Evolent Clinical Guideline 3000 for Abraxane™ (nab-paclitaxel)

Guideline Number:	Applicable Codes	
Evolent_CG_3000		
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Original Date:	**Last Revised Date:**	**Implementation Date:**
September 2011	July 2026	July 2026

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STATEMENT

Purpose

To define and describe the accepted indications for Abraxane (nab-paclitaxel) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Breast Cancer

- NOTE: Abraxane (nab-paclitaxel) and Abraxane-based regimens, [e.g., Abraxane (nab-paclitaxel) +/- Keytruda (pembrolizumab)] are not supported by Evolent Policy for adjuvant therapy of stages I-III breast cancer OR the treatment of recurrent unresectable or metastatic breast cancer. This policy position is based on the lack of Level 1 evidence to show superior outcomes with Abraxane (nab-paclitaxel) compared to Taxol (paclitaxel) in the neoadjuvant/adjuvant setting. Also, for metastatic breast cancer the results of the KEYNOTE-355 trial showed comparable outcomes with the above combination compared to [Taxol (paclitaxel) + Keytruda (pembrolizumab)] and [Gemcitabine + Carboplatin + Keytruda (pembrolizumab)]; see reference below. Abraxane (nab-paclitaxel) would be supported per Evolent Policy if the member has a history of a severe allergic reaction/anaphylaxis to Taxol (paclitaxel) or Taxotere (docetaxel). Please refer to Evolent alternative agents/regimens recommended by Evolent, including but not limited to regimens available at **Evolent Pathways**.

Cervical Cancer, Endometrial Cancer, and Ovarian Cancer

- NOTE: Abraxane (nab-paclitaxel) is not supported by Evolent Policy for the treatment of cervical cancer, endometrial cancer, and ovarian cancer. This policy position is based on

the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Abraxane (nab-paclitaxel) compared to Taxol (paclitaxel) or Taxotere (docetaxel). Abraxane (nab-paclitaxel) would be supported per Evolent Policy if the member has a history of a severe allergic reaction/anaphylaxis to Taxol (paclitaxel) or Taxotere (docetaxel). Please refer to the alternative agents/regimens recommended by Evolent, including but not limited to regimens available at **Evolent Pathways**.

Melanoma

- NOTE: Abraxane (nab-paclitaxel) is not supported by Evolent Policy for the treatment of unresectable/metastatic cutaneous melanoma. This policy position is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes with Abraxane (nab-paclitaxel) compared to the Evolent recommended alternatives agents/regimens, including but not limited to regimens at **Evolent Pathways**.

Non-Small Cell Lung Cancer (NSCLC)

- NOTE: Abraxane (nab-paclitaxel) +/- carboplatin +/- Keytruda (pembrolizumab) (for squamous histology)/atezolizumab (for non-squamous histology) are not supported by Evolent Policy for initial or subsequent treatment of NSCLC. This policy position is based on:
    - The results of the KEYNOTE- 407 trial which showed equivalent Progression Free Survival and Overall Survival with both Abraxane (nab-paclitaxel) and Taxol (paclitaxel). KEYNOTE-407 is referenced below.
    - Lack of Level 1 evidence (randomized trials and/or meta-analyses) showing superior outcomes with Abraxane-based combinations compared to Taxol (paclitaxel) combinations in patients with metastatic Non-Small Cell Lung Cancer.
- Abraxane (nab-paclitaxel) use in the above setting would be supported by Evolent Policy if there is a history of a severe allergic reaction/anaphylaxis to Taxol (paclitaxel). Please refer to the alternative agents/regimens recommended by Evolent including but not limited to regimens available at **Evolent Pathways**.

Pancreatic Adenocarcinoma

- Abraxane (nab-paclitaxel) may be used in combination with gemcitabine as neoadjuvant therapy for borderline resectable or locally advanced disease OR
- Abraxane (nab-paclitaxel) may be used in combination with gemcitabine for first or subsequent line therapy for recurrent/metastatic disease for members who have not received/progressed on prior Abraxane (nab-paclitaxel).

CONTRAINDICATIONS/WARNINGS

- Contraindications
    - Neutrophil counts of < 1,500 cells/mm3

- Severe hypersensitivity reactions to Abraxane (nab-paclitaxel) for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound), for intravenous use

- US Boxed Warning
  - Severe myelosuppression
    - Do not administer Abraxane (nab-paclitaxel) to patients with baseline neutrophil counts of <1,500 cells/mm^3. Monitor for neutropenia, which may be severe and result in infection or sepsis. Perform frequent complete blood cell counts on all patients receiving Abraxane (nab-paclitaxel).

EXCLUSION CRITERIA

- Disease progression while receiving Abraxane (nab-paclitaxel) or an Abraxane containing regimen.
- Dosing exceeds single dose limit of Abraxane (nab-paclitaxel) 260 mg/m^2 if given every 3 weeks.
- Investigational use of Abraxane (nab-paclitaxel) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
  - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
  - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
  - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
  - Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
  - That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
  - That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
  - That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

CODING AND STANDARDS

Codes

- J9264 - Injection, paclitaxel protein-bound particles, 1 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
July 2026	• Updated references
February 2026	• Updated contraindications/warnings section • Updated references
February 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1179 Abraxane (nab-paclitaxel)
February 2024	• Updated NCH verbiage to Evolent • Updated "continuation request" verbiage

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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