**Utilization Review Policy 261**

**POLICY:** Oncology (Injectable) – Abraxane Utilization Review Medical Policy
- Abraxane® (paclitaxel albumin-bound for injectable suspension – Celgene Corporation)

**EFFECTIVE DATE:** 1/1/2022
**REVIEW DATE:** 10/22/2025

**COVERAGE CRITERIA FOR:** All Aspirus Medicare Plans

## Summary of Evidence

Paclitaxel albumin-bound, a microtubule inhibitor, is indicated for the following uses:[1]

- **Breast cancer**, after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline (unless contraindicated).
- **Non-small cell lung cancer (NSCLC)**, in combination with carboplatin, for the first-line treatment of locally advanced or metastatic disease in patients who are not candidates for curative surgery or radiation therapy.
- **Pancreatic adenocarcinoma,** in combination with gemcitabine, for the first-line treatment of patients with metastatic disease.

Limited dosing is available regarding use of paclitaxel albumin-bound for conditions listed under "Other Uses with Supportive Evidence". Recommended doses in the product label for approved uses include 100 mg/m$^2$ administered by intravenous (IV) infusion three times in each 21-day cycle, 125 mg/m$^2$ administered by IV infusion three times in each 28-day cycle, and 260 mg/m$^2$ administered by IV infusion once every 21 days.[1]

## Guidelines

Paclitaxel albumin-bound is addressed in a variety of National Comprehensive Cancer Network (NCCN) guidelines:

- **Breast cancer:** Guidelines (version 4.2025 – April 17, 2025) recommend paclitaxel albumin-bound in combination with Keytruda® (pembrolizumab intravenous infusion) as one of the "Preferred" first-line regimens for programmed death-ligand 1 (PD-L1) positive triple-negative breast cancer (category 1).[2,3] It can be used or subsequent therapy (second or third-line) if no prior use of immunotherapy. Paclitaxel albumin-bound, as a single agent or in combination with carboplatin, is recommended for recurrent, unresectable (local or regional) or metastatic HER2-negative disease; and in combination with trastuzumab for recurrent, unresectable (local or regional) or metastatic HER2-positive disease. It is noted that paclitaxel albumin-bound may be substituted for paclitaxel or docetaxel due to medical necessity (i.e., hypersensitivity reaction).

- **NSCLC:** Guidelines (version 8.2025 – August 15, 2025) recommend paclitaxel albumin-bound as first-line therapy for recurrent, advanced, or metastatic PD-L1 expression positive (≥ 1%) tumors that are negative for *EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET,* and *RET*, in combination with Keytruda and carboplatin for squamous cell histology, and in combination with carboplatin and Tecentriq® (atezolizumab intravenous infusion) for non-squamous cell histology.[3,4] Paclitaxel albumin-bound is recommended for the treatment of recurrent, advanced, or metastatic squamous cell or nonsquamous cell disease, as a single-agent or in combination with carboplatin with or without Keytruda or Tecentriq, in a variety of clinical situations.
- **Pancreatic adenocarcinoma:** Guidelines (version 2.2025 – February 3, 2025) recommend therapy with paclitaxel albumin-bound in a variety of settings.[3,5] This includes neoadjuvant therapy; first-line or induction therapy followed by chemoradiation; first-line for metastatic disease (category 1); and in second-line settings after recurrence.
- **Other Uses with Supportive Evidence:** The NCCN Compendium supports the use of paclitaxel albumin-bound for the following conditions: Kaposi sarcoma, intra or extrahepatic cholangiocarcinoma, cervical cancer, ampullary adenocarcinoma, gallbladder cancer, endometrial carcinoma, melanoma, ovarian/fallopian/primary peritoneal cancer, small bowl adenocarcinoma, vaginal cancer, and uveal melanoma.[6-15] The criteria are consistent with the guideline recommendations.

## Analysis of Evidence

The information provided in the summary of evidence is supported by labeled indications, CMS-approved compendia, published clinical literature, clinical practice guidelines, and/or applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs). Refer to the Sources of Information section of this policy for additional information.

## Policy Statement

Prior authorization is recommended for medical benefit coverage of Abraxane. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Dosing.** All approvals are provided for the duration listed below.

This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the Sources of Information section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Sources of Information section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

*Indications with a ^ below are referenced in both the corresponding Standard Medical Utilization Management Internal Policy AND applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications may be internally developed and/or referenced in applicable NCDs, LCDs, and/or LCAs. For these indications, internally developed coverage criteria is denoted throughout the policy in the following manner: 1) IC-L (internal criteria supported by the labeled indication), 2) IC-COMP (internal criteria supported by CMS-approved compendia), 3) IC-ISGP (internal criteria intended to interpret or supplement general provisions outlined in applicable NCDs, LCDs, and/or LCAs), or 4) IC-EC (internal criteria intended to expand coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs). For these indications, coverage criteria that is NOT denoted with one of the above indicators is referenced in applicable NCDs, LCDs, and/or LCAs. Additional information supporting the rationale for determination of internal coverage criteria can be found via the Sources of Information section.*

*Indications with a @ below are referenced in the corresponding Standard Medical Utilization Management Internal Policy, but are NOT directly referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications is internally developed. These indications and their respective coverage criteria represent expanded coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs.*

*Indications with a # below are supported and referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs), but are NOT directly referenced in the corresponding Standard Medical Utilization Management Internal Policy. Coverage criteria for these indications is referenced in applicable NCDs, LCDs, and/or LCAs.*

Recommended Authorization Criteria

Coverage of paclitaxel albumin-bound is recommended in those who meet one of the following criteria:

**FDA-Approved Indications**

**1. Breast Cancer. ^**

**Criteria.** Approve for 1 year if the patient meets the following criteria (A and B):

**A)** Patient is ≥ 18 years of age; [IC-COMP] AND

**B)** Patient meets ONE of the following criteria (i or ii):

**i.** The patient has recurrent or metastatic breast cancer and meets ONE of the following criteria (a, b, or c): [IC-COMP]

**a.** The patient has human epidermal growth factor receptor 2 (HER2)-negative disease; [IC-COMP] OR
**b.** Patient has triple-negative breast cancer; [IC-COMP] OR
**c.** The patient has human epidermal growth factor receptor 2 (HER2)-positive disease and the medication will be used in combination with trastuzumab; [IC-COMP] OR

**ii.** Patient has had a hypersensitivity reaction to paclitaxel or docetaxel. [IC-COMP]

**Dosing.** Approve ONE of the following (A or B):
**A)** Approve up to 260 mg/m$^2$ administered as an intravenous infusion no more frequently than once every 3 weeks.
**B)** Approve up to 125 mg/m$^2$ administered as an intravenous infusion no more frequently than three times in each 28-day cycle.

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**2. Non-Small Cell Lung Cancer (NSCLC). ^**

**Criteria.** Approve for 1 year if the patient meets the following criteria (A, B and C):
**A)** Patient is ≥ 18 years of age; [IC-COMP] AND
**B)** The patient has recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC); [IC-COMP] AND
**C)** The patient meets ONE of the following criteria (i, ii, iii, iv or v):
**i.** Patient meets BOTH of the following (i and ii):
**a)** The tumor is negative for the following actionable biomarkers: epidermal growth factor receptor *(EGFR)* exon 19 deletion or exon 21 L858R, anaplastic lymphoma kinase *(ALK)*, *RET*, and *ROS1*; [IC-COMP] AND
**b)** The medication is used as initial or subsequent therapy; [IC-COMP] OR
**ii.** The patient meets BOTH of the following (a and b):
1. The medication will be used as subsequent therapy; [IC-COMP] AND
2. The tumor is positive for one of the following [(1), (2), (3), (4), or (5)]:
a. Epidermal growth factor receptor (*EGFR*) exon 19 deletion or exon 21 *L858R* mutation; [IC-COMP] OR
b. Epidermal growth factor receptor (*EGFR*) *S768I*, *L861Q*, and/or *G719X* mutation; [IC-COMP] OR
c. *RET* rearrangement positive; [IC-COMP] OR
d. Anaplastic lymphoma kinase (*ALK*) rearrangement positive; [IC-COMP] OR
e. *ROS1* rearrangement positive; [IC-COMP] AND
**iii.** Patient has experienced a hypersensitivity reaction after receiving paclitaxel or docetaxel. [IC-COMP]

**Dosing.** Approve up to 100 mg/m$^2$ administered as an intravenous infusion no more frequently than three times in each 21-day cycle.

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**3. Pancreatic Adenocarcinoma. ^**

**Criteria.** Approve for 1 year if the patient meets the following criteria (A and B):
**A)** Patient is ≥ 18 years of age; [IC-COMP] AND
**B)** The medication will be used in combination with gemcitabine. [IC-COMP]

**Dosing.** Approve up to 125 mg/m$^2$ as an intravenous infusion no more frequently than three times in each 28-day cycle.

**OTHER USES WITH SUPPORTIVE EVIDENCE**

**4. Ampullary Adenocarcinoma. ^**

**Criteria.** Approve for 1 year if the patient meets the following criteria (A and B):
**A)** Patient is ≥ 18 years of age; [IC-COMP] AND
**B)** The medication will be used in combination with gemcitabine. [IC-COMP]

**Dosing.** Approve up to 125 mg/m$^2$ as an intravenous infusion no more frequently than three times in each 28-day cycle.

**5. Melanoma. ^**

**Criteria.** Approve for 1 year if the patient meets the following criteria (A, B and C):
**A)** Patient is ≥ 18 years of age; [IC-COMP] AND
**B)** The patient has unresectable or metastatic melanoma; [IC-COMP] AND
**C)** At least one other systemic therapy for melanoma has been tried. [IC-COMP]
Note: Examples of systemic therapy are Keytruda [pembrolizumab for intravenous use], Opdivo [nivolumab injection for intravenous use], Yervoy [ipilimumab intravenous injection], high dose Proleukin [aldesleukin for intravenous infusion]; cytotoxic agents [e.g., dacarbazine, temozolomide, paclitaxel, carboplatin]; imatinib; Zelboraf [vemurafenib tablets]; Tafinlar [dabrafenib capsules]; Mekinist [trametinib tablets]).

**Dosing.** Approve up to 150 mg/m$^2$ administered as an intravenous infusion no more frequently than three times in each 28-day cycle.

**6. Cervical Cancer. ^**

**Criteria.** Approve for 1 year if the patient meets the following criteria (A and B):
**A)** Patient is ≥ 18 years of age; [IC-COMP] AND
**B)** The medication will be used as subsequent therapy. [IC-COMP]

**Dosing.** Approve up to 125 mg/m$^2$ as an intravenous infusion no more frequently than three times in each 28-day cycle.

**7. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer. ^**

**Criteria.** Approve for 1 year if the patient meets the following criteria (A and B):
**A)** Patient is ≥ 18 years of age; IC-COMP AND
**B)** Patient meets ONE of the following (i or ii):
- **i.** Patient meets BOTH of the following (a and b):
  - **a.** The patient has persistent or recurrent disease; IC-COMP AND
  - **b.** At least one other systemic chemotherapy regimen has been tried; IC-COMP OR
    Note: Examples of chemotherapy are docetaxel, paclitaxel plus carboplatin.
- **ii.** Patient has had a hypersensitivity reaction to paclitaxel or docetaxel. IC-COMP

**Dosing.** Approve one of the following (A or B):
**A)** Approve up to 260 mg/m$^2$ given as an intravenous infusion no more frequently than once every 3 weeks; OR
**B)** Approve up to 100 mg/m$^2$ administered as an intravenous infusion no more frequently than three times in each 28-day cycle.

**8. Uveal Melanoma. ^**

**Criteria.** Approve for 1 year if the patient meets the following criteria (A and B):
**A)** Patient is ≥ 18 years of age; IC-COMP AND
**B)** Patient has metastatic or unresectable disease. IC-COMP

**Dosing:** Approve up to 150 mg/m$^2$ administered as an intravenous infusion given no more frequently than three times in each 28-day cycle.

**9. Endometrial Carcinoma. ^**

**Criteria.** Approve for 1 year if the patient meets the following criteria (A and B):
**A)** Patient is ≥ 18 years of age; IC-COMP AND
**B)** Patient has recurrent or metastatic disease. IC-COMP

**Dosing.** Approve doses between 100 mg/m$^2$ and 260 mg/m$^2$ administered as an intravenous infusion given no more frequently than once every 21 days.

**10. Biliary Tract Cancer. ^**

**Criteria.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
**A)** Patient is ≥ 18 years of age; IC-COMP AND
**B)** Patient meets ONE of the following (i or ii):
- **i.** Patient meets BOTH of the following (a and b):
  - i. Patient has gallbladder cancer; IC-COMP AND
  - ii. The medication is used as neoadjuvant therapy; IC-COMP OR

**ii.** Patient meets BOTH of the following (a and b):
  i. Patient has unresectable, resected gross residual, or metastatic disease; [IC-COMP] AND
  ii. Patient has ONE of the following conditions [(1), (2) or (3)]:
    1. Gallbladder cancer; [IC-COMP] OR
    2. Intrahepatic cholangiocarcinoma; [IC-COMP] OR
    3. Extrahepatic cholangiocarcinoma; [IC-COMP] AND

**C)** The medication is used in combination with gemcitabine. [IC-COMP]

**Dosing:** Approve one of the following (A or B):

**A)** Approve up to 125 mg/m$^2$ administered as an intravenous infusion given no more frequently than twice every 21 days; OR

**B)** Approve up to 125 mg/m$^2$ administered as an intravenous infusion given no more frequently than three times every 28 days.

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**11. Kaposi Sarcoma. ^**

**Criteria.** Approve for 1 year if the patient meets the following criteria (A and B):

**A)** Patient is ≥ 18 years of age; [IC-COMP] AND

**B)** Patient has tried at least one systemic chemotherapy. [IC-COMP]
Note: Examples of systemic chemotherapy are doxorubicin, paclitaxel.

**Dosing.** Approve 100 mg administered as an intravenous infusion no more frequently than three times in each 28-day cycle.

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**12. Small Bowel Adenocarcinoma. ^**

**Criteria.** Approve for 1 year if the patient meets the following criteria (A and B):

**A)** Patient is ≥ 18 years of age; [IC-COMP] AND

**B)** The patient has advanced or metastatic disease. [IC-COMP]

**Dosing:** Approve one of the following doses (A or B):

**A)** Approve up to 260 mg/m$^2$ given as an intravenous infusion no more frequently than once every 3 weeks; OR

**B)** Approve up to 125 mg/m$^2$ administered as an intravenous infusion no more frequently than three times in each 28-day cycle.

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**13. Vaginal Cancer. ^**

**Criteria.** Approve for 1 year if the patient meets the following (A and B):

**A)** Patient is ≥ 18 years of age; [IC-COMP] AND

**B)** The medication will be used as subsequent therapy. [IC-COMP]

**Dosing.** Approve up to 125 mg/m$^2$ as an intravenous infusion no more frequently than three times in each 28-day cycle.

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**CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of paclitaxel albumin-bound is not recommended in the following situations:

**1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## Sources of Information

1. Abraxane® suspension, intravenous infusion [prescribing information]. Summit, NJ: Celgene; August 2020.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 4.2025 – April 17, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 13, 2025.
3. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 13, 2025. Search terms: paclitaxel, albumin bound.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 8.2025 – August 15, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 13, 2025.
5. The NCCN Pancreatic Adenocarcinoma Clinical Practice Guidelines in Oncology (version 2.2025 – February 3, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 13, 2025.
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7. The NCCN Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – July 16, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 13, 2025.
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10. The NCCN Small Bowel Adenocarcinoma Clinical Practice Guidelines in Oncology (version 3.2025 – March 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 13, 2025.
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12. The NCCN Kaposi Sarcoma Clinical Practice Guidelines in Oncology (version 2.2026 – September 16, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 13, 2025.
13. The NCCN Cervical Cancer Clinical Practice Guidelines in Oncology (version 4.2025 – March 24, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 13, 2025.
14. The NCCN Ampullary Adenocarcinoma Clinical Practice Guidelines in Oncology (version 2.2025 – January 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 13, 2025.
15. The NCCN Vaginal Cancer Clinical Practice Guidelines in Oncology (version 5.2025 – February 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 13, 2025.
16. Shroff RT, Javle MM, Xiao L, et al. Gemcitabine, cisplatin, and nab-paclitaxel for the treatment of advanced biliary tract cancers. A phase 2 clinical trial. *JAMA Oncol*. 2019;5:824-830.
17. Sahai V, Catalano PJ, Zalupski MM, et al. Nab-paclitaxel and gemcitabine as first-line treatment of advanced or metastatic cholangiocarcinoma. A Phase 2 clinical trial. *JAMA Oncol*. 2018;4:1707-1712.
18. Alberts DS, Blessing JA, Landrum LM, et al. Phase II trial of nab-paclitaxel in the treatment of recurrent or persistent advanced cervical cancer: A gynecologic oncology group study. *Gynecol Oncol*. 2012;127:451-455.
19. Hersh EM, O'Day SJ, Ribas A, et al. A phase 2 clinical trial of nab-paclitaxel in previously treated and chemotherapy-naïve patients with metastatic melanoma. *Cancer*. 2010;116:155-163.
20. Coleman RL, Brady WE, McMeekin DS, et al. A phase II evaluation of nanoparticle, albumin-bound (nab) paclitaxel in the treatment of recurrent or persistent platinum-resistant ovarian, fallopian tube, or primary peritoneal cancer: A Gynecologic Oncology Group Study. *Gynecol Oncol*. 2011;122(1):111-115.

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22. Centers for Medicare and Medicaid Services, National Government Services, Inc, Local Coverage Determination (LCD): Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394) [original date 10/01/2015; revision effective date 7/13/25]. Accessed on October 22, 2025.

## HISTORY

| Type of Revision | Summary of Changes | Date |
|---|---|---|
| Policy created | New Medicare Advantage Medical Policy | 07/11/18 |
| Policy revision | Reviewed and revised original policy created 07/11/2018 in accordance with Local Coverage Article A52448 and Oncology - Abraxane Utilization Review Policy. | 11/06/2019 |
| Policy revision | Completion of 2019 monthly monitoring process in accordance with Local Coverage Determination L33394, Local Coverage Article A52448, and Oncology - Abraxane Utilization Review Policy. | 12/16/2019 |
| Policy revision | Non-clinical update to policy to add the statement "This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the References section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Reference section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage." | 1/30/2020 |
| Policy revision | *Added the following to the Policy Statement "Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles."<br>*Updated references | 08/07/2020 |
| Policy revision | • **Acquired Immune Deficiency Syndrome (AIDS)-Related Kaposi Sarcoma**: Added new approval condition based on guideline recommendations.<br>• **Non-Small Cell Lung Cancer:** Added *MET* exon 14 skipping mutation and *RET* rearrangement-positive, to the list of targetable mutations where Abraxane can be used as initial or subsequent therapy.<br>• **Urothelial Carcinoma:** Deleted from policy, since it is no longer supported in guidelines. | 12/16/2020 |
| Policy revision | **Breast Cancer:** A requirement was added that the patient is ≥ 18 years of age. An exception was revised from "Abraxane will be used in combination with Tencentriq" to "will be used in combination with Keytruda" for programmed death-ligand 1 positive, triple-negative breast | 12/21/2021 |

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| | cancer. Added "Approve up to" verbiage to both dosing regimens. Removed 100 and 150 mg/m$^2$ doses and revised frequency to "no more than three times in" each 28-day cycle.<br>**Non-Small Cell Lung Cancer:** A requirement was added that the patient is ≥ 18 years of age. Removed non-squamous cell and squamous cell criteria. Removed Abraxane is used as subsequent therapy from exception if the tumor is positive for any of the targetable mutations, at least one of the specific targeted therapy options have been tried. Added exception if the tumor is EGFR exon 20 or KRAS G12C mutation positive, Abraxane is used first line. Removed "either as a single agent or in combination with platinum chemotherapy with or without an immune checkpoint inhibitor" from exception the tumor is negative or unknown for targetable mutations and Abraxane is used as initial therapy. Moved examples of targetable mutations to a Note. Add exception for patients who experience hypersensitivity reactions to paclitaxel or docetaxel. Added "up to" verbiage to dosing regimen and revised frequency to "no more frequently than three times" in each 21 day cycle.<br>**Pancreatic Adenocarcinoma:** A requirement was added that the patient is ≥ 18 years of age. Added "up to" verbiage to dosing regimen and revised frequency to "no more frequently than three times" in each 28 day cycle.<br>**Biliary Tract Cancer:** The condition of approval name was revised from Cholangiocarcinoma (Intra or Extrahepatic). A requirement was added that the patient is ≥ 18 years of age. A requirement was added that the patient has gallbladder cancer, intrahepatic cholangiocarcinoma, or extrahepatic cholangiocarcinoma.<br>**Endometrial Carcinoma:** A requirement was added that the patient is ≥ 18 years of age.<br>**Kaposi Sarcoma:** Acquired Immune Deficiency Syndrome (AIDS) Related was removed from the condition of approval. A requirement was added that the patient is ≥ 18 years of age. Revised dosing frequency to no more frequently than three times.<br>**Melanoma:** A requirement was added that the patient is ≥ 18 years of age. Revised dosing frequency to no more frequently than three times.<br>**Ovarian, Fallopian Tube, or Primary Peritoneal Cancer:** A requirement was added that the patient is ≥ 18 years of age. Added Approve up to verbiage to both dosing regimens. Added "Approve up to" verbiage to both dosing regimens. Revised frequency to "no more than three times in" each 28-day cycle.<br>**Small Bowel Adenocarcinoma:** A requirement was added that the patient is ≥ 18 years of age. Added "Approve up to" verbiage to both dosing regimens. Revised frequency to "no more than three times in" each 28-day cycle.<br>**Uveal Melanoma:** A requirement was added that the patient is ≥ 18 years of age. | |
| Policy revision | **Biliary Tract Cancer:** Revised dosing to 125 mg/m$^2$ given no more frequently than twice every 21 days, or no more frequently than three times every 28 days. | 03/17/2022 |
| Policy revision | **Non-Small Cell Lung Cancer (NSCLC):** Added "advanced" to requirement that the patient has recurrent, advanced, or metastatic NSCLC. For the requirement that the tumor is negative or unknown for targetable mutations, added examples of targetable mutations to the Note and added "or subsequent" to the requirement that paclitaxel albumin-bound is used as initial or subsequent therapy. For requirement that paclitaxel albumin-bound is used as subsequent therapy, added "exon 19 deletion or L858R" to Epidermal growth factor receptor (EGFR) exon 19 deletion or L858R criterion and added EGFR S7681, L861Q, and/or | 11/30/2022 |

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| | G719X mutation as optional for approval. Added Note with examples of targeted drug therapies. Added ERBB2 (HER2) as an optional for approval.<br>**Ampullary Adenocarcinoma:** Added new condition of approval.<br>**Cervical Cancer:** Added new condition of approval.<br>**Ovarian, Fallopian Tube, or Primary Peritoneal Cancer:** Added "patient has had a hypersensitivity reaction to paclitaxel or docetaxel" as an additional optional for approval.<br>**Small Bowel Adenocarcinoma:** Added Jemperli (dostarlimab intravenous infusion) to deficient mismatch repair/microsatellite instability-high criteria.<br>**Uveal Melanoma:** Revised dosing to "up to 150 mg/m$^2$" from 100 mg/m$^2$ and 260 mg/m$^2$, and dosing frequency to no more frequently than "three times is each 28-day cycle" from no more frequently than once every 21 days. | |
| Policy revision | **Non-Small Cell Lung Cancer:** Added exon 21 to the criterion Epidermal growth factor receptor (*EGFR*) exon 19 deletion or exon 21 *L858R* mutation. | 12/26/2023 |
| Aspirus P&T Review | Policy reviewed and approved by Aspirus P&T committee. Annual review process | 09/16/2024 |
| Policy review | No criteria changes.<br>Review based on LCD/LCA surveillance | 02/04/2025 |
| Policy revision | No criteria changes. Formatting and notation updates. | 03/07/2025 |
| Policy review | No criteria changes.<br>Review based on LCD/LCA surveillance | 09/09/2025 |
| Aspirus P&T Review | Policy reviewed and approved by Aspirus P&T committee. Annual review process | 09/15/2025 |
| Policy revision | **Breast Cancer:** In reference to triple-negative breast cancer, deleted requirement for programmed death ligand-1 (PD-L1) positive disease and also deleted requirement that the medication will be used in combination with Keytruda (pembrolizumab intravenous infusion). Also, in reference to patients with hypersensitivity reaction deleted requirements that the medication will be used for HER2 negative disease or for HER2 positive disease in combination with trastuzumab.<br>**Non-Small Cell Lung Cancer:** Deleted requirement the tumor is negative or unknown for targetable mutations and the note that lists examples of targetable mutations. Instead added requirement that the tumor is negative for the following actionable biomarkers: epidermal growth factor receptor (EGRF) exon 19 deletion or exon 21 L858R, anaplastic lymphoma kinase (ALK), RET, and ROS1. Add RET rearrangement positive to the list of targetable mutations that the medication can be use as subsequent therapy. Deleted requirement that the patient has received targeted drug therapy for the specific mutation and the note with examples of targeted therapy. Deleted requirement for medication use in first line setting for tumors positive for EGFR exon 20 or ERBB2 (HER2) mutation. Also deleted requirement where the medication can be used as first-line or subsequent therapy for BRAF V600E, MET exon 14 skipping mutation, RET rearrangement or NTRK 1/2/3 gene fusion. For patients with hypersensitivity reaction deleted requirements about premedication use. | 10/22/2025 |