JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP043
		Effective Date	06/01/2022
		Review Date	04/20/2022
	Subject **Abraxane**	*Revision Date*	04/20/2022
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Abraxane

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I. POLICY

A. Abraxane (paclitaxel, albumin-bound) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Abraxane may be approved for patients who meet the following:
   1. Pancreatic adenocarcinoma
      a. Documentation has been submitted showing the patient has a diagnosis of pancreatic adenocarcinoma
   2. Breast cancer
      a. Documentation has been submitted showing that Abraxane will be used for one of the following:
         I. Treatment of recurrent or metastatic breast cancer
         II. As a substitute for paclitaxel or docetaxel due to hypersensitivity reactions or contraindication to standard hypersensitivity premedications
   3. Non-small cell lung cancer(NSCLC)
      a. Documentation has been submitted showing that Abraxane will be used for one of the following:
         I. Treatment of recurrent, advanced or metastatic NSCLC
         II. As a substitute for paclitaxel or docetaxel due to hypersensitivity reactions or contraindication to standard hypersensitivity premedications
   4. Cutaneous melanoma
      a. Documentation has been submitted showing the following:
         I. Patient has a diagnosis of metastatic or unresectable cutaneous melanoma
         II. Abraxane will be used for second-line, or subsequent therapy as one of the following:
            i. Monotherapy
            ii. Combination with carboplatin
   5. Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer
      a. Documentation has been submitted showing the patient has a diagnosis of persistent or recurrent epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer
   6. AIDS-related Kaposi sarcoma

a. Documentation has been submitted showing the patient has a diagnosis of AIDS-related Kaposi sarcoma

7. Endometrial carcinoma
   a. Documentation has been submitted showing the patient has a diagnosis of endometrial carcinoma
8. Hepatobiliary Cancers
   a. Documentation has been submitted show that Abraxane will be used in combination with gemcitabine for unresectable or metastatic progression of one of the following:
      I. intrahepatic cholangiocarcinoma
      II. extrahepatic cholangiocarcinoma
      III. gallbladder cancer
9. Uveal melanoma
   a. Documentation has been submitted showing Abraxane will be used as monotherapy for distant metastatic uveal melanoma
10. Small Bowel Adenocarcinoma
    a. Documentation has been submitted showing Abraxane will be used as either monotherapy or in combination with gemcitabine, for advanced or metastatic small bowel adenocarcinoma

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 6 months of therapy
B. Continuation of therapy may be approved in 6-month intervals with documentation showing the patient is continuing to tolerate the regimen and there has not been disease progression while on treatment

IV. EXCLUSIONS

A. Abraxane will not be covered for the following:
   1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/ HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, paclitaxel protein-bound particles, 1 mg	J9264

VII. REFERENCES

1. Abraxane [prescribing information]. Summit, NJ: Celgene Corporation; August 2020.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed March 7, 2022.

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2022	Policy Creation

Review Date: 04/20/2022

Revision Date: