

# Jurisdiction Specific Medicare Part B Paclitaxel

## 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	Dosage Form
paclitaxel (all brands)	paclitaxel	injection

## Indications

### Covered Uses

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

The FDA-Labeled Indications and Recognized Compendia (Off-Label) Uses are Below:

- Advanced ovarian carcinoma
- Breast Cancer
- Non-small cell lung cancer
- Kaposi's sarcoma
- Uveal melanoma
- Anaplastic thyroid carcinoma
- Testicular cancer
- Thymoma
- Thymic carcinoma
- Penile cancer
- Vulvar cancer
- Small cell lung cancer
- Head and neck cancer
- Small bowel adenocarcinoma

- Ovarian cancer/fallopian tube cancer/ primary peritoneal cancer
- Cervical cancer
- Kidney cancer
- Esophageal and esophagogastric junction cancers
- Gastric cancer
- Occult primary cancer
- Cutaneous melanoma
- Endometrial carcinoma
- Bladder cancer
- Angiosarcoma
- Epithelioid hemangioendothelimoa
- Anal carcinoma
- Oligodendroglioma of the brain
- Malignant lymphoma
- Multiple myeloma
- Squamous cell skin cancer
- Gestational trophoblastic neoplasia
- Carcinoma of the pancreas
- Hodgkin's disease
- Malignant glioma
- Vaginal cancer
- Central Nervous System cancers mestastases
- Biliary Tract cancers
- Small Bowel Adenocarcinoma
- Pancreatic Adenocarcinoma
- Ampullary Adenocarcinoma
- Germ Cell tumors
- Malignant melanoma
- Cancer of unknown origin
- Nasopharyngeal cancer
- Hormone-refactory Prostate cancer

#### Compendial Uses- ICD-10 Codes Supported by the Medicare Administrative Contractor

- The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>

All other indications will be assessed on an individual basis. Submissions for indications other than those in this policy should be accompanied by supporting evidence from Medicare approved compendia.

## Coverage Criteria

### Advanced Ovarian Carcinoma<sup>4</sup>

Authorization of 12 months may be granted for treatment of advanced ovarian carcinoma.

## Breast Cancer<sup>4</sup>

Authorization of 12 months may be granted for treatment of breast cancer.

## Non-Small Cell Lung Cancer<sup>4</sup>

Authorization of 12 months may be granted for treatment of non-small cell lung cancer.

## Kaposi Sarcoma<sup>4</sup>

Authorization of 12 months may be granted for treatment of Kaposi sarcoma.

## Compendial Uses<sup>1,2,5,6</sup>

Authorization of 12 months may be granted for the following indications:

- Uveal melanoma
- Anaplastic thyroid carcinoma
- Testicular cancer, including germ cell tumors
- Thymoma
- Thymic carcinoma
- Penile cancer
- Vulvar cancer
- Small cell lung cancer
- Head and neck cancer
- Small bowel adenocarcinoma
- Ovarian cancer/fallopian tube cancer/ primary peritoneal cancer
- Cervical cancer
- Kidney cancer
- Esophageal and esophagogastric junction cancers
- Gastric cancer
- Occult primary cancer
- Cutaneous melanoma
- Endometrial carcinoma
- Bladder cancer, including urothelial and non-urothelial carcinoma, upper genitourinary tract cancer, urothelial carcinoma of the prostate, primary carcinoma of the urethra
- Angiosarcoma
- Epithelioid hemangioendothelioma
- Anal carcinoma
- Oligodendroglioma of the brain
- Malignant lymphoma
- Multiple myeloma
- Squamous cell skin cancer
- Gestational trophoblastic neoplasia
- Carcinoma of the pancreas
- Hodgkin disease
- Malignant glioma
- Vaginal cancer

- Central Nervous System cancers, including limited brain metastases, extensive brain metastases
- Biliary Tract cancers, including gallbladder cancer, intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma
- Small Bowel Adenocarcinoma
- Pancreatic Adenocarcinoma
- Ampullary Adenocarcinoma
- Germ Cell Tumors
- Malignant melanoma
- Cancer of unknown origin
- Nasopharyngeal cancer, recurrent or metastatic
- Hormone-refractory Prostate cancer

## All Other Indications<sup>2</sup>

Authorization of 12 months may be granted for treatment of all other approvable indications listed in LCA A52450 that pertain to paclitaxel.

## Dosage and Administration

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

## References

1. Drugs and Biologicals LCD (L33394) Version R16. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 7, 2025.
2. Billing and Coding: Paclitaxel (A52450) Version R24. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 7, 2025.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R9. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 7, 2025.
4. Paclitaxel [package insert]. Lake Forest, IL: Hospira, Inc.; April 2021.
5. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed January 7, 2025.
6. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: [www.micromedexsolutions.com](http://www.micromedexsolutions.com). Accessed January 8, 2025.