

# Drug Policy

<b>Policy:</b>	<b>201415-CC</b>	<b>Initial Effective Date: 07/30/2014</b>  <b>Annual Review Date: 04/01/2019</b>  <b>Policy Retirement Date: 04/01/2019</b>
<b>Code(s):</b>	<b>HCPCS J9171</b>	
<b>SUBJECT:</b>	<b>docetaxel intravenous (IV) injection</b> <ul style="list-style-type: none"> <li>• Docefrez™ (docetaxel lyophilized powder for IV injection – Caraco Pharmaceuticals Laboratories)</li> <li>• Taxotere® (docetaxel injection concentrate for IV injection – sanofi-aventis, generics)</li> <li>• docetaxel concentrate or solution for IV injection – various manufacturers</li> </ul>	

**As of 4/1/2019, Prior approval is not required for the procedure codes listed in this Corporate Drug Policy.**

## Overview

Docetaxel for IV injection, Docefrez, and Taxotere all contain docetaxel, a microtubule inhibitor.<sup>1-4</sup> Docetaxel is an antineoplastic agent that disrupts the microtubular network of cells essential for mitotic and interphase cellular functions.<sup>1-4</sup> 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.

All are approved for the following indications:

- 1) Breast cancer, as a single agent for locally advanced or metastatic breast cancer after chemotherapy failure; AND
- 2) Non-small cell lung cancer (NSCLC), as a single agent for locally advanced or metastatic NSCLC after platinum-therapy failure; AND
- 3) Hormone-refractory prostate cancer (HRPC), with prednisone in androgen-independent (hormone-refractory) metastatic prostate cancer.

Docetaxel for IV injection and Taxotere are also approved in the following indications:<sup>2,4</sup>

- 1) Breast cancer, with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive cancer; AND
- 2) NSCLC, with a cisplatin for unresectable, locally advanced or metastatic untreated NSCLC; AND
- 3) Gastric carcinoma (GC), with cisplatin and fluorouracil for untreated, advanced GC, including the gastroesophageal junction; AND
- 4) Squamous cell carcinoma of the head and neck, with cisplatin and fluorouracil for induction treatment of locally advanced squamous cell carcinoma of the head and neck cancer.

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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.<sup>1-3</sup> Docefrez (100 mg/m<sup>2</sup>) delivers 1.425 g/m<sup>2</sup> of ethanol.<sup>1</sup> Taxotere (100 mg/m<sup>2</sup>) delivers 2.0 g/m<sup>2</sup> of ethanol.<sup>2</sup> There are also multiple generic formulations of docetaxel that have varying amounts of alcohol.

## Policy Statement

This policy involves the use of docetaxel infusion. Prior authorization is recommended for medical benefit coverage of docetaxel. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy, and Labs/Diagnostics** for the diagnosis provided. The requirement that the patient meet the Criteria for coverage of the requested medication applies to the initial authorization only. **Waste Management** applies for all covered conditions. **Exclusions** are listed following the recommended authorization criteria and Waste Management section.

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. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy.

## Indications, Medically Necessary

### Food and Drug (FDA)-Approved Indications

#### 1. Breast Cancer.

**Criteria.** *Patient must meet the following criteria (a).*<sup>1-6</sup>

- a) Docetaxel is prescribed by or in consultation with an oncologist;

Docetaxel for IV injection, Docefrez and Taxotere are indicated as a single agent for locally advanced or metastatic breast cancer after chemotherapy failure.<sup>1-4</sup> Docetaxel for IV injection and Taxotere are also indicated with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive cancer.<sup>2-4</sup>

The National Comprehensive Cancer Network (NCCN) breast cancer guidelines (version 1.2018 - 03/20/2018) 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 alternative treatment regimens.<sup>5</sup> 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.

**Dosing in Breast Cancer.** *Dosing must meet the following:* Dosing regimen is individualized; however, each single dose of docetaxel must not exceed 100 mg/m<sup>2</sup>.

The approved dosing of docetaxel for locally advanced or metastatic breast cancer, after failure of prior chemotherapy, is 60 to 100 mg/m<sup>2</sup> administered by IV infusion every 3 weeks.<sup>1-4</sup> For adjuvant treatment of operable node-positive breast cancer, the approved dosage of docetaxel is 75 mg/m<sup>2</sup> administered 1 hour after doxorubicin and

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cyclophosphamide every 3 weeks for six courses.<sup>1-2</sup> However, multiple alternative regimens with dosing have been evaluated and are recommended in NCCN guidelines.<sup>5</sup> Note that docetaxel is administered in a cycle (e.g., 60 to 100 mg/m<sup>2</sup> on Day 1, cycled every 21 days). Some docetaxel-containing regimens for breast cancer include the following dosing of docetaxel: 75 to 100 mg/m<sup>2</sup> as an IV infusion on Day 1, cycled every 21 days; 60 to 100 mg/m<sup>2</sup> IV on Day 1, cycled every 21 days; 35 mg/m<sup>2</sup> IV weekly for 6 weeks followed by a 2-week rest, then repeat; and 75 to 100 mg/m<sup>2</sup> IV on Day 1, cycled every 21 days; and 35 mg/m<sup>2</sup> IV Days 1, 8, and 15 every 28 days.

**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.<sup>1-5</sup> 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).<sup>1-4</sup>

### **Initial Approval/Extended Approval.**

- a. **Initial Approval:** Initial approval is for 6 months of therapy.
- b. **Extended Approval:** Approve at additional 6-month intervals if the patient has a response, as determined by the prescribing physician.

**Duration of Therapy in Breast Cancer.** Duration of treatment is usually 3 to 6 cycles; therapy may be extended based on the opinion of the prescribing physician.<sup>5,7</sup>

**Labs/Diagnostics.** None required.

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## **2. Gastric Carcinoma (GC) including the Gastroesophageal Junction.**

**Criteria.** *The patient must meet the following criteria (a):*<sup>2-4,6,8</sup>

- a) Docetaxel is prescribed by or in consultation with an oncologist.

Docetaxel for IV injection and Taxotere are indicated with cisplatin and fluorouracil for untreated, advanced GC, including the gastroesophageal junction.<sup>2-4</sup> In patients with metastatic or locally advanced cancer when local therapy is not indicated, the NCCN gastric cancer guidelines (version 2.2018 – 02/28/2018) mention monotherapy or combination therapy regimens using docetaxel as appropriate other 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.

**Dosing in GC.** *Dosing must meet the following:* Dosing regimen is individualized; however, each single dose of docetaxel must not exceed 100 mg/m<sup>2</sup>.

The approved dosing in gastric adenocarcinoma is 75 mg/m<sup>2</sup> on Day 1 (along with cisplatin, followed by fluorouracil);<sup>2-4</sup> however, multiple alternative regimens with dosing have been evaluated and many are recommended in NCCN guidelines.<sup>8</sup> Note that docetaxel is administered in a cycle (e.g., 75 mg/m<sup>2</sup> on Day 1, cycled every 21 days). Some

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docetaxel-containing regimens for gastric cancer include the following dosing of docetaxel: 60 to 100 mg/m<sup>2</sup> IV on Day 1, cycled every 21 to 28 days; 35 mg/m<sup>2</sup> IV Days 1 and 8, cycled every 21 days; and 40 to 50 mg/m<sup>2</sup> 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.<sup>1-4,8</sup> 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).<sup>1-4</sup>

## **Initial Approval/Extended Approval.**

A) *Initial Approval:* Initial approval is for 6 months of therapy.

B) *Extended Approval:* Approve at additional 6-month intervals if the patient has a response, as determined by the prescribing physician.<sup>8-9</sup>

**Duration of Therapy in GC.** Duration of treatment varies, but is usually up to 6 cycles.<sup>8-11</sup> 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).<sup>9</sup>

**Labs/Diagnostics.** None required.

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### 3. **Head and Neck Cancer.**

**Criteria.** *Patient must meet the following criteria (a).*<sup>2-4,6,12</sup>

a) Docetaxel is prescribed by or in consultation with an oncologist.

Docetaxel for IV infusion and Taxotere are indicated with cisplatin and 5-FU for induction treatment of locally advanced squamous cell carcinoma of the head and neck.<sup>2-4</sup> The NCCN guidelines for head and neck cancers (version 1.2018 – February 15, 2018) indicate the choice of chemotherapy should be individualized based on patient characteristics, including location, performance status, and goals of therapy.<sup>12</sup> The guidelines mention docetaxel/cisplatin and/or docetaxel/cisplatin/5-FU as a treatment option for a variety of squamous cell head and neck cancers. In patients with recurrent, very advanced, or metastatic head and neck cancers, docetaxel is listed as a first-line therapeutic option as monotherapy or in combination with other agents.

**Dosing in Head and Neck Cancer.** *Dosing must meet the following:* Dosing regimen is individualized; however, each single dose of docetaxel must not exceed 75 mg/m<sup>2</sup>.<sup>1-4</sup>

The approved dosing of docetaxel in squamous cell carcinoma of the head and neck is 75 mg/m<sup>2</sup> (followed by cisplatin and fluorouracil), for 3 or 4 cycles.<sup>2-4</sup> Note that docetaxel is administered in a cycle (e.g., 75 mg/m<sup>2</sup> on Day 1, cycled every 21 days).

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**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.<sup>1-4</sup> 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).

### **Initial Approval/Extended Approval.**

- a) **Initial Approval:** Initial approval is for 6 months of docetaxel.
- b) **Extended Approval:** Approve at additional 6-month intervals only if the patient has locally advanced, recurrent, or metastatic disease AND has a response to therapy, as determined by the prescribing physician.

**Duration of Therapy in Head and Neck Cancer.** Duration of treatment is up to 4 cycles, unless the patient has advanced, recurrent, or metastatic disease where duration of treatment is usually 3 to 6 cycles.<sup>12-13</sup> Therapy may be extended in advanced, recurrent, or metastatic disease based on the opinion of the prescribing physician.

**Labs/Diagnostics.** None required.

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## **4. Non-Small Cell Lung Cancer (NSCLC).**

**Criteria.** *Patient must meet the following criteria (a.).*<sup>1-4,6,14</sup>

- a) Docetaxel is prescribed by or in consultation with an oncologist;

Docetaxel for IV infusion, Docefrez, and Taxotere are indicated in NSCLC as a single agent for locally advanced or metastatic NSCLC after platinum-therapy failure.<sup>1-4</sup> Docetaxel for IV infusion and Taxotere are also indicated with cisplatin for unresectable, locally advanced or metastatic untreated NSCLC.<sup>2-4</sup>

The NCCN NSCLC guidelines (version 4.2018 – April 26, 2018) mention docetaxel as a treatment option in a variety of clinical scenarios. First-line therapy for advanced or metastatic NSCLC includes combination regimens containing docetaxel. In patients with performance status 2, monotherapy with docetaxel is a first-line systemic option in patients with advanced or metastatic large cell adenocarcinoma or squamous cell carcinoma. For adjuvant/neoadjuvant use, docetaxel + cisplatin is a recommended chemotherapy regimen.<sup>14</sup> In various patient populations who experience disease progression during or after first-line therapy, docetaxel has a role ± other agents as a subsequent therapy or as monotherapy as switch-maintenance therapy.

**Dosing in NSCLC.** *Dosing must meet the following:* Dosing regimen is individualized; however, each single dose of docetaxel must not exceed 100 mg/m<sup>2</sup>.

The approved dosing of docetaxel in NSCLC is 75 mg/m<sup>2</sup>;<sup>1-3</sup> however, use of other dosages (e.g., 60 to 100 mg/m<sup>2</sup>) are supported in the literature.<sup>15-17</sup> Note that docetaxel is administered in a cycle (e.g., 60 to 100 mg/m<sup>2</sup> on Day 1, cycled every 21 days).<sup>1-4,15-17</sup>



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**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.<sup>1-4</sup> 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).

## **Initial Approval/Extended Approval.**

- a) **Initial Approval.** Initial approval is for up to 6 months of docetaxel.
- b) **Extended Approval.** Approve at additional 6-month intervals if the patient has unresectable, locally advanced, or metastatic NSCLC and has responsive or stable disease, as determined by the prescribing physician.<sup>17</sup>

**Duration of Therapy in NSCLC.** Duration of treatment is usually 3 to 6 cycles; therapy may be extended based on the opinion of the prescribing physician.<sup>14-18</sup>

**Labs/Diagnostics.** None required.

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## **5. Prostate Cancer.**

**Criteria.** *Patient must meet the following criteria (a AND b):*<sup>1-4,6,19</sup>

- 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)

Docetaxel features prominently in the NCCN prostate cancer guidelines (version 2.2018 – March 8, 2018). NCCN indicates that the preferred first-line chemotherapy treatment for symptomatic metastatic castration-recurrent prostate cancer is docetaxel ± prednisone (category 1).<sup>19</sup> Docetaxel + ADT is among the treatment options for patients with metastatic castration-naïve high-volume disease. Docetaxel may also be considered in patients with castration-recurrent prostate cancer with signs of rapid progression or visceral metastases despite lack of symptoms. Docetaxel rechallenge is an option for certain patients. NCCN also notes that docetaxel should not be used in patients *without* metastatic disease; these patients have not shown to have improved survival outcomes.

**Dosing in Prostate Cancer.** *Dosing must meet the following:* Dosing regimen is individualized; however, each single dose of docetaxel must not exceed 75 mg/m<sup>2</sup>.

Docetaxel dosed every 3 weeks, administered in ± prednisone, is the preferred first-line chemotherapy treatment based on Phase III clinical trial data for men with symptomatic castration-recurrent prostate cancer.<sup>19</sup> The approved dose is 75 mg/m<sup>2</sup>; however, other dosages (60 to 70 mg/m<sup>2</sup>) are supported in the literature.<sup>20</sup> Note that docetaxel is administered in a cycle (e.g., 60 to 75 mg/m<sup>2</sup> on Day 1, cycled every 21 days).<sup>1-4</sup> In a Phase II study (n = 346), men treated with docetaxel 50 mg/m<sup>2</sup> every 3 weeks survived longer than men treated with docetaxel 75 mg/m<sup>2</sup> every 3 weeks (19.5 months vs. 17.0 months; P = 0.015).<sup>19</sup> In hormone-refractory prostate cancer, prednisone 5 mg twice

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daily can be administered continuously.<sup>1-4</sup> 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.<sup>1-4</sup> 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).

## **Initial Approval/Extended Approval.**

- a) *Initial Approval.* Initial approval is for 6 months.
- b) *Extended Approval.* Approve at additional 6-month intervals if the patient has a response, as determined by the prescribing physician.<sup>19</sup>

The NCCN guidelines for prostate cancer note that the duration of therapy should be based on benefit risk profile.<sup>19</sup> 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].

**Duration of Therapy in Prostate Cancer.** Duration of therapies varies.<sup>19</sup>

The NCCN guidelines for prostate cancer note that the duration of therapy should be based on benefit and toxicities.<sup>19</sup> 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.

**Labs/Diagnostics.** None required.

## **Other Uses with Supportive Evidence**

### **6. Esophageal Cancer, Including the Esophagogastric Junction.**

**Criteria.** *Patient must meet the following criteria (a):*<sup>27</sup>

- a) Docetaxel is prescribed by or in consultation with an oncologist;

The National Comprehensive Cancer Network (NCCN) esophageal and esophagogastric junction cancer guidelines (version 2.2018 – May 22, 2018) indicate that multiple docetaxel-containing regimens are preferred first-line or other

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regimens.<sup>27</sup> As second-line therapy for locally advanced or metastatic disease, docetaxel monotherapy (category 1) is a preferred regimen and docetaxel/irinotecan (category 2B) is listed as another regimen.

**Dosing in Esophageal Cancer.** *Dosing must meet the following:*<sup>27</sup> Dosing regimen is individualized; however, each single dose of docetaxel must not exceed 100 mg/m<sup>2</sup>.

Multiple doses of docetaxel are supported in the current NCCN esophageal cancer guidelines.<sup>27</sup> Some docetaxel-containing regimens for esophageal cancer include the following dosing of docetaxel: 60 mg/m<sup>2</sup> as an IV infusion on Days 1 and 22; 20 to 30 mg/m<sup>2</sup> as an IV infusion on Day 1; 70 to 100 mg/m<sup>2</sup> IV on Day 1, cycled every 21 days; 40 to 50 mg/m<sup>2</sup> IV on Day 1, cycled every 14 days; 70 to 85 mg/m<sup>2</sup> on Day 1, cycled every 21 days; and 35 mg/mm<sup>2</sup> 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.<sup>1-5</sup> 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).<sup>1-4</sup>

### **Initial Approval/Extended Approval.**

A) Initial Approval: Initial approval is for 6 months of therapy.

B) Extended Approval: Approve at additional 6-month intervals if additional treatment is required, as determined by the prescribing physician

**Duration of Therapy in Esophageal Cancer.** 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 at total of 8 cycles (4 preoperative cycles and 4 post-operative cycles).<sup>27</sup> 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 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.<sup>28</sup>

**Labs/Diagnostics.** None required.

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## **7. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.**

**Criteria.** *Patient must meet the following criteria (a):*

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



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The NCCN guidelines for ovarian cancer (including fallopian tube and primary peritoneal cancer) [version 2.2018 – March 9, 2018] indicate that docetaxel/carboplatin is a therapeutic option for primary chemotherapy and primary adjuvant chemotherapy in certain patients with stage I through IV ovarian, fallopian tube, or primary peritoneal cancer, including for treatment of certain less common ovarian histopathologies.<sup>21</sup> Docetaxel (for platinum-resistant disease) [preferred regimen] and docetaxel/carboplatin (combination therapy for platinum-sensitive disease) [other regimen] are mentioned as therapeutic options for recurrent epithelial ovarian, fallopian tube, and primary peritoneal cancers. Docetaxel is listed as a therapy for malignant sex cord-stromal tumors (category 2A), and docetaxel ± carboplatin is listed as a palliative therapy for malignant germ cell tumors.<sup>6</sup>

**Dosing in Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.** *Dosing must meet the following:* Dosing regimen is individualized; however, each single dose of docetaxel must not exceed 100 mg/m<sup>2</sup>.

Docetaxel doses of 60 to 75 mg/m<sup>2</sup> IV, repeated every 3 weeks are supported in the NCCN Ovarian Cancer guidelines; however, other dosages (up to 100 mg/m<sup>2</sup>) are supported in the literature.<sup>21-25</sup> A Phase II trial (n = 36) used a docetaxel dose of 35 mg/m<sup>2</sup> on Days 1, 8, and 15 of a 28-day cycle.<sup>26</sup> Note that docetaxel is administered in a cycle (e.g., 60 to 100 mg/m<sup>2</sup> on Day 1, cycled every 21 days).<sup>21-25</sup>

**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.<sup>1-4</sup> 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).

**Initial Approval/Extended Approval.**

*Initial Approval.* Initial approval is for 6 months.<sup>5</sup>

*Extended Approval.* Approve up to an additional 6 months if the patient has a response, as determined by the prescribing physician.

**Duration of Therapy in Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.** For docetaxel-containing regimens, NCCN guidelines recommend some regimens for 6 cycles.<sup>21</sup> Up to 8 cycles with docetaxel-containing regimens has been used in the literature.<sup>23,25</sup>

**Labs/Diagnostics.** None required.

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**8. Patient has been Started on Docetaxel.** Approve if the patient meets the conditions for coverage required for **Dosing, Extended Approval, Duration of Therapy, and Labs/Diagnostics** for an approved use in this *docetaxel Utilization Review* policy.

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**9. Other Cancer Indications.** Forward to the Medical Director for review. 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.<sup>6</sup>

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## Waste Management for All Indications.

Dosing is based on body surface area ( $\text{kg}/\text{m}^2$ ); the dose should be calculated and the number of vials needed assessed.

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## Exclusions.

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.

## Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

## REFERENCES

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<b>HCPCS Code(s):</b>	
J9171	Injection, docetaxel, 1 mg