

Medical Drug Clinical Criteria

Subject:	Docetaxel (Taxotere)		
Document #:	CC-0093	Publish Date:	03/27/202304/01/2024
Status:	Revised	Last Review Date:	02/24/202302/23/2024

Table of Contents

Overview	Coding	References
Clinical criteria	Document history	

Overview

This document addresses the use of docetaxel (Taxotere). Docetaxel is a taxane derivative that acts by disrupting the microtubular network in cells that is essential for mitotic and interphase cellular functions. Docetaxel is used in the treatment of various types of cancer including breast cancer, lung cancer and head and neck cancer.

The FDA approved indications for docetaxel include the following:

- Breast cancer: locally advanced or metastatic breast cancer after failure of prior chemotherapy or in combination with doxorubicin and cyclophosphamide for the adjuvant treatment of those with operable node positive breast cancer
- Non-small cell lung cancer (NSCLC): locally advanced or metastatic NSCLC after failure of prior platinum- based chemotherapy; in combination with cisplatin for unresectable, locally advanced or metastatic NSCLC in those who have not previously received chemotherapy
- Prostate cancer: in combination with prednisone for metastatic castration-resistant prostate cancer
- Gastric adenocarcinoma: in combination with cisplatin and fluorouracil for advanced gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, in those who have not received prior chemotherapy for advanced disease
- Head and neck cancer: In combination with cisplatin and fluoruracil for induction treatment of locally advanced squamous cell carcinoma of the head and neck (SCCHN)

The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the use of docetaxel:

- Bladder cancer, including urothelial carcinoma of the bladder, primary carcinoma of the urethra, upper genitourinary (GU) tract tumors and urothelial carcinoma of the prostate
- Bone cancer, including Ewing's sarcoma and osteosarcoma
- Esophageal and esophagogastric junction cancer
- Small cell lung cancer (SCLC)
- Occult primary tumors – adenocarcinoma and squamous cell carcinoma
- Ovarian cancer, including fallopian tube cancer and primary peritoneal cancer
- Small Bowel Adenocarcinoma
- Soft tissue sarcoma
- Thyroid carcinoma – anaplastic carcinoma in combination with doxorubicin
- Uterine neoplasms

Docetaxel is also used in the treatment of penile cancer. Historic NCCN Penile Cancer Guidelines (V1.2014) stated "palliative options may include docetaxel as a single agent." Current NCCN Penile Cancer Guidelines (V2.2018) report that no standard subsequent-line systemic therapy exists. NCCN recommends consideration of participation in a clinical trial as data are limited for second-line therapy. However, specialty consensus opinion suggests that docetaxel may be considered as a treatment option for penile cancer.

Other Uses

NCCN also provides a 2A recommendation (formerly 2B) for second-line or subsequent therapy as a single agent for recurrent or metastatic cervical cancer. One phase II trial is cited which evaluated 23/27 enrolled (Garcia et.al. 2007). 2 individuals had a partial response, 8 had stable disease and 9 had increasing disease. The study concluded that docetaxel had minimal activity in refractory squamous cell carcinoma of the cervix.

Docetaxel has a black box warning regarding treatment mortality increases with abnormal liver function, at higher doses, and in those with NSCLC and prior platinum-based therapy receiving docetaxel at 100 mg/m². Docetaxel should not be given if bilirubin is greater than upper limit of normal (ULN) or if AST and/or ALT are greater than 1.5 time ULN concomitant with alkaline phosphatase > 2.5 ULM. Liver function tests (LFTs) should be obtained before each treatment cycle. Docetaxel should not be given if neutrophil counts are less than 1,500 cells/mm³. The black box also includes warnings regarding severe hypersensitivity and fluid retention.

Definitions and Measures

Adenocarcinoma: Cancer originating in cells that line specific internal organs and that have gland-like (secretory) properties.

Adjuvant therapy: Treatment given after the primary treatment to increase the chances of a cure; may include chemotherapy, radiation, hormone or biological therapy.

Chemotherapy: Medical treatment of a disease, particularly cancer, with drugs or other chemicals.

Line of Therapy:

- First-line therapy: The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
- Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (second-line therapy) are not effective or there is disease progression.

Locally advanced cancer: Cancer that has spread only to nearby tissues or lymph nodes.

Malignant: Cancerous. Malignant cells can invade and destroy nearby tissue and spread to other parts of the body.

Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

Microtubule inhibitors (MTI): A class of drugs including taxanes, vinca alkaloids, and epothilones that stabilize or destabilize microtubules, thereby suppressing microtubule dynamics required for proper mitotic function, effectively blocking cell cycle progression and resulting in cell death.

Non-small cell lung cancer: A group of lung cancers that are named for the kinds of cells found in the cancer and how the cells look under a microscope. The three main types of non-small cell lung cancer are squamous cell carcinoma, large cell carcinoma, and adenocarcinoma.

Primary treatment: The first treatment given for a disease. It is often part of a standard set of treatments, such as surgery followed by chemotherapy and radiation. Also called first-line therapy, induction therapy, and primary therapy.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Taxane: A type of mitotic inhibitor and antimicrotubule drug used to treat cancer that blocks cell growth by stopping mitosis (cell division).

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Docetaxel (Taxotere)

Requests for docetaxel (Taxotere, Docefrez) may be approved if the individual has any of the following conditions:

- I. Bladder cancer (NCCN 2A); **OR**
- II. Bone cancer (NCCN 2A):
 - A. Used in combination with gemcitabine with or without vincristine as second-line therapy for Ewing's sarcoma; **OR**
 - B. Used in combination with gemcitabine as second-line therapy for Osteosarcoma; **OR**
- III. Breast cancer (Label, NCCN 1, 2A); **OR**
- IV. Esophageal and esophagogastric junction cancers (NCCN 1,2A); **OR**

- V. Gastric (stomach) adenocarcinoma; **AND**
 A. Not using in combination with irinotecan;
- OR**
- VI. Head and neck cancer (Label, NCCN 1, 2A); **AND**
 A. Not using in combination with cetuximab;
- V-OR**
- VI-VII. Lung cancer (non-small cell lung cancer [Label, NCCN 1, 2A], and small cell lung cancer (NCCN 2A); **OR**
- VII-VIII. Occult primary tumors (cancer of unknown primary) (NCCN 2A):
 A. Adenocarcinoma; **OR**
 B. Squamous cell carcinoma; **OR**
- VIII-IX. Ovarian cancer, including fallopian tube cancer and primary peritoneal cancer (NCCN 1, 2A); **OR**
- IX-X. Penile cancer; **OR**
- X-XI. Prostate cancer (Label, NCCN 1, 2A); **OR**
- XI-XII. Small Bowel Adenocarcinoma (NCCN 2A); **OR**
- XII-XIII. Soft tissue sarcoma (NCCN 2A); **OR**
- XIII-XIV. Thyroid Carcinoma - Anaplastic Carcinoma:
 A. Used in combination with doxorubicin for stage IVA or IVB (locoregional) disease (NCCN 2A); **OR**
 B. Used as a single agent with concurrent radiation (NCCN 2A);
- OR**
- XV. Uterine neoplasms (NCCN 2A);
 A. Used in combination with carboplatin as first-line therapy for systemic therapy in recurrent disease; **OR**
 B. Used in combination with gemcitabine as first-line therapy for systemic therapy in advanced, recurrent/metastatic or inoperable disease.

Formatted: Font: Bold

Formatted: Font: Bold

Formatted: Outline numbered + Level: 2 + Numbering
 Style: A, B, C, ... + Start at: 1 + Alignment: Left +
 Aligned at: 0.75" + Tab after: 1" + Indent at: 1"

Formatted: No bullets or numbering, Tab stops:
 0.13", Left

Formatted: Font: Bold

Formatted: No bullets or numbering

Formatted: No underline

Formatted: Outline numbered + Level: 2 + Numbering
 Style: A, B, C, ... + Start at: 1 + Alignment: Left +
 Aligned at: 0.75" + Tab after: 1" + Indent at: 1"

Requests for docetaxel (Taxotere) may not be approved when the above criteria are not met and for all other indications

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9171	Injection, docetaxel, 1 mg [Docefrez, Taxotere]
J9172	Injection, docetaxel (ingenus) not therapeutically equivalent to j9171, 1 mg

ICD-10 Diagnosis

C00.0-C14.8	Malignant neoplasm of lip, oral cavity, and pharynx
C15.30-C16.9	Malignant neoplasm of esophagus, stomach
C17.0-C17.9	Malignant neoplasm of small intestine
C30.0-C32.9	Malignant neoplasm of nasal cavities, ear, sinuses, larynx
C33-C34.92	Malignant neoplasm of trachea, bronchus and lung
C40.00-C41.9	Malignant neoplasm of bone and articular cartilage of limbs, other and unspecified sites
C44.02	Squamous cell carcinoma of skin of lip
C44.121-C44.129	Squamous cell carcinoma of skin of eyelid, including canthus
C44.221-C44.229	Squamous cell carcinoma of skin of ear and external auditory canal
C44.320-C44.329	Squamous cell carcinoma of skin of other and unspecified parts of face
C44.42	Squamous cell carcinoma of skin of scalp and neck
C48.0-C48.8	Malignant neoplasm of retroperitoneum and peritoneum
C49.0-C49.9	Malignant neoplasm of other connective and soft tissue
C50.011-C50.929	Malignant neoplasm of breast
C53.0-C53.9	Malignant neoplasm of endocervix
C54.0-C55	Malignant neoplasm of corpus uteri, uterus part unspecified
C56.1-C57.9	Malignant neoplasm of ovary, other and unspecified female genital organs

C60.0-C60.9	Malignant neoplasm of penis
C61	Malignant neoplasm of prostate
C64.1-C66.9	Malignant neoplasm of kidney, renal pelvis, ureter
C67.0-C67.9	Malignant neoplasm of 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
C79.81	Secondary malignant neoplasm of breast
C79.82	Secondary malignant neoplasm of genital organs
C79.89	Secondary malignant neoplasm of other specified sites [thyroid]
C80.0-C80.1	Malignant neoplasm without specification of site
D00.00-D00.2	Carcinoma in situ of lip, oral cavity, pharynx, esophagus, stomach
D02.0	Carcinoma in situ of larynx
D02.20-D02.22	Carcinoma in situ of bronchus and lung
D05.00-D05.92	Carcinoma in situ of breast
D07.39	Carcinoma in situ of other female genital organs
D09.0	Carcinoma in situ of bladder
D09.3	Carcinoma in situ of thyroid and other endocrine glands
Z85.01	Personal history of malignant neoplasm of esophagus
Z85.028	Personal history of other malignant neoplasm of stomach
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.21-Z85.22	Personal history of malignant neoplasm of larynx, nasal cavities, middle ear, and accessory sinuses
Z85.3	Personal history of malignant neoplasm of breast
Z85.43	Personal history of malignant neoplasm of ovary
Z85.46	Personal history of malignant neoplasm of prostate
Z85.51	Personal history of malignant neoplasm of bladder
Z85.59	Personal history of malignant neoplasm of other urinary tract organ [urethra]
Z85.810-Z85.819	Personal history of malignant neoplasm of lip, oral cavity, and pharynx
Z85.830	Personal history of malignant neoplasm of bone
Z85.850	Personal history of malignant neoplasm of thyroid

Document History

Revised: 02/23/2024

Document History:

- 02/23/2024 – Annual Review: For existing gastric cancer criteria, add criteria to exclude use in combination with irinotecan (NCCN 2B). For existing head and neck cancer criteria, add criteria to exclude use in combination with cetuximab (NCCN 2B). For existing uterine neoplasm criteria, add criteria for use in combination with carboplatin or gemcitabine as first-line therapy in systemic therapy. Add references. Coding Reviewed: No changes.
- 02/24/2023 – Annual Review: Add 2A recommendation for use in Small Bowel Adenocarcinoma. Clarify current criteria language for Bone Cancer and Thyroid Cancer. Clarify criteria with references. Coding Reviewed: Added ICD-10-CM C17.0-C17.9. Effective 1/1/2024 Added HCPCS J9172.
- 02/25/2022 – Annual Review: No changes. Coding Reviewed: No changes.
- 02/19/2021 – Annual Review: No changes. Coding Reviewed: No changes.
- 02/21/2020 – Annual Review: Remove examples of bladder cancer for conciseness. Remove obsolete brand Docefrez from document. Wording and formatting changes. Coding reviewed: No changes. 7/20/2020: Added ICD-10-CM C53.0-C53.9

- 05/17/2019 – Annual Review: Initial review of docetaxel. Wording and formatting changes. Coding reviewed: No changes.

References

1. Aldrich JD, Raghav KPS, Varadhachary GR, et al. Retrospective analysis of taxane-based therapy in small bowel adenocarcinoma. *Oncologist*. 2019;24:e384-6.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2024. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Garcia AA, Blessing JA, Vaccarello L, Roman LD. Phase II clinical trial of docetaxel in refractory squamous cell carcinoma of the cervix: a Gynecologic Oncology Group Study. *Am J Clin Oncol* 2007;30:428-431. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/17762444>
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed January 11, 2024
 - a. Anal Carcinoma. V1.2023. Revised January 9, 2023.
 - b. Bladder cancer. V3.2023. Revised May 25, 2023.
 - c. Bone cancer. V1.2024. Revised August 7, 2023.
 - d. Breast cancer. V5.2023. Revised. December 5, 2023.
 - e. Cervical Cancer. V1.2024. Revised September 20, 2023.
 - f. Esophageal and esophagogastric junction cancers. V3.2023. Revised August 29, 2023.
 - g. Gastric cancer. V2.2023. Revised August 29, 2023.
 - h. Head and neck cancers. V2.2024. Revised December 8, 2023.
 - i. Non-Small Cell Lung Cancer. V1.2024. Revised December 21, 2023.
 - j. Occult primary. V1.2024. Revised September 06, 2023.
 - k. Ovarian cancer. V2.2023. Revised June 2, 2023.
 - l. Prostate cancer. V4.2023. Revised September 7, 2023.
 - m. Small Bowel Adenocarcinoma. V1.2024. Revised December 20, 2023.
 - n. Small cell lung cancer. V2.2024. Revised November 21, 2023.
 - o. Soft tissue sarcoma. V3.2023. Revised December 12, 2023.
 - p. Thyroid carcinoma. V4.2023. Revised August 16, 2023.
 - q. Uterine neoplasms. V1.2024. Revised September 20, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

© CPT Only – American Medical Association