

The following policy is for medication that falls under the Medicare Part D benefit only.

Prior Authorization Group: ABRAXANE Policy

Drug(s): ABRAXANE (paclitaxel protein-bound particles)

Covered Uses: Metastatic breast cancer after failure of combination chemotherapy or relapse within 6 months of adjuvant chemotherapy. Prior therapy must include an anthracycline unless clinically contraindicated **AND** prior therapy should include Taxol (paclitaxel) or Taxotere (docetaxel) unless contraindicated. All criteria in "other criteria" section must be met for coverage.

Required Medical Information:

- Radiologic report confirming diagnosis.
- Complete blood Count (CBC).
- Chemistries.
- Medical history.
- Documentation supporting criteria.

Age Restrictions: Restricted to 18 years of age or older.

Prescriber Restrictions: Oncologist

Other Criteria: Extension of therapy criteria includes no progression of disease based on radiologic reports and no significant adverse reactions. Dosing and frequency must follow FDA approved package label dose and frequency.

Exclusion Criteria:

Abraxane will not be considered medically necessary for the following:

- No documented failure or toxicity to prior combination therapies with an anthracycline (e.g. doxorubicin) **AND** no clinical documentation submitted supporting the use of Abraxane over paclitaxel or docetaxel.
- Baseline serum bilirubin greater than 1.5mg/dL.
- Baseline serum creatinine greater than 2mg/dL.
- Neutrophils less than 1500 cells/mm³.
- Contraindications listed in FDA approved package labeling.
- Off-label use not identified in any of the Part D compendia.
- Abraxane is not covered when used for adjuvant treatment.
- Dose and frequency exceeding package labeling.

Coverage Duration: 3 months initial approval. 6 months for extension of therapy