

Title: paclitaxel Protein Bound Particles (Abraxane)

Origination: 07/28/10	Revised:	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

- Abraxane for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) is an antimicrotubule agent that promotes the assembly of microtubules from tubulin dimers and stabilizes microtubules by preventing depolymerization. This stability results in the inhibition of the normal dynamic reorganization of the microtubule network that is essential for vital interphase and mitotic cellular functions. Paclitaxel induces abnormal arrays or "bundles" of microtubules throughout the cell cycle and multiple asters of microtubules during mitosis.
- Abraxane is indicated for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within six (6) months of adjuvant chemotherapy; in non small cell lung cancer (NSCLC) patients who have experienced hypersensitivity reactions to docetaxel or paclitaxel.
- The recommended regimen for Abraxane is 260 mg/m² administered intravenously over 30 minutes every three (3) weeks.

Reference Statement

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible and have applicable benefit coverage (i.e., self-injectable rider) within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criteria

- Do not use with Members who have baseline neutrophil counts of less than 1,500 cell/mm³.

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Procedure:

- 1.0 Request for *initial therapy* with Abraxane for **metastatic disease or metastatic breast cancer** requires documentation from the Member's medical; records maintained by the requesting independent practitioner verifying all of the following:
 - 1.1 Member has failed combination chemotherapy or relapsed within six (6) months of adjuvant chemotherapy;
 - 1.2 If the above criteria are met, Abraxane is approvable for up to six (6) months.
- 2.0 Request for *continuation of therapy* beyond initial authorization period of Abraxane for **metastatic breast cancer** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following:
 - 2.1 Member is experiencing tumor response;
 - 2.2 Member tolerated previous infusion without serious adverse effects.
- 3.0 Request for *initial therapy* with Abraxane for **non small cell lung cancer** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying all of the following:
 - 3.1 Member has experienced hypersensitivity reactions to docetaxel or paclitaxel;
 - 3.2 If the above criteria are met, Abraxane is approvable for up to six (6) months.
- 4.0 Request for *continuation of therapy* with Abraxane for **non-small cell lung cancer** requires documentation from the Member's medical; records maintained by the requesting independent practitioner verifying all of the following:
 - 4.1 Member is experiencing tumor response;
 - 4.2 Member tolerated previous infusion without serious adverse effects.

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References:

1. Abraxane (paclitaxel protein-bound particles for injectable suspension) Prescribing Information. Abraxis BioScience, LLC. Bridgewater, NJ. Revised March 2010.
2. Facts and Comparisons 4.0, St. Louis, MO. Walters Kluwer Health URL: www.factsandcomparisons.com. Updated 2010.
3. National Comprehensive Cancer Network, Inc. (NCCN) Practice Guidelines in Oncology Version 2.2010, March 2010. Available at: www.nccn.org/professionals/physician_gls/f_guidelines.asp
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2010. Available at: <http://clinicalpharmacology.com>

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.