

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 carcinoma⁴
- Ampullary Adenocarcinoma²
- Anal carcinoma⁵
- Anaplastic thyroid carcinoma⁵
- Angiosarcoma^{5,6}
- Biliary Tract cancers²
- Bladder cancer⁵
- Breast cancer⁴⁻⁷
- Cancer of unknown origin⁶
- Carcinoma of the pancreas⁶
- Carcinoma of the renal pelvis and ureter¹
- Central Nervous System cancers⁵
- Cervical cancer^{5,6,8}
- Cutaneous melanoma⁵

- Endometrial carcinoma⁵⁻⁸
- Epithelioid hemangioendothelioma⁵
- Esophageal and esophagogastric junction cancers^{5,6,8}
- Gastric cancer^{5,6,8}
- Germ Cell tumors⁶
- Gestational trophoblastic neoplasia⁵
- Head and neck cancer^{5,6,8}
- Hodgkin's disease⁶
- Hormone-refractory Prostate cancer¹
- Kaposi's sarcoma^{4,5}
- Kidney cancer⁵
- Leiomyosarcoma¹
- Malignant glioma⁶
- Malignant lymphoma⁶
- Malignant melanoma⁶
- Multiple myeloma⁶
- Nasopharyngeal cancer⁶
- Non-small cell lung cancer⁴⁻⁷
- Occult primary cancer⁵
- Oligodendroglioma of the brain⁶
- Ovarian cancer/fallopian tube cancer/ primary peritoneal cancer⁵⁻⁷
- Pancreatic Adenocarcinoma⁶
- Penile cancer^{5,7}
- Prostate cancer⁶
- Rhabdomyosarcoma¹
- Small Bowel Adenocarcinoma⁵
- Small cell lung cancer⁵⁻⁷
- Squamous cell skin cancer⁵
- Testicular cancer^{5,6}
- Thymic carcinoma⁵
- Thymoma⁵
- Uveal melanoma⁵
- Vaginal cancer⁵
- Vulvar cancer⁵

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 Carcinoma⁴

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

Breast Cancer^{4,5,6,7}

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

Non-Small Cell Lung Cancer^{4,5,6,7}

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

Kaposi Sarcoma^{4,5}

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

Compendial Uses^{1,2,5,6,7,8}

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

- Ampullary Adenocarcinoma
- Anal carcinoma
- Anaplastic thyroid carcinoma
- Angiosarcoma
- Biliary Tract cancers
- Bladder cancer
- Cancer of unknown origin
- Carcinoma of the pancreas
- Carcinoma of the renal pelvis and ureter
- Central Nervous System cancers
- Cervical cancer
- Cutaneous melanoma
- Endometrial carcinoma
- Epithelioid hemangioendothelioma
- Esophageal and esophagogastric junction cancers
- Gastric cancer
- Germ Cell tumors
- Gestational trophoblastic neoplasia
- Head and neck cancer
- Hodgkin's disease
- Hormone-refractory Prostate cancer
- Kidney cancer
- Leiomyosarcoma
- Malignant glioma
- Malignant lymphoma
- Malignant melanoma
- Multiple myeloma
- Nasopharyngeal cancer

- Occult primary cancer
- Oligodendroglioma of the brain
- Ovarian cancer/fallopian tube cancer/ primary peritoneal cancer
- Pancreatic Adenocarcinoma
- Penile cancer
- Prostate cancer
- Rhabdomyosarcoma
- Small Bowel Adenocarcinoma
- Small cell lung cancer
- Squamous cell skin cancer
- Testicular cancer
- Thymic carcinoma
- Thymoma
- Uveal melanoma
- Vaginal cancer
- Vulvar cancer

All Other Indications²

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 R17. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 14, 2026.
2. Billing and Coding: Paclitaxel (A52450) Version R25. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 14, 2026.
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 14, 2026.
4. Paclitaxel [package insert]. Bedminster, NJ: Alembic Pharmaceutical, Inc.; November 2022.
5. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed January 14, 2026.
6. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed January 14, 2026.
7. Gold Standard, Inc. Clinical Pharmacology [Internet]. Tampa, FL: Elsevier; 2026. Available from: <https://www.clinicalkey.com/pharmacology/clinical-pharmacology>. Accessed January 14, 2026.
8. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: UpToDate, Inc.; 2026; Accessed January 14, 2026.