Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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Docetaxel

CG-DRUG-34

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Taxotere (docetaxel) Docefrez (docetaxel)

APPROVAL CRITERIA

Requests for docetaxel (Docefrez, Taxotere) **may be approved** for the treatment of any of the following indications:

I. Bladder cancer, recurrent or locally advanced or metastatic disease (includes urothelial carcinoma of the bladder; primary carcinoma of the urethra; upper genitourinary [GU] tract tumors; and urothelial carcinoma of the prostate);
II. Bone cancer:
    A. Ewing's sarcoma; **OR**
    B. Osteosarcoma;
III. Breast cancer;
IV. Esophageal and esophagogastric junction cancers;
V. Gastric (stomach) adenocarcinoma;
VI. Head and neck cancer;
VII. Lung cancer (non-small cell lung cancer and small cell lung cancer);
VIII. Occult primary tumors (cancer of unknown primary):
    A. Adenocarcinoma; **OR**
    B. Squamous cell carcinoma;
IX. Ovarian cancer, including fallopian tube cancer and primary peritoneal cancer
X. Penile cancer;
XI. Prostate cancer;
XII. Soft tissue carcinoma;
XIII. Thyroid Carcinoma - Anaplastic Carcinoma, used in combination with doxorubicin;
XIV. Uterine neoplasms.

Docetaxel (Docefrez, Taxotere) **may not be approved** for all other indications.

Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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Note: Docefrez, Taxotere (docetaxel) has black box warnings for toxic deaths, hepatotoxicity, neutropenia, hypersensitivity reactions, and fluid retention. Treatment-related mortality increases in individuals with abnormal liver function, higher dose therapy, and NSCLC with a history of prior platinum-based treatment who receive docetaxel 100 mg/m2 as a single agent. Docetaxel should not be given to individuals with bilirubin greater than the upper limit of normal (ULN), or to individuals with AST and/or ALT greater than 1.5 x ULN concomitant with alkaline phosphatase greater than 2.5 x ULN. These individuals are at increased risk for developing severe or life-threatening toxicities (such as grade 4 neutropenia, febrile neutropenia, infections, severe thrombocytopenia, severe stomatitis, severe skin toxicity, and toxic death). Bilirubin, AST or ALT, and alkaline phosphatase should be obtained prior to each therapy cycle. Docetaxel should not be given to individuals with neutrophil counts of less than 1500 cells/mm3. Frequent blood counts should be performed to monitor for neutropenia. Severe hypersensitivity reactions, including fatal anaphylaxis, have been reported in individuals who received premedication with dexamethasone. Use is contraindicated in individuals with a severe hypersensitivity to docetaxel or polysorbate 80. Severe fluid retention may occur despite use of dexamethasone premedication.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

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2. Docetaxel. In: DrugPoints System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated February 27, 2017. Available at: http://www.micromedexsolutions.com. Accessed on March 23, 2017.
3. Docetaxel monograph. Lexicomp® Online, American Hospital Formulary Service® (AHFS®) Online, Hudson, Ohio, Lexi-Comp., Inc. Last revised June 24, 2015. Accessed on March 23, 2017.
4. Giordano SH, Temin S, Kirshner JJ, et al.; American Society of Clinical Oncology. Systemic therapy for patients with advanced human epidermal growth factor receptor 2-positive breast cancer: American Society of Clinical Oncology clinical practice guideline. J Clin Oncol. 2014; 32(19):2078-2099.
5. National Comprehensive Cancer Network®. NCCN Drugs & Biologic Compendium™ (electronic version). For additional information visit the NCCN website: http://www.nccn.org. Accessed on March 23, 2017.

Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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6. NCCN Clinical Practice Guidelines in Oncology© 2017 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org. Accessed on March 24, 2017.
   - Anal Carcinoma (V1.2017). Revised November 23, 2016.
   - Bone (V2.2017). Revised November 7, 2016.
   - Bladder (V2.2017). Revised February 15, 2017.
   - Breast (V1.2017). Revised March 10, 2017.
   - Esophageal and Esophagogastric Junction Cancers (V1.2017). Revised March 21, 2017.
   - Gastric (V1.2017). Revised March 21, 2017.
   - Head and Neck Cancers (V1.2017). Revised February 6, 2017.
   - Non-Small Cell Lung Cancer (V5.2017). Revised March 16, 2017.
   - Occult Primary (Cancer of Unknown Primary) (V2.2017). Revised October 17, 2016.
   - Ovarian (V1. 2016). Revised June 30, 2016.
   - Penile Cancer (V2.2017). Revised March 10, 2017.
   - Prostate (V2. 2017). Revised February 21, 2017.
   - Small Cell Lung Cancer (V3.2017). Revised February 23, 2017.
   - Soft Tissue Sarcoma (V2.2017). Revised February 8, 2017.
   - Thyroid Carcinoma (V1.2016). Revised July 8, 2016.
   - Uterine Neoplasms (V1.2017). Revised November 21, 2016.
7. Smallridge RC, Ain KB, Asa SL, et al; American Thyroid Association Anaplastic Thyroid Cancer Guidelines Taskforce. American Thyroid Association guidelines for management of patients with anaplastic thyroid cancer. Thyroid. 2012; 22(11):1104-1139.
8. Taxotere [Product Information]. Bridgewater, NJ. Sanofi-Aventis U.S. LLC; December 2015. Available at: http://products.sanofi.us/Taxotere/taxotere.pdf. Accessed on March 23, 2017.