

- POLICY:** Oncology – Docetaxel intravenous (IV) injection
- Docefrez™ (docetaxel lyophilized powder for IV injection – Caraco Pharmaceuticals Laboratories)
 - Taxotere® (docetaxel injection concentrate for IV injection – sanofi-aventis, generics)
 - docetaxel concentrate or solution for IV injection – various manufacturers

APPROVAL DATE: 06/18/2019

OVERVIEW

Docetaxel for IV injection, Docefrez, and Taxotere all contain docetaxel, a microtubule inhibitor.¹⁻⁴ Docetaxel is an antineoplastic agent that disrupts the microtubular network of cells essential for mitotic and interphase cellular functions.¹⁻⁴ By binding to free tubulin, the assembly of tubulin into stable microtubules is promoted while disassembly is inhibited. The result is production of microtubule bundles without normal function and stabilization of microtubules, resulting in inhibition of mitosis in cells. With docetaxel, there is not an alteration in the number of protofilaments in the bound microtubules.

Docetaxel intravenous products are approved for the following indications:

- 1) Breast cancer, in the following situations:
 - as a single agent for locally advanced or metastatic breast cancer after chemotherapy failure; AND
 - with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive cancer; AND
- 2) Non-small cell lung cancer (NSCLC), in the following situations:
 - as a single agent for locally advanced or metastatic NSCLC after platinum-therapy failure; AND
 - in combination with a cisplatin for unresectable, locally advanced or metastatic untreated disease; AND
- 3) Hormone-refractory prostate cancer (HRPC), with prednisone in androgen-independent (hormone-refractory) metastatic prostate cancer; AND
- 4) Gastric carcinoma (GC), with cisplatin and fluorouracil for untreated, advanced GC, including the gastroesophageal junction; AND
- 5) Squamous cell carcinoma of the head and neck, with cisplatin and fluorouracil for induction treatment of locally advanced disease.

There are warnings for all of these products concerning the alcohol content and cases of intoxication in patients receiving docetaxel-containing products; however, the alcohol content differs amongst the products.¹⁻³ For example, Taxotere (100 mg/m²) delivers 2.0 g/m² of ethanol.² There are also multiple generic formulations of docetaxel that have varying amounts of alcohol.

Guidelines

Docetaxel features prominently in multiple guidelines from the National Comprehensive Cancer Network (NCCN).

- Breast Cancer: NCCN guidelines (version 1.2019 – March 14, 2019) indicate that for preoperative/adjuvant treatment, docetaxel is included as a part of preferred chemotherapy regimens for HER2-negative disease and HER2-positive disease, as well as in multiple
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alternative treatment regimens.⁵ In patients with recurrent or metastatic disease, NCCN guidelines indicate that docetaxel may be used as a single agent or as part of various combination regimens.

- Gastric Carcinoma (GC), including the Gastroesophageal Junction: NCCN guidelines (version 2.2019 – June 3, 2019) list docetaxel among the agents used as monotherapy or combination regimens in the first-line setting and as part of second-line or subsequent preferred and other regimens. Docetaxel is also included as a component of a preferred peri-operative regimen.
- Head and Neck Cancer: NCCN guidelines (version 1.2019 – March 6, 2019) indicate the choice of chemotherapy should be individualized based on patient characteristics, including location, performance status, and goals of therapy.¹² The guidelines mention docetaxel as a single agent or part of a combination regimen for a variety of squamous cell head and neck cancers in the first-line setting.
- Non-Small Cell Lung Cancer: Guidelines (version 5.2019 – June 7, 2019) include docetaxel ± other therapies as an initial or subsequent therapy option for advanced or metastatic squamous cell carcinoma or large cell adenocarcinoma.
- Prostate Cancer: Guidelines (version 2.2019 – April 17, 2019) list docetaxel among the first-line, second-line, and subsequent therapies for systemic treatment of metastatic, castration-recurrent, adenocarcinoma with or without visceral metastasis. Docetaxel is also among the first-line and subsequent treatment options for metastatic small cell/neuroendocrine disease. Docetaxel + ADT is among the treatment options for patients with metastatic castration-naïve disease.
- Esophageal and Esophagogastric Junction Cancer: Guidelines (version 2.2019 – May 29, 2019) indicate that multiple docetaxel-containing regimens are preferred or other regimens in the first- and second-line setting for treatment of unresectable, locally advanced, recurrent, or metastatic disease.²⁷ Docetaxel is also used in the peri-operative setting and with definitive chemoradiation.
- Ovarian, Fallopian Tube, and Primary Peritoneal Cancer: Guidelines (version 1.2019 – March 8, 2019) indicate that docetaxel is recommended in primary treatment regimens for Stage I through IV disease. Docetaxel ± other therapies is also among the treatment options for recurrent disease (platinum-resistant disease and platinum-sensitive disease). Docetaxel is listed as part of regimens for malignant sex cord-stromal tumors malignant germ cell tumors.⁶

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of docetaxel products. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Because of the of the specialized skills required for evaluation and diagnosis of patients treated with docetaxel as well as the monitoring required for adverse events and long-term efficacy, initial approval requires docetaxel to be prescribed by or in consultation with a physician who specializes in the condition being treated.

RECOMMENDED AUTHORIZATION CRITERIA

FDA-Approved Indications

- 1. Breast Cancer.** Approve for 6 months if prescribed by or in consultation with an oncologist.

Dosing. Approve if each single dose of docetaxel is less than or equal to 100 mg/m².

The approved dosing of docetaxel for locally advanced or metastatic breast cancer, after failure of prior chemotherapy, is 60 to 100 mg/m² administered by IV infusion every 3 weeks.¹⁻⁴ For adjuvant treatment of operable node-positive breast cancer, the approved dosage of docetaxel is 75 mg/m² administered 1 hour after doxorubicin and cyclophosphamide every 3 weeks for six courses.¹⁻² However, multiple alternative regimens with dosing have been evaluated and are recommended in NCCN guidelines.⁵ Note that docetaxel is administered in a cycle (e.g., 60 to 100 mg/m² on Day 1, cycled every 21 days). Some docetaxel-containing regimens for breast cancer include the following dosing of docetaxel: 60 to 100 mg/m² as an IV infusion on Day 1, cycled every 21 days; 35 mg/m² IV weekly for 6 weeks followed by a 2-week rest, then repeat; and 35 mg/m² IV Days 1, 8, and 15 of each cycle.

Note: Multiple doses have been evaluated in the literature; therefore, alternate doses will be evaluated on a case-by-case basis. Dose modifications are recommended for the management of toxicities and are determined by the prescribing physician. Dosing modifications are recommended in the prescribing information and are dependent on diagnosis, concomitant therapy, patient variability, prior treatment, comorbidities, initial docetaxel dose, and toxicity.¹⁻⁵ It is also recommended that the prescriber considers a dose reduction of docetaxel if the patient requires co-administration of a strong cytochrome P450 (CYP) 3A4 inhibitor (e.g., ketoconazole).¹⁻⁴ Duration of treatment is usually 3 to 6 cycles; therapy may be extended based on the opinion of the prescribing physician.^{5,7}

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- 2. Gastric Carcinoma (GC), including the Gastroesophageal Junction.** Approve for 6 months if prescribed by or in consultation with an oncologist.

Dosing. Approve if each single dose of docetaxel is less than or equal to 100 mg/m².

The approved dosing in gastric adenocarcinoma is 75 mg/m² on Day 1 (along with cisplatin, followed by fluorouracil);²⁻⁴ however, multiple alternative regimens with dosing have been evaluated and many are recommended in NCCN guidelines.^{8,27} Note that docetaxel is administered in a cycle (e.g., 75 mg/m² on Day 1, cycled every 21 days). Some docetaxel-containing regimens for gastric cancer include the following dosing of docetaxel: 60 to 100 mg/m² IV on Day 1, cycled every 21 days; 35 mg/m² IV Days 1 and 8, cycled every 21 days; and 40 to 50 mg/m² IV on Day 1, cycled every 14 days.

Note: Multiple doses have been evaluated in the literature; therefore, other doses will be assessed individually on a case-by-case basis. Note that dose and/or schedule modifications are recommended for the management of toxicities and are determined by the prescribing physician. Certain modifications are recommended in the prescribing information and are dependent on diagnosis, concomitant therapy, initial docetaxel dose, toxicity, prior treatment, nutritional status, comorbidity, and patient variability.^{1-4,8} It is also recommended that the prescriber considers a dose reduction of docetaxel if the patient requires co-administration of a strong CYP 3A4 inhibitor (e.g.,

ketoconazole).¹⁻⁴ Duration of treatment varies, but is usually up to 6 cycles.⁸⁻¹¹ When docetaxel is part of perioperative chemotherapy, NCCN recommends a total of 6 cycles of chemotherapy (3 preoperative cycles and 3 postoperative cycles). In a Phase III study with docetaxel used in a first-line regimen for advanced gastric cancer, patients received treatment with a docetaxel-containing regimen for a mean of 6 cycles (range, 1 to 16 cycles).⁹

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- 3. Head and Neck Cancer.** Approve for 6 months if prescribed by or in consultation with an oncologist.

Dosing. Approve if each single dose of docetaxel is less than or equal to 75 mg/m².

Note that docetaxel is administered in a cycle (e.g., 75 mg/m² on Day 1, cycled every 21 days).

Note: Alternate dosing will be assessed individually on a case-by-case basis. Dose modifications are recommended for the management of toxicities and are determined by the prescribing physician. Dosing modifications are recommended in the prescribing information and are dependent on diagnosis, concomitant therapy, initial docetaxel dose, and toxicity.¹⁻⁴ It is also recommended that the prescriber considers a dose reduction of docetaxel if the patient requires co-administration of a strong CYP 3A4 inhibitor (e.g., ketoconazole).

Duration of treatment varies; however, in most cases the duration of treatment is up to 6 cycles.¹²⁻¹³ Therapy may be extended based on the opinion of the prescribing physician.

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- 4. Non-Small Cell Lung Cancer (NSCLC).** Approve for 6 months if prescribed by or in consultation with an oncologist.

Dosing. Approve if each single dose of docetaxel is less than or equal to 100 mg/m².

The approved dosing of docetaxel in NSCLC is 75 mg/m²; ¹⁻³ however, use of other dosages (e.g., 60 to 100 mg/m²) are supported in the literature.¹⁵⁻¹⁷ Note that docetaxel is administered in a cycle (e.g., 60 to 100 mg/m² on Day 1, cycled every 21 days).^{1-4,15-17}

Note: Alternate dosing will be assessed individually on a case-by-case basis. Dose modifications are recommended for the management of toxicities and are determined by the prescribing physician. Dosing modifications are recommended in the prescribing information and are dependent on diagnosis, concomitant therapy, initial docetaxel dose, and toxicity.¹⁻⁴ It is also recommended that the prescriber considers a dose reduction of docetaxel if the patient requires co-administration of a strong CYP 3A4 inhibitor (e.g., ketoconazole).

Duration of treatment is usually 3 to 6 cycles; therapy may be extended based on the opinion of the prescribing physician.¹⁴⁻¹⁸

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- 5. Prostate Cancer.** Approve for 6 months if the patient meets BOTH of the following conditions (A and B):

A) Docetaxel is prescribed by or in consultation with an oncologist; AND

B) The patient meets ONE of the following conditions (i OR ii):

- i. The patient has castration-recurrent (hormone-refractory) metastatic prostate cancer; OR
- ii. The patient will be initiating docetaxel in combination with androgen deprivation therapy (ADT).

Dosing. Approve if each single dose of docetaxel is less than or equal to 75 mg/m².

The approved dose is 75 mg/m²; however, other dosages (60 to 70 mg/m²) are supported in the literature.²⁰ Note that docetaxel is administered in a cycle (e.g., 60 to 75 mg/m² on Day 1, cycled every 21 days).¹⁻⁴ In a Phase II study (n = 346), men treated with docetaxel 50 mg/m² every 3 weeks survived longer than men treated with docetaxel 75 mg/m² every 3 weeks (19.5 months vs. 17.0 months; P = 0.015).¹⁹ In hormone-refractory prostate cancer, prednisone 5 mg twice daily can be administered continuously.¹⁻⁴ For premedication, 8 mg of oral dexamethasone is recommended 12 hours, 3 hours, and 1 hour prior to the infusion.

Note: Alternate dosing will be assessed individually on a case-by-case basis. Dose modifications are recommended for the management of toxicities and are determined by the prescribing physician. Dosing modifications are recommended in the prescribing information and are dependent on diagnosis, concomitant therapy, initial docetaxel dose, and toxicity.¹⁻⁴ It is also recommended that the prescriber considers a dose reduction of docetaxel if patients require co-administration of a strong CYP 3A4 inhibitor (e.g., ketoconazole).

Duration of therapies varies.¹⁹ In the pivotal trial, patients received up to 10 cycles with docetaxel. Response is according to the prescribing physician and is not based solely on rising prostate specific antigen (PSA) [e.g., response may incorporate clinical and radiographic response]. Retreatment with docetaxel may be used in some patients, particularly in those who did not show definitive progression on prior docetaxel therapy.

Other Uses with Supportive Evidence

6. Esophageal Cancer, Including the Esophagogastric Junction. Approve for 6 months if prescribed by or in consultation with an oncologist.

Dosing. Approve if each single dose of docetaxel is less than or equal to 100 mg/m².

Multiple doses of docetaxel are supported in the current NCCN esophageal cancer guidelines.²⁷ Some docetaxel-containing regimens for esophageal cancer include the following dosing of docetaxel: 60 mg/m² as an IV infusion on Days 1 and 22; 20 to 30 mg/m² as an IV infusion on Day 1; 70 to 100 mg/m² IV on Day 1, cycled every 21 days; 40 to 50 mg/m² IV on Day 1, cycled every 14 days; 70 to 85 mg/m² on Day 1, cycled every 21 days; and 35 mg/mm² on Days 1 and 8, cycled every 21 days.

Note: Multiple doses have been evaluated in the literature; alternate doses will be evaluated on a case-by-case basis. Dose modifications are recommended for the management of toxicities and are determined by the prescribing physician. Dosing modifications are recommended in the prescribing information and are dependent on diagnosis, concomitant therapy, patient variability, prior treatment, comorbidities, initial docetaxel dose, and toxicity.¹⁻⁵ It is also recommended that the prescriber considers a dose reduction of docetaxel if the patient requires co-administration of a strong cytochrome P450 (CYP) 3A4 inhibitor (e.g., ketoconazole).¹⁻⁴ Duration of treatment varies,

depending on the treatment approach; therapy may be extended based on the opinion of the prescribing physician.

For perioperative chemotherapy, NCCN guidelines note that fluorouracil/leucovorin/oxaliplatin plus docetaxel is recommended to be cycled every 14 days for a total of 8 cycles (4 preoperative cycles and 4 post-operative cycles).²⁷ For definitive chemoradiation, docetaxel may be given with cisplatin for 1 cycle, administered on Days 1 and 22; alternatively, docetaxel and cisplatin can be given on Day 1 of five weekly cycles. When given for metastatic or locally advanced disease, docetaxel is most often part of a regimen that is cycled every 14 or 21 days. In a Phase III study, patients with esophagogastric adenocarcinoma were treated for up to 6 cycles.²⁸

7. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer. Approve for 6 months if prescribed by or in consultation with an oncologist.

Dosing. Approve if each single dose of docetaxel is less than or equal to 100 mg/m².

Docetaxel doses of 60 to 75 mg/m² IV, repeated every 3 weeks are supported in the NCCN Ovarian Cancer guidelines; however, other dosages (up to 100 mg/m²) are supported in the literature.²¹⁻²⁵ A Phase II trial (n = 36) used a docetaxel dose of 35 mg/m² on Days 1, 8, and 15 of a 28-day cycle.²⁶ Note that docetaxel is administered in a cycle (e.g., 60 to 100 mg/m² on Day 1, cycled every 21 days).²¹⁻²⁵

Note: Alternate dosing will be assessed individually on a case-by-case basis. Dose modifications are recommended for the management of toxicities and are determined by the prescribing physician. Dosing modifications are recommended in the prescribing information and are dependent on diagnosis, concomitant therapy, initial docetaxel dose, and toxicity.¹⁻⁴ It is also recommended that prescribers consider a dose reduction of docetaxel if patients require co-administration of a strong CYP 3A4 inhibitor (e.g., ketoconazole).

For docetaxel-containing regimens, NCCN guidelines recommend some regimens for 6 cycles.²¹ Up to 8 cycles with docetaxel-containing regimens has been used in the literature.^{23,25}

8. Other Cancer Indications. Forward to a clinician (i.e., Medical Director or Pharmacist) for review on a case-by-case basis. Other indications supported in the *NCCN Compendium*, mainly with category 2A or 2B recommendations, include: bladder cancer, bone cancer, cervical cancer, occult primary cancer, pancreatic cancer, small cell lung cancer, soft tissue sarcoma, thyroid cancer, and uterine cancer.⁵

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Docetaxel products have not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

- 1. Other Indications (Non-Cancer).** Coverage is not recommended for circumstances not listed in the Authorization Criteria (FDA-approved indications and Other Uses with Supportive Evidence). Criteria will be updated as new published data are available.
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HISTORY

Type of Revision	Summary of Changes	Approval Date
Annual revision	---	05/17/2017
Annual revision	<p><u>Criteria:</u> Gastric Carcinoma – Remove requirement that docetaxel be used to treat metastatic, locally recurrent, or locally advanced disease. (Previous criteria did not allow for perioperative use of docetaxel, which is recommended in NCCN guidelines.); Head and Neck Cancer – Remove criterion that requires docetaxel to be prescribed either in combination with cisplatin or for recurrent, unresectable, or metastatic disease (including patients unfit for surgery). [Previous criteria did not address non-surgical treatment for resectable disease or address the unclear consensus of resectability.] <u>Initial and Extended Approval:</u> Gastric Carcinoma – Simplify criteria so that all approvals are for 6 months. Previously, approval durations were specific for definitive chemoradiation or metastatic or locally advanced disease but did not address peri-operative use. <u>Extended Approval:</u> Gastric Carcinoma, Head and Neck Cancer, Prostate Cancer, Esophageal Cancer, and Ovarian, Fallopian Tube, or Peritoneal Cancer – For patients who require an extended approval, remove the requirement that patient has responded to therapy; change to “if additional treatment is required” as determined by the prescriber. <u>Duration of Therapy:</u> Breast Cancer – Simplify to state that initial therapy is for up to 6 cycles; Gastric Carcinoma – Update policy to state that duration of therapy varies but is usually up to 6 cycles. Previously, policy stated duration is usually 3-6 cycles; Head and Neck Cancer – Update policy to state that duration of therapy varies but is usually up to 6 cycles. Previously, policy stated duration is usually 4 cycles or 3-6 cycles in advanced, recurrent, or metastatic disease; Esophageal Cancer – Update policy to state that duration of therapy varies depending on treatment approach, and that treatment may be extended based on the opinion of the prescriber. Previously duration of therapy was specific for definitive chemoradiation or metastatic or locally advanced disease. The duration of therapy in these situations and in the peri-operative setting was added to the supporting information; Ovarian, Fallopian Tube, or Peritoneal Cancer – Update policy to state that NCCN recommends 6 cycles for some docetaxel-containing regimens.</p>	06/13/2018
Annual revision	<p>Patient has Been Started on Docetaxel: Remove this coverage condition from the policy. All reviews must meet criteria in this policy.</p> <p>All Indications: Remove criterion for continuation of therapy that reauthorizes treatment if additional treatment is required, according to the prescriber. For reauthorization, all reviews must meet criteria in this policy.</p>	06/18/2019