POLICY Document for DOCIVYX (docetaxel)
TAXOTERE (docetaxel)
docetaxel

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 2: Oncology Clinical Policy
- Policy information specific to regimen review per NCCN Guidelines.

Section 1: Clinical Criteria

Medical Prior Authorization
Docetaxel

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Docivyx	docetaxel
Taxotere	docetaxel
docetaxel (all other barnds)	docetaxel

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications

This section of the document is organized by the drug or drugs covered by this criteria. Limitations of use for the drug are also identified here.

Breast Cancer (BC)

Docetaxel is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy.

Docetaxel in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with operable node-positive breast cancer.

Non-Small Cell Lung Cancer (NSCLC)

- Docetaxel as a single agent is indicated for the treatment of patients with locally advanced or metastatic NSCLC after failure of prior platinum-based chemotherapy.
- Docetaxel in combination with cisplatin is indicated for the treatment of patients with unresectable, locally advanced or metastatic NSCLC who have not previously received chemotherapy for this condition.

Prostate Cancer

Docetaxel in combination with prednisone is indicated for the treatment of patients with metastatic castration-resistant prostate cancer.

Gastric Adenocarcinoma (GC)

Docetaxel in combination with cisplatin and fluorouracil is indicated for the treatment of patients with advanced gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for advanced disease.

Head and Neck Cancer

Docetaxel in combination with cisplatin and fluorouracil is indicated for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN).

Compendial Uses

- Anal cancer
- Bladder cancer, primary carcinoma of the urethra, upper genitourinary (GU) tract tumors, and urothelial carcinoma of the prostate
- Bone cancer: Ewing's sarcoma and osteosarcoma
- Breast cancer
- Cervical cancer
- Esophageal and esophagogastric junction cancers
- Gastric cancer
- Head and neck cancer (including very advanced head and neck cancer and cancers of the lip (mucosa), oral cavity, salivary gland, oropharynx, hypopharynx, nasopharynx, glottic larynx, supraglottic larynx, ethmoid sinus, and maxillary sinus)
- Non-small cell lung cancer
- Occult primary tumors (cancer of unknown primary)
- Ovarian cancer/fallopian tube cancer/primary peritoneal cancer: epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, malignant germ cell tumors, malignant sex cord-stromal tumors, carcinosarcoma (malignant mixed Müllerian tumors), clear cell

carcinoma of the ovary, mucinous carcinoma of the ovary, low-grade serous carcinoma/ovarian borderline epithelial tumor (low malignant potential), and grade 1 endometrioid carcinoma.
- Prostate cancer
- Small bowel adenocarcinoma
- Small cell lung cancer
- Soft tissue sarcoma (including angiosarcoma, extremity/body wall, head/neck, retroperitoneal/intra-abdominal, pleomorphic rhabdomyosarcoma, dermatofibrosarcoma protuberans (DFSP) with fibrosarcomatous transformation, dedifferentiated chordoma, and solitary fibrous tumor)
- Thyroid carcinoma: anaplastic carcinoma
- Uterine neoplasms: endometrial carcinoma and uterine sarcoma
- Vaginal cancer

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Anal Cancer

Authorization of 6 months may be granted for treatment of metastatic or unresectable locally recurrent anal squamous cell carcinoma.

Bladder Cancer, Primary Carcinoma of the Urethra, Upper Genitourinary Tract Tumors, and Urothelial Carcinoma of the Prostate

Bladder Cancer

Authorization of 6 months may be granted for treatment of bladder cancer.

Primary Carcinoma of the Urethra

Authorization of 6 months may be granted for treatment of recurrent or metastatic primary carcinoma of the urethra.

Upper Genitourinary Tract Tumors and Urothelial Carcinoma of the Prostate

Authorization of 6 months may be granted for treatment of metastatic upper genitourinary tract tumors or urothelial carcinoma of the prostate.

Bone Cancer

Ewing's Sarcoma

Authorization of 6 months may be granted for treatment of relapsed, progressive, or metastatic Ewing's sarcoma.

Osteosarcoma

Authorization of 6 months may be granted for treatment of relapsed, refractory, or metastatic osteosarcoma.

Breast Cancer

Authorization of 6 months may be granted for treatment of breast cancer in members when any of the following criteria are met:

- Member has human epidermal growth factor receptor 2 (HER2)-negative recurrent unresectable or metastatic disease or no response to preoperative systemic therapy, as a single agent or in combination with capecitabine.
- Member has human epidermal growth factor receptor 2 (HER2)-positive recurrent unresectable or metastatic disease or no response to preoperative systemic therapy, and the requested medication will be used in one of the following regimens (with or without endocrine therapy):
  - In combination with pertuzumab and trastuzumab.
  - In combination with trastuzumab.
- The requested medication will be used as adjuvant therapy.
- The requested medication will be used as preoperative therapy.
- The requested medication will be used as a substitute for other taxanes (e.g., paclitaxel or albumin-bound paclitaxel) in select patients due to medical necessity.

Cervical Cancer

Authorization of 6 months may be granted for subsequent treatment of advanced, persistent, recurrent, or metastatic cervical cancer as a single agent or in combination with carboplatin.

Esophageal and Esophagogastric Junction Cancers

Authorization of 6 months may be granted for treatment of esophageal or esophagogastric junction cancer.

Gastric Cancer

Authorization of 6 months may be granted for treatment of gastric cancer.

Head and Neck Cancer

Authorization of 6 months may be granted for treatment of head and neck cancer (including very advanced head and neck cancer, cancers of the lip (mucosa), oral cavity, salivary gland, oropharynx, hypopharynx, nasopharynx, glottic larynx, supraglottic larynx, ethmoid sinus, and maxillary sinus).

Non-Small Cell Lung Cancer (NSCLC)

Authorization of 6 months may be granted for treatment of non-small cell lung cancer.

Occult Primary Tumors (cancer of unknown primary)

Authorization of 6 months may be granted for treatment of occult primary cancer.

Ovarian Cancer, Fallopian Tube Cancer, and Primary Peritoneal Cancer

Authorization of 6 months may be granted for treatment of epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma of the ovary, grade 1 endometrioid carcinoma, low-grade serous carcinoma/ovarian borderline epithelial tumor (low malignant potential), mucinous carcinoma of the ovary, malignant sex-cord stromal tumors, or recurrent malignant germ cell tumors.

Prostate Cancer

Authorization of 6 months may be granted for treatment of prostate cancer.

Small Bowel Adenocarcinoma

Authorization of 6 months may be granted for treatment of advanced or metastatic small bowel adenocarcinoma.

Small Cell Lung Cancer (SCLC)

Authorization of 6 months may be granted for treatment of small cell lung cancer.

Soft Tissue Sarcoma

Authorization of 6 months may be granted for treatment of soft tissue sarcoma (including angiosarcoma, extremity/body wall, head/neck, retroperitoneal/intra-abdominal, pleomorphic rhabdomyosarcoma, dermatofibrosarcoma protuberans (DFSP) with fibrosarcomatous transformation, dedifferentiated chordoma, and solitary fibrous tumor.

Thyroid Carcinoma – Anaplastic Carcinoma

Authorization of 6 months may be granted for treatment of thyroid carcinoma-anaplastic carcinoma.

Uterine Neoplasms

Authorization of 6 months may be granted for treatment of uterine neoplasms (including endometrial carcinoma and uterine sarcoma).

Vaginal Cancer

Authorization of 6 months may be granted for subsequent treatment of recurrent or metastatic vaginal cancer when used as a single agent.

Continuation of Therapy

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication in the coverage criteria when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Section 2: Oncology Clinical Policy

PURPOSE

The purpose of this policy is to define the Novologix NCCN® Regimen Prior Authorization Program.

SCOPE

This policy applies to clients who have implemented the Novologix NCCN® Program as a part of their medical and/or pharmacy prior authorization solution.

PROGRAM DESCRIPTION

The National Comprehensive Care Network® (NCCN®) is an alliance of leading cancer centers devoted to patient care, research and education dedicated to improving the quality, effectiveness, and efficiency of cancer care so patients can live better lives.[1] It is comprised of oncology experts who convene regularly to establish the best treatments for patients. NCCN develops various resources for use by stakeholders in the health care delivery system. These resources include, but are not limited to, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), the NCCN Drugs & Biologics Compendium (NCCN Compendium®) and the NCCN Chemotherapy Order Templates (NCCN Templates®).

NCCN Templates® are based on NCCN Guidelines® and NCCN Compendium®. The NCCN Compendium lists the appropriate drugs and biologics as treatment options for specific cancers using U.S. Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category.

NCCN Categories of Evidence and Consensus[2]

- Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
- Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

POLICY

Policy for Regimen Prior Authorization

A regimen prior authorization allows submission of a single prior authorization request for all oncology drugs or biologics within an NCCN template that require prior authorization.

PROCEDURE

This policy provides coverage of a regimen review when all of the following criteria are met:

1. Regimen prior authorization reviews, based on NCCN templates, are initiated through the provider portal.
   - If the prior authorization request is submitted via phone or fax, each drug or biologic will need to be submitted and reviewed as a separate prior authorization request for review with drug-specific criteria.
2. The prior authorization review is requested for an oncology drug or biologic.
3. The member is eligible for regimen review.
4. The indication is for a cancer that is eligible for regimen review. Currently, the cancer types in scope for regimen review include the following:
   - Ampullary Adenocarcinoma
   - Anal Carcinoma
   - B-Cell Lymphomas
   - Basal Cell Skin Cancer
   - Biliary Tract Cancers
   - Bone Cancer
   - Breast Cancer
   - Bladder Cancer
   - Central Nervous System Cancers
   - Cervical Cancer
   - Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
   - Chronic Myeloid leukemia

- Colon Cancer
- Dermatofibrosarcoma Protuberans
- Esophageal Cancer
- Gastric Cancer
- Gastrointestinal Stromal Tumors
- Gestational Trophoblastic Neoplasms
- Hairy Cell Leukemia
- Head and Neck Cancers
- Histiocytic Neoplasms
- Hodgkin Lymphoma
- Hepatocellular Carcinoma
- Kaposi Sarcoma
- Kidney Cancer
- Melanoma: Cutaneous
- Melanoma: Uveal
- Merkel Cell Carcinoma
- Mesothelioma: Peritoneal
- Mesothelioma: Pleural
- Multiple Myeloma
- Myelodysplastic Syndromes
- Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions
- Myeloproliferative Neoplasms
- Neuroendocrine and Adrenal Tumors
- Non-Small Cell Lung Cancer
- Occult Primary
- Ovarian Cancer
- Pancreatic Cancer
- Penile Cancer
- Primary Cutaneous Lymphomas
- Prostate Cancer
- Rectal Cancer
- Small Bowl Adenocarcinoma
- Small Cell Lung Cancer
- Soft Tissue Sarcoma
- Squamous Cell Skin Cancer
- Systemic Mastocytosis
- Systemic Light Chain Amyloidosis
- T-Cell Lymphomas
- Testicular Cancer
- Thymomas and Thymic Carcinomas
- Thyroid Carcinoma
- Uterine Neoplasms
- Vaginal Cancer
- Vulvar Cancer
- Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma
- Wilms Tumor (Nephroblastoma)

In addition, the following criteria must be met for approval:

1. The requested regimen for the drug(s) or biologic(s) and indication is consistent with an NCCN recommendation with a level of evidence category of 1 or 2A.
2. The NCCN template must be accepted by the provider without modification.

Further review may be indicated when the above criteria are not met.

Authorizations may be granted for 12 months or as medically required, based on the member's condition and provider's assessment.

Supportive Care: Myeloid Growth Factor Therapy

Granulocyte colony stimulating factors are recommended for primary prophylaxis based on the febrile neutropenia risk of the chemotherapy regimen. Febrile neutropenia risk levels vary by NCCN Chemotherapy Order template and are listed at the top of the template. Regimens associated with a high or intermediate risk of febrile neutropenia may include a granulocyte colony stimulating factor as part of the prior authorization.

Continuation of Therapy

To submit a request for continuation of therapy, a new regimen prior authorization review must be requested. Upon template selection, the template must be modified to include the appropriate therapies being used for maintenance treatment. The regimen request will be submitted for further review.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and evidence-based practice guidelines.

REFERENCES:

SECTION 1

1. Taxotere [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; January 2023.
2. Docetaxel [package insert]. Gujarat, India: Sun Pharmaceutical Ind. Ltd; February 2021.
3. Docivyx [package insert]. Parsippany, NJ: Avyxa Pharma, LLC; June 2024.
4. Lexicomp [database online]. Hudson, OH: Lexi-Comp, Inc.; https://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed July 13, 2023.
5. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed July 12, 2024.

SECTION 2

1. National Comprehensive Cancer Network. About NCCN website. https://www.nccn.org/home/about, accessed September 9, 2024.
2. National Comprehensive Cancer Network. NCCN Categories of Evidence and Consensus website, https://www.nccn.org/guidelines/guidelines-process/development-and-update-of-guidelines, accessed September 9, 2024.
3. National Comprehensive Cancer Network. NCCN Guidelines website. https://www.nccn.org/guidelines/category_1, accessed September 9, 2024. (Note: An account may be required.)

4. National Comprehensive Cancer Network. NCCN Drugs and Biologics Compendium website https://www.nccn.org/compendia-templates/compendia/drugs-and-biologics-compendia, accessed September 9, 2024. (Note: A subscription may be required.)
5. 5. National Comprehensive Cancer Network. NCCN Chemotherapy Order Templates (NCCN Templates) website. https://www.nccn.org/compendia-templates/nccn-templates-main/browse-by-cancer-type, accessed September 9, 2024. (Note: A subscription may be required.)