. Endometrial carcinoma
    f. Esophageal and esophagogastric junction cancer
    g. Gastric adenocarcinoma
    h. Head and neck cancer
    i. Non-small cell lung cancer (NSCLC)
    j. Occult primary tumors (cancer of unknown primary)
    k. Ovarian cancer (including epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer)
    l. Prostate cancer
    m. Small cell lung cancer
    n. Soft tissue sarcoma
    o. Uterine neoplasms
    p. Other FDA-approved or NCCN supported diagnosis (not previously listed above)
        i. Member meets one of the following:
            - Member is diagnosed with a condition that is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert) AND member meets any additional requirements listed in the "Indications and Usage" section of the FDA-approved prescribing information (or package insert)
            - Indication AND usage is recognized in NCCN Drugs and Biologics Compendium as a Category 1 or 2A recommendation
2. Dose does not exceed 100 mg/m^2
3. Beizray and Docivyx only: Docetaxel (Taxotere) is unavailable due to national drug shortage

    Note: To verify non-availability, the status of docetaxel (Taxotere) must be listed as "Currently in Shortage" on the FDA Drug Shortages webpage http://www.accessdata.fda.gov/scripts/drugshortages/) **AND** all listed manufactures must have all strengths unavailable.

Approval duration: 1 year

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved: docetaxel is FDA-approved for the following indications

- Breast Cancer
- Non-Small Cell Lung Cancer (NSCLC)
- Prostate Cancer
- Gastric Adenocarcinoma
- Head and Neck Cancer

Docetaxel is administered as an intravenous (IV) infusion over 1 hour. The appropriate dose is based on the indication. The typical dose is 60-100 mg/m2 every 3 weeks. For all indications, toxicities may warrant dosage adjustments. Docetaxel administration has been associated with complications, including anaphylaxis; as such, it should be administered in a facility equipped to manage complications.

Drug Availability: docetaxel is available in a variety of concentrations and formulations including a concentrate for solution for injection and a non-concentrate solution for injection.

PRECAUTIONS:

Boxed Warning:

- Treatment-related mortality increases with abnormal liver function, at higher doses, and in persons with NSCLC and prior platinum-based therapy receiving docetaxel at 100 mg/m2
- Docetaxel should not be administered if bilirubin > ULN, or if AST and/or ALT > 1.5 × ULN concomitant with alkaline phosphatase > 2.5 × ULN. LFT elevations increase risk of severe or life-threatening complications. Obtain LFTs before each treatment cycle
- Docetaxel should not be administered if neutrophil counts are < 1500 cells/mm3. Obtain frequent blood counts to monitor for neutropenia
- Severe hypersensitivity, including very rare fatal anaphylaxis, has been reported in patients who received dexamethasone premedication. Severe reactions require immediate discontinuation of docetaxel and administration of appropriate therapy (5.4)
- Docetaxel is contraindicated in persons with a history of severe hypersensitivity reactions to docetaxel or to drugs formulated with polysorbate 80 (4)
- Severe fluid retention may occur despite dexamethasone pre-medication.

Warnings:

Acute myeloid leukemia: in persons administered docetaxel, doxorubicin and cyclophosphamide monitor for delayed myelodysplasia or myeloid leukemia.

Cutaneous reactions: reactions including erythema of the extremities with edema followed by desquamation may occur. Severe skin toxicity may require dose adjustment.

Neurologic reactions: reactions including paresthesia, dysesthesia, and pain may occur. Severe neurosensory symptoms require dose adjustment or discontinuation if persistent.

Asthenia: severe asthenia may occur and may require treatment discontinuation.

Pregnancy: Fetal harm can occur when docetaxel is administered to pregnant women. Women of childbearing potential should be advised not to become pregnant when receiving docetaxel.

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding

J9171	Injection, docetaxel, 1 mg
J9172	Injection, docetaxel (Docivyx), 1 mg
J9174	Injection, docetaxel (Beizray), 1 mg

ICD-10 Diagnosis Codes That Support Medical Necessity

C00.0 – C02.9	Malignant neoplasm of lip, base of tongue and other and unspecified part of tongue
C03.0 – C03.9	Malignant neoplasm of gum
C04.0 – C04.9	Malignant neoplasm of floor of mouth
C05.0 – C06.9	Malignant neoplasm of palate and other and unspecified parts of ought
C07	Malignant neoplasm of parotid gland
C09.0 – C10.9	Malignant neoplasm of tonsil and oropharynx
C11.0 – C11.9	Malignant neoplasm of nasopharynx
C12 – C13.9	Malignant neoplasm of pyriform sinus and hypopharynx
C14.0 – C14.8	Malignant neoplasm of other and ill-defined sites in the lip, oral cavity and pharynx
C15.3 – C15.9	Malignant neoplasm of esophagus
C16.0 – C16.9	Malignant neoplasm of stomach
C26.9	Malignant neoplasm of ill-defined sites within the digestive system
C31.0 – C31.1	Malignant neoplasm of maxillary sinus and ethmoidal sinus
C32.0 – C32.9	Malignant neoplasm of larynx
C33 – C34.92	Malignant neoplasm of trachea and bronchus and lung
C40.00 – C44.09	Malignant neoplasm of bone and articular cartilage of limbs
C41.0 – C41.9	Malignant neoplasm of bone and articular cartilage of other and unspecified sites
C44.00	Unspecified malignant neoplasm of skin of lip
C44.01	Basal cell carcinoma of skin of lip

C44.02	Squamous cell carcinoma of skin of lip
C44.09	Other specified malignant neoplasm of skin of lip
C45.0	Mesothelioma of pleura
C45.1	Mesothelioma of peritoneum
C48.0 – C48.8	Malignant neoplasm of retroperitoneum and peritoneum
C49.0 – C49.9	Malignant neoplasm of other connective and soft tissue
C49.A0 – C49.A9	Gastrointestinal stromal tumor
C50.011 – C50.929	Malignant neoplasm of breast, female and male
C54.0 – C57.4	Malignant neoplasm of corpus uteri, uterus, part unspecified, ovary, fallopian tube, broad ligament, round ligament, parametrium and uterine adnexa, unspecified
C61	Malignant neoplasm of prostate
C63.7	Malignant neoplasm of other specified male genital organs
C63.8	Malignant neoplasm of overlapping sites of male genital organs
C65.0 – C67.9	Malignant neoplasm of unspecified renal pelvis, ureter and bladder
C68.0	Malignant neoplasm of urethra
C73	Malignant neoplasm of thyroid gland
C76.0	Malignant neoplasm of head, face and neck
C77.0	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck
C78.00 – C78.02	Secondary malignant neoplasm of lung
C79.31	Secondary malignant neoplasm of brain
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C79.89	Secondary malignant neoplasm of other specified sites
C79.9	Secondary malignant neoplasm of unspecified site
C80.0	Disseminated malignant neoplasm, unspecified
C80.1	Malignant (primary) neoplasm, unspecified
D09.0	Carcinoma in situ of bladder
D37.01	Neoplasm of uncertain behavior of lip
D37.02	Neoplasm of uncertain behavior of tongue
D37.030 – D37.039	Neoplasm of uncertain behavior of the major salivary glands
D37.04	Neoplasm of uncertain behavior of the minor salivary glands
D37.05	Neoplasm of uncertain behavior of pharynx
D37.09	Neoplasm of uncertain behavior of other specified sites of the oral cavity
D37.1	Neoplasm of uncertain behavior of stomach
D37.2	Neoplasm of uncertain behavior of small intestine
D37.3	Neoplasm of uncertain behavior of appendix
D37.4	Neoplasm of uncertain behavior of colon
D37.5	Neoplasm of uncertain behavior of rectum
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
D38.0	Neoplasm of uncertain behavior of larynx

D38.5	Neoplasm of uncertain behavior of other respiratory organs
D38.6	Neoplasm of uncertain behavior of respiratory organ, unspecified
D48.1	Neoplasm of uncertain behavior of connective and other soft tissue
D49.0 – D49.2	Neoplasm of unspecified behavior of digestive system, respiratory system and bone, soft tissue, and skin
D49.511	Neoplasm of unspecified behavior of right kidney
D49.512	Neoplasm of unspecified behavior of left kidney
D49.519	Neoplasm of unspecified behavior of unspecified kidney
D49.59	Neoplasm of unspecified behavior of other genitourinary organ
D49.6	Neoplasm of unspecified behavior of brain
D49.81 – D49.9	Neoplasm of unspecified behavior of retina and choroid, other specified sites and unspecified site
G73.1	Lambert-Eaton syndrome

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: The following Local Coverage Determination (LCD) was reviewed on the last guideline revised date: DOCETAXEL (Taxotere®) (L33989) located at fcso.com. No National Coverage Determination (NCD) was found at the time of the last guideline revised date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

Azacitidine (Vidaza®) Injection, 09-J0000-84
Cabazitaxel (Jevtana®) 09-J1000-77
Carboplatin (Paraplatin®) IV, 09-J0000-93
Doxorubicin HCl Liposome (Doxil®) IV, 09-J0000-91
Enzalutamide (Xtandi®), 09-J1000-85

Fulvestrant (Faslodex®) IM, 09-J1000-04
Gemcitabine (Gemzar®), 09-J0000-96
Irinotecan HCl (Camptosar®) IV, 09-J0000-99
Octreotide Acetate (Sandostatin LAR® Depot) Injection, 09-J0000-90
Oxaliplatin (Eloxatin®) IV, 09-J1000-00
Pemetrexed (Alimta®) IV, 09-J1000-01
Rituximab (Rituxan®), 09-J0000-59
Sipuleucel-T (Provenge), 09-J1000-29
Topotecan HCl (Hycamtin®) IV, 09-J1000-02
Trastuzumab (Herceptin®) Injection, 09-J0000-86
Vinorelbine Tartrate (Navelbine®) IV, 09-J1000-03

OTHER:

None applicable.

REFERENCES:

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 05/14/25.

GUIDELINE UPDATE INFORMATION:

04/15/09	New Medical Coverage Guideline.
10/15/09	Revision to guideline; consisting of clarifying dosage and updating coding.
01/01/10	Annual HCPCS coding update: added HCPCS code J9171 and deleted code J9170.
01/15/10	Revision to guideline; consisting of updating coding.
04/15/10	Review and revision to guideline; consisting of updating codes and references.
08/01/10	Revision to guideline; consisting of updating coding.

11/15/10	Revision to guideline; consisting of updating coding.
04/15/11	Review and revision to guideline; consisting of updating references.
05/15/11	Revision to guideline; consisting of adding new indication and updating coding.
10/01/11	Revision to guideline; consisting of updating coding.
04/15/12	Review and revision to guideline; consisting of updating precautions, coding and references.
10/15/12	Revision to guideline; consisting of adding penile cancer and removing cervical and pancreatic cancer indications and updating coding.
12/15/12	Revision to guideline; consisting of updating coding.
04/15/13	Review and revision to guideline; consisting of revising position statement to include malignant melanoma and approval duration; revising and reformatting description, dosage/administration, and precautions sections; and updating references, related guidelines, and coding.
04/15/14	Review and revision to guideline; consisting of position statement, program exceptions, references.
04/15/15	Review and revision to guideline; consisting of position statement, references, coding.
10/01/15	Revision to guidelines consisting of coding updates and update to Program Exceptions section.
11/01/15	Revision: ICD-9 Codes deleted.
04/15/16	Review and revision; updated description, position statement, coding, references.
07/15/16	Revision to guideline; consisting of updating ICD10 codes.
10/01/16	Revision to guideline; consisting of updating ICD10 codes.
04/15/17	Review and revision to guidelines; updated references.
04/15/18	Review and revision to guidelines; updated position statement and references.
04/15/19	Review and revision to guidelines; updated position statement and references.
01/01/24	Revision: Added HCPCS code J9172.
07/01/24	Revision: Grammatical revision to HCPCS code J9172.
10/01/24	Revision: Updated description of HCPCS code J9172.
07/01/25	Revision to guideline, updated position statement and coding.