

Paclitaxel Protein Bound: Abraxane

Effective Date: 5/2/22

Revision Date(s): 9/21, 11/22, 12/22, 7/23, 12/23, 4/8/2024, 5/23/24

Review Date: 5/23/24

Policy type: Medical Necessity

Line of Business: Commercial

Authorizations are for 6 months, after which time they must be reviewed for efficacy, safety, and tolerability.

Preference	Requires Prior Auth	Drug Name	HCPCS Code	Description
Preferred	No	Paclitaxel (Taxol)	J9267	Injection, paclitaxel, 1 mg
Preferred	No	Docetaxel (Taxotere)	J9171	Injection, docetaxel, 1 mg
Preferred	No	Docetaxel (Ingenus)	J9172	Injection, docetaxel (ingenus) not therapeutically equivalent to J9171, 1 mg
Non-Preferred**	Yes	Paclitaxel Protein-Bound (Abraxane)	J9264	Injection, paclitaxel protein-bound particles, 1 mg
Non-Preferred**	Yes	Paclitaxel Protein-Bound (Teva)	J9258	Injection, paclitaxel protein-bound particles (teva) not therapeutically equivalent to J9264, 1 mg
Non-Preferred**	Yes	Paclitaxel Protein-Bound (American Regent)	J9259	Injection, paclitaxel protein-bound particles (american regent) not therapeutically equivalent to J9264, 1 mg
Non-Preferred	Yes	Docetaxel (Docivyx)	J9999	Not otherwise classified, antineoplastic drugs

**Does not apply in the setting of Pancreatic Cancer, Ampullary Adenocarcinoma, and Biliary Tract Cancers.

Members must have documentation of a contraindication, failure, or intolerance to any of the preferred agents prior to approval of a non-preferred product.

Universal Criteria:

- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature.; **AND**
- In the instance that a request is made for drug(s) that was (were) previously tried (including in the same pharmacologic class or with the same mechanism of action) and such drug(s) was (were) discontinued due to a lack of efficacy or effectiveness, diminished effect, or an adverse event, the request may be subject to an off-label review for medical necessity unless supported by the NCCN or high quality literature (prospective phase 2 or 3 studies published as full manuscripts in a CMS-supported journal).

Universal Approval Criteria:

Unless otherwise noted above the review criteria used by OncoHealth to determine medical necessity for anticancer treatments and supportive agents include, but is not limited to:

- New drugs or regimens (combinations of drugs) approved by the United States Food and Drug Administration (FDA).
- Drugs and biologics may be used off-label if they are considered medically accepted or necessary if supported by any of the following 5 compendia below.
 - NCCN Drugs & Biologics Compendium® (Category 1 and 2a)
 - Clinical Pharmacology (Strong For)
 - American Hospital Formulary Service Drug Information (AHFS DI) (Level 1)
 - Thompson Micromedex DrugDex® (Class I and IIa)
 - Wolters Kluwer Lexi-Drugs® (Level A)
- Other use of drugs and biologics may be considered medically accepted if supported as safe and effective according to peer-reviewed articles from one of the following journals
 - American Journal of Medicine; Annals of Internal Medicine; Annals of Oncology; Annals of Surgical Oncology; Biology of Blood and Marrow Transplantation; Blood; Bone Marrow Transplantation; British Journal of Cancer; British Journal of Hematology; British Medical Journal; Cancer; Clinical Cancer Research; Drugs; European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); Gynecologic Oncology; International Journal of Radiation, Oncology, Biology, and Physics; The Journal of the American Medical Association, Journal of Clinical Oncology; Journal of the National Cancer Institute; Journal of the National Comprehensive Cancer Network (NCCN); Journal of Urology; Lancet; Lancet Oncology; Leukemia; The New England Journal of Medicine; Radiation Oncology
 - **Meeting abstracts and case reports are excluded from consideration.**
- Non-standard protocols may be approved based on unique clinical circumstances.

Billing

Drug Name	HCPCS Code	Description
Docetaxel (Taxotere)	J9171	Injection, docetaxel, 1 mg
Docetaxel (Ingenus)	J9172	Injection, docetaxel (ingenus) not therapeutically equivalent to J9171, 1 mg
Paclitaxel Protein-Bound (Teva)	J9258	Injection, paclitaxel protein-bound particles (teva) not therapeutically equivalent to J9264, 1 mg
Paclitaxel Protein-bound (American Regent)	J9259	Injection, paclitaxel protein-bound particles (american regent) not therapeutically equivalent to J9264, 1 mg
Abraxane	J9264	Injection, paclitaxel protein-bound particles, 1 mg
Paclitaxel (Taxol)	J9267	Injection, paclitaxel, 1 mg
Docetaxel (Docivyx)	J9999	Not otherwise classified, antineoplastic drugs

References

1. Abraxane [package insert]. Abraxis BioScience, LLC, Summit, NJ. Available at: https://packageinserts.bms.com/pi/pi_abraxane.pdf
2. Paclitaxel Protein-Bound Particles [package insert]. American Regent, Inc., Shirley, NY. Available at: https://americanregent.com/media/3397/ref-2269_paclitaxel-albumin-full-prescribing-information-rev-07-2022.pdf

3. Paclitaxel Protein-Bound Particles [package insert]. Teva Pharmaceuticals, Parsippany, NJ. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216338s000lbl.pdf
4. Abraxane. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/
5. Docetaxel [package insert]. Hospira, Inc., Lake Forest, IL. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022234s03lbl.pdf
6. Docetaxel [package insert]. Ingenus Pharmaceuticals, LLC., Orlando, FL. Available at: <https://www.ingenus.com/products/docetaxel-injection-usp/>
7. Docivyx [package insert]. Avyxa Pharma, LLC. New Jersey 07054. Available at: <https://www.dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4763744e-360e-4d37-be05-cce4114548cd>
8. Docetaxel. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/
9. Paclitaxel [package insert]. Bristol-Myers Squibb Company. Princeton, NJ. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020262s049lbl.pdf
10. Paclitaxel. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/
11. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed May 23th, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org.

Disclaimer

Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, “Off-Label Use of Anti-Cancer Drugs and Biologics.” This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from OncoHealth, Inc.

For Internal Use ONLY

Date	Updates
5/2/2022	Policy approved at P&T
10/14/22	Policy updated to include additional criteria for biliary tract cancers

11/7/22	Policy approved at P&T to include update from 10/14/22
12/12/22	Updated formatting and incorporated universal criteria
7/18/23	Policy updated indication specific criteria (Deleted Hepatobiliary indication due to updated NCCN Category 2B recommendation) and to include 505(b)(2) HCPCS
12/4/24	Updated Step Therapy Table; Removed Indication Specific Universal Criteria; Added J9258; Updated References
4/8/24	Annual review. Updated Universal Criteria.
5/23/24	Addition of Docivyx as a Non-Preferred product.