

JURISDICTION SPECIFIC MEDICARE PART B

PACLITAXEL (generic)

POLICY

I. 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 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>. The FDA-labeled indications and recognized compendia (off-label) uses are listed below:

- A. Advanced ovarian carcinoma
- B. Breast Cancer
- C. Non-small cell lung cancer
- D. Acquired immunodeficiency syndrome (AIDS)-related Kaposi's sarcoma
- E. Uveal melanoma
- F. Anaplastic thyroid carcinoma
- G. Testicular cancer
- H. Thymoma
- I. Thymic carcinoma
- J. Penile cancer
- K. Vulvar cancer
- L. Small cell lung cancer
- M. Cancer of the nasopharynx
- N. Head and neck cancer
- O. Small bowel adenocarcinoma
- P. Epithelial ovarian cancer/fallopian tube cancer/ primary peritoneal cancer
- Q. Cervical cancer
- R. Kidney cancer
- S. Esophageal and esophagogastric junction cancers
- T. Gastric cancer
- U. Occult primary cancer
- V. Cutaneous melanoma
- W. Endometrial carcinoma
- X. Bladder cancer
- Y. Angiosarcoma
- Z. Anal carcinoma
- AA. Oligodendroglioma of the brain
- BB. Malignant lymphoma
- CC. Multiple myeloma
- DD. Hormone refractory prostate cancer

EE. Carcinoma of the renal pelvis and ureter
 FF. Rhabdomyosarcoma
 GG. Leiomyosarcoma

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

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

- A. Relevant medical history, physical examination, results of pertinent diagnostic tests or procedures
- B. Medical record with name of drug administered, route of administration, dosage, duration of the administration.

III. CRITERIA FOR APPROVAL

A. Advanced Ovarian Carcinoma

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

B. Breast Cancer

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

C. Non-Small Cell Lung Cancer

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

D. Acquired Immunodeficiency Syndrome (AIDS)-Related Kaposi Sarcoma

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

E. Compendial Uses

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

1. Uveal melanoma
2. Anaplastic thyroid carcinoma
3. Testicular cancer
4. Thymoma
5. Thymic carcinoma
6. Penile cancer
7. Vulvar cancer
8. Small cell lung cancer
9. Cancer of the nasopharynx
10. Head and neck cancer
11. Small bowel adenocarcinoma
12. Epithelial ovarian cancer/fallopian tube cancer/ primary peritoneal cancer
13. Cervical cancer
14. Kidney cancer
15. Esophageal and esophagogastric junction cancers
16. Gastric cancer
17. Occult primary cancer
18. Cutaneous melanoma

19. Endometrial carcinoma
20. Bladder cancer
21. Angiosarcoma
22. Anal carcinoma
23. Oligodendroglioma of the brain
24. Malignant lymphoma
25. Multiple myeloma
26. Hormone refractory prostate cancer
27. Carcinoma of the renal pelvis and ureter
28. Rhabdomyosarcoma
29. Leiomyosarcoma

IV. DOSAGE AND ADMINISTRATION

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

V. REFERENCES

1. Drugs and Biologicals LCD (L33394) Version R14. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 25, 2021.
2. Billing and Coding: Paclitaxel (A52450) Version R11. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 25, 2021.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R7. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 25, 2021.
4. Paclitaxel [package insert]. Lake Forest, IL: Hospira, Inc.; May 2018.