Paclitaxel Albumin-Bound:
Abraxane®; Paclitaxel Albumin-Bound Ψ
(Intravenous)

-E-

Document Number: OHSU HEALTHSERVICES-0360

Date Reviewed: 09/2025

Date of Origin: 02/04/2019

Dates Approved: 02/2019, 04/2019, 07/2019, 10/2019, 01/2020, 04/2020, 07/2020, 10/2020, 01/2021, 04/2021, 07/2021, 10/2021, 01/2022, 04/2022, 07/2022, 10/2022, 01/2023, 04/2023, 07/2023, 10/2023, 01/2024, 05/2024, 07/2024, 10/2024, 12/2024, 04/07/2025, 06/05/2025, 06/24/2025, 08/05/2025, 10/02/2025

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months, unless otherwise specified.
  - Prior authorization validity will be provided for up to a maximum of 24 weeks of therapy (18 doses) for the following indications:
    - ❖ Pancreatic Adenocarcinoma neoadjuvant and induction therapy
  - Non-Small Cell Lung Cancer (NSCLC) in combination with tremelimumab, durvalumab, and carboplatin OR in combination with pembrolizumab and carboplatin: Prior authorization validity will be provided for up to a maximum of 12 weeks of therapy (12 doses).
  - NSCLC in combination with atezolizumab and carboplatin: Prior authorization validity will be provided for up to a maximum of 18 weeks of therapy (18 doses).
- Renewal: Prior authorization validity may be renewed every 6 months thereafter, unless otherwise specified.
  - Prior authorization validity may NOT be renewed for the following indications:
    - ❖ NSCLC in combination with tremelimumab, durvalumab, and carboplatin OR in combination with pembrolizumab and carboplatin OR in combination with atezolizumab and carboplatin
    - ❖ Pancreatic Adenocarcinoma neoadjuvant and induction therapy

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- **NSCLC**
  - 900 billable units per 21 days
- **Cervical Cancer, Biliary Tract Cancers, Vaginal Cancer, & Ampullary Adenocarcinoma**
  - 900 billable units per 28 days
- **Breast Cancer, Small Bowel Adenocarcinoma, Pancreatic Adenocarcinoma, & Ovarian Cancer, Fallopian Tube & Primary Peritoneal Cancer**
  - 2800 billable units per 84 days

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Breast Cancer † ‡ 1-3,9,21,27,16e,18e-20e,22e,23e,25e,30e,121e,126e,130e,132e,156e

- Patient failed on combination chemotherapy for metastatic disease or relapsed within 6 months of adjuvant therapy †; **AND**
  - Used as a single agent; **AND**
  - Previous chemotherapy included an anthracycline unless clinically contraindicated; **OR**
- Patient has recurrent unresectable (local or regional) or metastatic (stage IV [M1]) disease OR inflammatory breast cancer with no response to preoperative systemic therapy ‡; **AND**
  - Patient has HER2-negative hormone receptor-positive disease; **AND**
    - Patient is refractory to endocrine therapy or has visceral crisis; **AND**
    - Used as a single agent; **AND**
    - Used in one of the following treatment settings:
      - First-line therapy if no germline BRCA 1/2 mutation and/or HER2 IHC 0+, 1+, or 2+/ISH negative
      - Second-line therapy if not a candidate for fam-trastuzumab deruxtecan-nxki
      - Third-line therapy and beyond; **OR**
  - Patient has triple negative breast cancer (TNBC) ***; **AND**
    - Used in combination with pembrolizumab for PD-L1 positive (PD-L1 CPS ≥10) disease; **AND**
      - Used as first-line therapy; **OR**
    - Used as a single agent; **AND**

  - Used as first-line therapy if PD-L1 CPS <10 and no germline BRCA 1/2 mutation; **OR**
  - Used as subsequent therapy; **OR**
- Used in combination with carboplatin in patients with high tumor burden, rapidly progressing disease, and visceral crisis; **AND**
  - Used as first-line therapy if PD-L1 CPS <10 and no germline BRCA 1/2 mutation; **OR**

- May be substituted for paclitaxel or docetaxel if the patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication ‡; **AND**
  - Patient has a negative skin test to paclitaxel (if available); **AND**
  - Patient has not experienced a severe grade 3 taxane hypersensitivity reaction [e.g., symptoms involving at least 2 organs/systems with a significant decrease in blood pressure (systolic ≤90 mm Hg and/or syncope) and/or oxygen saturation (≤92%), etc.]

Non-Small Cell Lung Cancer (NSCLC) † ‡ [1,2,4,10,30-32,26e,27e,30e,43e,122e,129e,131e,134e,148e]

- Used as first-line therapy for locally advanced or metastatic disease, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy †; **OR**
- May be substituted for paclitaxel or docetaxel if the patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication; **AND**
  - Patient has a negative skin test to paclitaxel (if available); **AND**
  - Patient has not experienced a severe grade 3 taxane hypersensitivity reaction [e.g., symptoms involving at least 2 organs/systems with a significant decrease in blood pressure (systolic ≤90 mm Hg and/or syncope) and/or oxygen saturation (≤92%), etc.]; **OR**
- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first-line therapy; **AND**
    - Used in one of the following:
      - Patients who have tumors that are negative for actionable molecular biomarkers* (may be KRAS G12C mutation positive)
      - Patients who have tumors that are positive for one of the following molecular mutations: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, NRG1 gene fusion, or ERBB2 (HER2); **AND**
    - Used in combination with carboplatin and pembrolizumab for squamous cell histology; **AND**

- Use of albumin-bound paclitaxel will be restricted to patients with a contraindication or intolerance to cemiplimab/paclitaxel/(carboplatin or cisplatin); **OR**

– Used in combination with carboplatin and atezolizumab for non-squamous histology; **AND**

- Use of albumin-bound paclitaxel will be restricted to patients with a contraindication or intolerance to cemiplimab/(paclitaxel or pemetrexed)/(carboplatin or cisplatin); **OR**

– Used in combination with tremelimumab, durvalumab, and carboplatin *(excluding use in patients with PD-L1 ≥50%)*; **AND**

Squamous NSCLC:

- Use of albumin-bound paclitaxel will be restricted to patients with a contraindication or intolerance to cemiplimab/paclitaxel/(carboplatin or cisplatin); **OR**

Nonsquamous NSCLC:

- Use of albumin-bound paclitaxel will be restricted to patients with a contraindication or intolerance to cemiplimab/(paclitaxel or pemetrexed)/(carboplatin or cisplatin); **OR**

- Used as a single agent or in combination with carboplatin in patients with contraindications **¥** to PD-1 or PD-L1 inhibitors; **AND**
  - Used in patients with tumors that are negative for actionable molecular biomarkers***** (may be KRAS G12C mutation positive); **OR**
  - Used in patients with tumors that are positive for one of the following molecular mutations: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, NRG1 gene fusion, or ERBB2 (HER2); **OR**

o Used as subsequent therapy; **AND**

- Used in one of the following:
  - Patients who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping
  - Patients who are positive for one of the following molecular mutations and have received prior targeted therapy**§** for those aberrations: EGFR S768I, L861Q, and/or G719X mutation; **AND**
  - Used in combination with carboplatin and pembrolizumab for squamous cell histology; **AND**

- Use of albumin-bound paclitaxel will be restricted to patients with a contraindication or intolerance to cemiplimab/paclitaxel/(carboplatin or cisplatin); **OR**

– Used in combination with carboplatin and atezolizumab for non-squamous histology; **AND**

- Use of albumin-bound paclitaxel will be restricted to patients with a contraindication or intolerance to cemiplimab/(paclitaxel or pemetrexed)/(carboplatin or cisplatin); **OR**

– Used in combination with tremelimumab, durvalumab, and carboplatin; **AND**

Squamous NSCLC:

- Use of albumin-bound paclitaxel will be restricted to patients with a contraindication or intolerance to cemiplimab/paclitaxel/(carboplatin or cisplatin); **OR**

Nonsquamous NSCLC:

- Use of albumin-bound paclitaxel will be restricted to patients with a contraindication or intolerance to cemiplimab/(paclitaxel or pemetrexed)/(carboplatin or cisplatin); **OR**

- Used as a single agent or in combination with carboplatin in patients with contraindications **¥** to PD-1 or PD-L1 inhibitors; **AND**
  - Used in patients with tumors that are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping; **OR**
  - Used in patients with tumors that are positive for one of the following molecular mutations and have received prior targeted therapy**§** for those aberrations: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, RET rearrangement, or ROS1 rearrangement; **OR**
  - Used in patients with PD-L1 expression-positive (≥1%) tumors that are negative for actionable molecular biomarkers***** with prior PD-1/PD-L1 inhibitor therapy but no prior platinum-containing chemotherapy; **OR**
- Used as a single agent for first progression after initial systemic therapy (if not previously used)

- *******Note: Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, NRG1 and ERBB2 (HER2). Complete genotyping for EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, NRG1 and ERBB2 (HER2), via biopsy and/or plasma testing. If a clinically actionable marker is found, it is reasonable to start therapy based on the identified marker. Treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*

- *¥ Note: Contraindications for treatment with PD-1/PD-L1 inhibitors may include active or previously documented auto-immune disease and/or current use of immunosuppressive agents, and some oncogenic drivers (e.g., EGFR exon 19 deletion, or exon 21 L858R, ALK, RET, or ROS1 rearrangements) have been shown to be associated with less benefit from PD-1/PD-L1 inhibitors.*

- *§ Genomic Aberration/Mutational Driver Targeted Therapies: Refer to guidelines for appropriate use.*

Ovarian, Fallopian Tube, and Primary Peritoneal Cancer ‡ [2,8,22,23]

- Patient has Grade 1 Endometrioid Carcinoma, Carcinosarcoma (Malignant Mixed Müllerian Tumors), Mucinous Neoplasms of the Ovary, Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer, or Clear Cell Carcinoma of the Ovary; **AND**
  - Patient has recurrent or persistent disease; **AND**
  - Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); **AND**
    - Patient has platinum-resistant disease; **AND**
      - Used as a single agent; **AND**
        - Used for progression on primary, maintenance, or recurrence therapy; **OR**
        - Used for stable or persistent disease if not currently on maintenance therapy; **OR**
        - Used for complete remission and relapse <6 months after completing chemotherapy; **OR**
    - Patient has platinum-sensitive disease; **AND**
      - Used as a single agent; **AND**
        - Used for complete remission and relapse ≥6 months after completing chemotherapy; **OR**
      - Used in combination with carboplatin in patients with confirmed taxane hypersensitivity; **AND**
        - Used for complete remission and relapse ≥6 months after completing chemotherapy; **AND**
        - Patient has a negative skin test to paclitaxel (if available); **AND**
        - Patient has not experienced a severe grade 3 taxane hypersensitivity reaction [e.g., symptoms involving at least 2 organs/systems with a significant decrease in blood pressure (systolic ≤90 mm Hg and/or syncope) and/or oxygen saturation (≤92%), etc.]; **OR**
- Patient has low-grade serous carcinoma; **AND**
  - Patient has recurrent disease; **AND**

    - Used as a single agent; **OR**
    - Used in combination with carboplatin for platinum-sensitive disease in patients with confirmed taxane hypersensitivity; **AND**
        - Patient has a negative skin test to paclitaxel (if available); **AND**
        - Patient has not experienced a severe grade 3 taxane hypersensitivity reaction [e.g., symptoms involving at least 2 organs/systems with a significant decrease in blood pressure (systolic ≤90 mm Hg and/or syncope) and/or oxygen saturation (≤92%), etc.]; **OR**
- May be substituted for paclitaxel if the patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication; **AND**
    - Patient has a negative skin test to paclitaxel (if available); **AND**
    - Patient has not experienced a severe grade 3 taxane hypersensitivity reaction [e.g., symptoms involving at least 2 organs/systems with a significant decrease in blood pressure (systolic ≤90 mm Hg and/or syncope) and/or oxygen saturation (≤92%), etc.]

Pancreatic Adenocarcinoma † ‡ Φ [1,2,5-7,24,34,35]

- Used in combination with gemcitabine; **AND**
    - Patient has locally advanced or metastatic disease; **AND**
        - Used as first-line therapy; **OR**
        - Used as induction therapy followed by chemoradiation *(locally advanced disease only)*; **OR**
        - Used as subsequent therapy after disease progression with a fluoropyrimidine-based therapy; **OR**
    - Patient has local recurrence disease in the pancreatic operative bed OR recurrent metastatic disease after resection; **AND**
        - Used ≥ 6 months after completion of primary therapy; **OR**
        - Used < 6 months from completion of primary therapy and previously treated with fluoropyrimidine-based therapy; **OR**
    - Used as neoadjuvant therapy; **AND**
        - Patient has resectable disease; **OR**
        - Patient has biopsy positive borderline resectable disease; **OR**
- Used in combination with gemcitabine and cisplatin; **AND**
    - Patient has metastatic disease; **AND**
    - Patient has ECOG PS 0-1; **AND**
    - Used as first-line therapy

Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma) ‡ [2,11,35]

- Used in combination with gemcitabine; **AND**
- Patient has unresectable, gross residual (R2), or metastatic disease; **AND**
- Used as primary treatment

Small Bowel Adenocarcinoma ‡ [2,17,18,26]

- Patient has advanced or metastatic disease; **AND**
- Used as single agent; **AND**
  - Used as initial therapy after previous FOLFOX/CAPEOX in the adjuvant setting within past 12 months or contraindication; **AND**
    - Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; **OR**
  - Used as subsequent therapy if not previously given

Ampullary Adenocarcinoma ‡ [2,24]

- Used in combination with gemcitabine; **AND**
- Patient has pancreatobiliary or mixed type disease; **AND**
- Used as first-line therapy for metastatic disease

Cervical Cancer ‡ [2,28]

- Used as a single agent as subsequent therapy; **AND**
- Patient has recurrent or metastatic disease

Vaginal Cancers ‡ [2]

- Used as a single agent as subsequent therapy; **AND**
- Patient has recurrent or metastatic disease

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

Enhanced Oncology Value (EOV) Program – Redacted indications
• Uses not listed above have inadequate data to support efficacy and are excluded from coverage. • Other treatment options including, but are not limited to, the following may be appropriate: radiation therapy, surgery, traditional chemotherapy (e.g., platinum, taxane), compassionate

use/expanded access programs, clinical trials, supportive care, integrative and complementary therapies.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

*** ER Scoring Interpretation *(following ER testing by validated IHC assay)*[21]	
Results	**Interpretation**
– 0% – <1% of nuclei stain	– ER-negative
– 1%–10% of nuclei stain	– ER-low–positive*
– >10% of nuclei stain	– ER-positive
**Note: Invasive cancers with between 1%–10% ER positivity are considered ER-low–positive. However, this group is noted to be heterogeneous and the biologic behavior of ER-low–positive cancers may be more similar to ER-negative cancers. This should be considered in decision making for other adjuvant therapy and overall treatment pathway.*	

IV. Renewal Criteria [1,2]

Prior authorization validity may be renewed based upon the following criteria:

- Patient continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Duration of authorization has not been exceeded *(refer to Section I)*; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe myelosuppression (e.g., severe neutropenia [absolute neutrophil count < 1,500 cell/mm^3] or thrombocytopenia), sensory neuropathy, sepsis, pneumonitis, severe hypersensitivity reactions (including anaphylactic reactions), hepatic impairment, etc.

V. Dosage/Administration [1,11,15,16-19,21,22,25-46]

Indication	Dose
Breast Cancer	Single agent: Administer 260 mg/m² intravenously every 21 days until disease progression or unacceptable toxicity

	OR Administer 100 mg/m² OR 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity <u>In combination with pembrolizumab:</u> Administer 100 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity <u>In combination with carboplatin:</u> Administer 125 mg/m² intravenously days 1 and 8 of a 21-day cycle until disease progression or unacceptable toxicity ***NOTE:** If being used as a substitute for weekly paclitaxel or docetaxel, the weekly dose of albumin-bound paclitaxel should not exceed 125 mg/m²*
NSCLC	<u>Single agent:</u> Administer 260 mg/m² intravenously every 21 days until disease progression or unacceptable toxicity OR Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity <u>In combination with carboplatin:</u> Administer 100 mg/m² intravenously days 1, 8, and 15 of a 21-day cycle until disease progression or unacceptable toxicity <u>In combination with tremelimumab, durvalumab, and carboplatin</u>: Administer 100 mg/m² intravenously days 1, 8, and 15 of a 21-day cycle for 4 cycles <u>In combination with pembrolizumab and carboplatin:</u> Administer 100 mg/m² intravenously days 1, 8, and 15 of a 21-day cycle for 4 cycles <u>In combination with atezolizumab and carboplatin</u>: Administer 100 mg/m² intravenously days 1, 8, and 15 of a 21-day cycle for 4 to 6 cycles
Ovarian Cancer, Fallopian Tube Cancer, & Primary Peritoneal Cancer	<u>Single agent:</u> Administer 260 mg/m² intravenously day 1 of a 21-day cycle until disease progression or unacceptable toxicity <u>All other treatment settings:</u> Administer 100 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity

Cervical Cancer, Vaginal Cancer	Administer 100 - 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity
Ampullary Adenocarcinoma, Biliary Tract Cancers	Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity
Pancreatic Adenocarcinoma	<u>In combination with gemcitabine for neoadjuvant therapy:</u> Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle for 6 cycles <u>In combination with gemcitabine as induction therapy:</u> Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity for 4 - 6 cycles <u>In combination with gemcitabine for all other settings:</u> Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity <u>In combination with gemcitabine and cisplatin:</u> Administer 125 mg/m² intravenously days 1 and 8 of a 21-day cycle until disease progression or unacceptable toxicity
Small Bowel Adenocarcinoma	<u>Single agent:</u> Administer 220 – 260 mg/m² intravenously every 21 days until disease progression or unacceptable toxicity

VI. Billing Code/Availability Information

Product Formulation	Drug	Manufacturer	Type	HCPCS Code	NDC
Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) Lyophilized powder for injection	Abraxane 100 mg powder for inj. SDV¤	Bristol-Myers Squibb Company	Brand	J9264	68817-0134-xx
	Paclitaxel (albumin-bound) 100mg powder for inj. SDV **§ Ψ**	Multiple	Brand/ Generic		Multiple

§ Multiple manufacturers produce ANDA generics
¤ Available as NDA authorized generic(s)
Ψ *Designated products approved by the FDA as a 505(b)(2) NDA of the innovator product. These products may be available from several different manufacturers. For a complete list of all available products and NDCs please reference the FDA website at National Drug Code Directory for Paclitaxel Albumin Bound. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book and are therefore considered single source products based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. For a complete list of all approved 505(b)(2) NDA products please reference the latest edition of the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book | FDA*

- **J9264 – Injection, paclitaxel protein-bound particles, 1 mg; 1 billable unit = 1 mg**

VII. References (STANDARD)

1. Abraxane [package insert]. Princeton, NJ; Bristol-Myers Squibb Company; October 2022. Accessed September 2025.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) paclitaxel, albumin bound. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed September 2025.
3. Gradishar WJ, Tjulandin S, Davidson N, et al. Phase Ill trial of nanoparticle albumin-bound paclitaxel compared with polyethylated castor oil-based paclitaxel in women with breast cancer. J Clin Oncol. 2005;23(31):7794-7803.
4. Socinski MA, Bondarenko I, Karaseva NA, et al. Weekly nab-paclitaxel in combination with carboplatin versus solvent-based paclitaxel plus carboplatin as first-line therapy in patients with advanced non-small-cell lung cancer: Final results of a phase Ill trial. J Clin Oncol. 2012;30(17):2055-2062.
5. Tabernero J, Chiorean EG, Infante JR, et al. Prognostic factors of survival in a randomized phase III trial (MPACT) of weekly nab-paclitaxel plus gemcitabine alone in patients with metastatic pancreatic cancer. Oncologist. 2015;20(2):143-150.
6. Goldstein D, El-Maraghi RH, Hammel P, et al. nab-Paclitaxel plus gemcitabine for metastatic pancreatic cancer: long-term survival from a phase III trial. J Natl Cancer Inst. 2015;107(2):1-10.
7. Scheithauer W, Ramanathan RK, Moore M, et al. Dose modification and efficacy of nab-paclitaxel plus gemcitabine vs. gemcitabine for patients with metastatic pancreatic cancer: phase III MPACT trial. J Gastrointest Oncol. 2016;7(3):469-478.
8. Teneriello, MG, Tseng PC, Crozier M, et al. Phase II evaluation of nanoparticle albumin-bound paclitaxel in platinum-sensitive patients with recurrent ovarian, peritoneal, or fallopian tube cancer. J Clin Oncol. 2009 Mar 20; 27(9):1426-31. Epub 2009 Feb 17.
9. Gradishar WJ, Krasnojon D, Cheporov S, et al, “Significantly Longer Progression-Free Survival With nab-paclitaxel Compared With Docetaxel as First-Line Therapy for Metastatic Breast Cancer,” J Clin Oncol, 2009, 27(22):3611-9.
10. Rizvi NA, Riely GJ, Azzoli CG, et al, “Phase I/II Trial of Weekly Intravenous 130-nm Albumin-Bound Paclitaxel as Initial Chemotherapy in Patients With Stage IV Non-Small-Cell Lung Cancer,” J Clin Oncol, 2008, 26(4):639-43.
11. Sahai V, Catalano PJ, Zalupski MM, et al. Nab-Paclitaxel and Gemcitabine as First-line Treatment of Advanced or Metastatic Cholangiocarcinoma: A Phase 2 Clinical Trial. JAMA Oncol. 2018;4(12):1707–1712. doi:10.1001/jamaoncol.2018.3277.

12. Fahrenbruch R, Kintzel P, Bott AM, et al. Dose Rounding of Biologic and Cytotoxic Anticancer Agents: A Position Statement of the Hematology/Oncology Pharmacy Association. J Oncol Pract. 2018 Mar;14(3):e130-e136.
13. Hematology/Oncology Pharmacy Association (2019). Intravenous Cancer Drug Waste Issue Brief. Retrieved from http://www.hoparx.org/images/hopa/advocacy/Issue-Briefs/Drug_Waste_2019.pdf
14. Bach PB, Conti RM, Muller RJ, et al. Overspending driven by oversized single dose vials of cancer drugs. BMJ. 2016 Feb 29;352:i788.
15. Hersh EM, O'Day SJ, Ribas A, et al. A phase 2 clinical trial of nab-paclitaxel in previously treated and chemotherapy-naive patients with metastatic melanoma. Cancer. 2010 Jan 1;116(1):155-63.
16. Kottschade LA, Suman VJ, Amatruda T 3rd, et al. A phase II trial of nab-paclitaxel (ABI-007) and carboplatin in patients with unresectable stage IV melanoma: a North Central Cancer Treatment Group Study, N057E(1). Cancer. 2011 Apr 15;117(8):1704-10.
17. Overman MJ, Adam L, Raghav K, et al. Phase II study of nab-paclitaxel in refractory small bowel adenocarcinoma and CpG island methylator phenotype (CIMP)-high colorectal cancer. Ann Oncol. 2018 Jan 1;29(1):139-144.
18. Aldrich JD, Raghav KPS, Varadhachary GR, et al. Retrospective Analysis of Taxane-Based Therapy in Small Bowel Adenocarcinoma. Oncologist. 2019 Jun;24(6):e384-e386.
19. Fortino S, Santoro M, Luliano E, et al. Treatment of Kaposi's Sarcoma (KS) with nab-paclitaxel. Ann Oncol 2016;27:suppl_4: iv124.
20. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Uterine Neoplasms 3.2025. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed September 2025.
21. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Breast Cancer, Version 4.2025. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org. Accessed September 2025.
22. Benigno BB, Burrell MO, Daugherty P, et al. A phase II nonrandomized study of nab-paclitaxel plus carboplatin in patients with recurrent platinum-sensitive ovarian or primary peritoneal cancer. DOI: 10.1200/jco.2010.28.15_suppl.5011 *Journal of Clinical Oncology* 28, no. 15_suppl (May 20, 2010) 5011-5011.
23. Coleman RL, Brady WE, McMeekin DS, et al. A phase II evaluation of nanoparticle, albumin-bound (nab) paclitaxel in the treatment of recurrent or persistent platinum-resistant ovarian,

fallopian tube, or primary peritoneal cancer: a Gynecologic Oncology Group study. Gynecol Oncol. 2011 Jul;122(1):111-5. doi: 10.1016/j.ygyno.2011.03.036. Epub 2011 Apr 15.

24. Von Hoff DD, Ervin T, Arena FP, et al. Increased survival in pancreatic cancer with nab-paclitaxel plus gemcitabine. N Engl J Med. 2013 Oct 31;369(18):1691-703. doi: 10.1056/NEJMoa1304369. Epub 2013 Oct 16.
25. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Kaposi Sarcoma, Version 2.2025. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org. Accessed September 2025.
26. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Small Bowel Adenocarcinoma, Version 3.2025. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org. Accessed September 2025.
27. Straughn K, Hood R, Carrera L, et al. Hypersensitivity Reactions to Taxanes and Subsequent Treatment with Nab-Paclitaxel: Case Reports of 2 Women with Early-Stage Breast Cancer. J Hematol Oncol Pharm. 2021;11 (6):329-334 www.JHOPonline.com
28. Alberts D, Blessing J, Landrum L, et al. Phase II trial of nab-paclitaxel in the treatment of recurrent or persistent advanced cervix cancer: A gynecologic oncology group study. Gynecol Oncol. 2012 Dec;127(3):451-5. doi: 10.1016/j.ygyno.2012.09.008. Epub 2012 Sep 14.
29. Mirtsching B, Cosgriff T, Harker G, et al. A phase II study of weekly nanoparticle albumin-bound paclitaxel with or without trastuzumab in metastatic breast cancer. Clin Breast Cancer. 2011 Apr;11(2):121-8. doi: 10.1016/j.clbc.2011.03.007. Epub 2011 Apr 11.
30. West H, et al. Atezolizumab in combination with carboplatin plus nab-paclitaxel chemotherapy compared with chemotherapy alone as first-line treatment for metastatic non-squamous non-small-cell lung cancer (IMpower130): a multicentre, randomised, open-label, phase 3 trial. Lancet Oncol 2019;20:924-937.
31. Novello S, Kowalski DM, Luft A, et al. Pembrolizumab Plus Chemotherapy in Squamous Non-Small-Cell Lung Cancer: 5-Year Update of the Phase III KEYNOTE-407 Study. J Clin Oncol. 2023 Apr 10;41(11):1999-2006. doi: 10.1200/JCO.22.01990. Epub 2023 Feb 3.
32. Johnson ML, et al. Durvalumab with or without tremelimumab in combination with chemotherapy as first-line therapy for metastatic non-small-cell lung cancer: the phase III POSEIDON study. J Clin Oncol 2023;41:1213-1227.

33. Green M, Manikhas G, Orlov S, et al. Abraxane®, a novel Cremophor® -free, albumin-bound particle form of paclitaxel for the treatment of advanced non-small-cell lung cancer. Ann Oncol 2006;17:1263- 1268.
34. Jameson GS, Borazanci E, Babiker HM, et al. Response rate following albuminbound paclitaxel plus gemcitabine plus cisplatin treatment among patients with advanced pancreatic cancer: A phase 1b/2 pilot clinical trial [published online ahead of print, 2019 Oct 3] [published correction appears in JAMA Oncol 2019;5:1643]. JAMA Oncol 2019;6:125-132.
35. Shroff RT, Javle MM, Xiao L, et al. Gemcitabine, cisplatin, and nab-paclitaxel for the treatment of advanced biliary tract cancers: A phase 2 clinical trial. JAMA Oncol 2019;5:824-830.
36. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Albumin-bound PACLitaxel: Vaginal Cancer, VAG24. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed July 2025.
37. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Albumin-bound PACLitaxel: Melanoma: Cutaneous, MEL19. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed July 2025.
38. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Albumin-bound PACLitaxel: Melanoma: Uveal, UVMEL8. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed July 2025.
39. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Albumin-bound PACLitaxel: Endometrial Carcinoma, UTE18. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed July 2025.
40. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Albumin-bound PACLitaxel: Ampullary Adenocarcinoma, AMP8. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed July 2025.

41. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Albumin-bound PACLitaxel: Biliary Tract Cancers, BIL15. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed July 2025.
42. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Albumin-bound PACLitaxel: Pancreatic Adenocarcinoma, PAN21. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed July 2025.
43. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Albumin-bound PACLitaxel: Pancreatic Adenocarcinoma, PAN50. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed July 2025.
44. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Albumin-bound PACLitaxel: Non-Small Cell Lung Cancer, NSC48. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed July 2025.
45. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Albumin-bound PACLitaxel: Breast Cancer, BRS150. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed July 2025.
46. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Albumin-bound PACLitaxel: Breast Cancer, BRS151. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed July 2025.
47. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Cervical Cancer Version 4.2025. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are

trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed September 2025.

48. National Government Services, Inc. Local Coverage Article: Billing and Coding: Paclitaxel (e.g., Taxol®/Abraxane™) (A52450). Centers for Medicare & Medicaid Services, Inc. Updated 01/03/2025 with effective date of 01/01/2025. Accessed September 2025.

VIII. References (ENHANCED)

1e. Ko YJ, Canil CM, Mukherjee SD, et al. Nanoparticle albumin-bound paclitaxel for second-line treatment of metastatic urothelial carcinoma: a single group, multicentre, phase 2 study. Lancet Oncol. 2013 Jul;14(8):769-76.

2e. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Non-Small Cell Lung Cancer, Version 8.2025. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org. Accessed September 2025.

3e. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer, Version 3.2025. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org. Accessed September 2025.

4e. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Pancreatic Adenocarcinoma, Version 2.2025. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org. Accessed September 2025.

5e. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Melanoma: Cutaneous, Version 2.2025. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org. Accessed September 2025.

6e. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Melanoma: Uveal, Version 1.2025. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are

trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org. Accessed September 2025.

7e. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Biliary Tract Cancers, Version 2.2025. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org. Accessed September 2025.

8e. Sledge GW, Neuberg D, Bernardo P, et al. Phase III trial of doxorubicin, paclitaxel, and the combination of doxorubicin and paclitaxel as front-line chemotherapy for metastatic breast cancer: an intergroup trial (E1193). J Clin Oncol. 2003 Feb 15;21(4):588-92.

9e. Jones SE, Erban J, Overmoyer B, et al. Randomized Phase III Study of Docetaxel Compared With Paclitaxel in Metastatic Breast Cancer. Journal of Clinical Oncology 2005 23:24, 5542-5551.

10e. Kaufman PA, Awada A, Twelves C, et al. Phase III open-label randomized study of eribulin mesylate versus capecitabine in patients with locally advanced or metastatic breast cancer previously treated with an anthracycline and a taxane. J Clin Oncol. 2015;33(6):594-601.

11e. Twelves C, Awada A, Cortes J, et al. Subgroup Analyses from a Phase 3, Open-Label, Randomized Study of Eribulin Mesylate Versus Capecitabine in Pretreated Patients with Advanced or Metastatic Breast Cancer. Breast Cancer (Auckl). 2016;10:77-84. Published 2016 Jun 28. doi:10.4137/BCBCR.S39615.

12e. Rugo HS, Barry WT, Moreno-Aspitia A, et al. Randomized Phase III Trial of Paclitaxel Once Per Week Compared With Nanoparticle Albumin-Bound Nab-Paclitaxel Once Per Week or Ixabepilone With Bevacizumab As First-Line Chemotherapy for Locally Recurrent or Metastatic Breast Cancer: CALGB 40502/NCCTG N063H (Alliance). J Clin Oncol. 2015;33(21):2361-9.

13e. Fumoleau P, Largillier R, Clippe C, et al. Multicentre, phase II study evaluating capecitabine monotherapy in patients with anthracycline- and taxane-pretreated metastatic breast cancer. Eur J Cancer. 2004 Mar;40(4):536-42.

14e. Blackstein M, Vogel CL, Ambinder R, et al. Gemcitabine as first-line therapy in patients with metastatic breast cancer: a phase II trial. Oncology. 2002;62(1):2-8.

15e. Martín M, Ruiz A, Muñoz M, et al. Gemcitabine plus vinorelbine versus vinorelbine monotherapy in patients with metastatic breast cancer previously treated with anthracyclines and taxanes: final results of the phase III Spanish Breast Cancer Research Group (GEICAM) trial. Lancet Oncol. 2007 Mar;8(3):219-25.

16e. Baselga J, Cortés J, Kim SB, et al. Pertuzumab plus trastuzumab plus docetaxel for metastatic breast cancer. N Engl J Med. 2011;366(2):109-19.

17e. Swain SM, Baselga J, Kim SB, et al. Pertuzumab, trastuzumab, and docetaxel in HER2-positive metastatic breast cancer. N Engl J Med. 2015;372(8):724-34.

18e. Robert N, Leyland-Jones B, Asmar L, et al. Randomized Phase III Study of Trastuzumab, Paclitaxel, and Carboplatin Compared With Trastuzumab and Paclitaxel in Women With HER-2–Overexpressing Metastatic Breast Cancer. Journal of Clinical Oncology 2006 24:18, 2786-2792.

19e. Andersson M, Lidbrink E, Bjerre K, et al. Phase III Randomized Study Comparing Docetaxel Plus Trastuzumab With Vinorelbine Plus Trastuzumab As First-Line Therapy of Metastatic or Locally Advanced Human Epidermal Growth Factor Receptor 2–Positive Breast Cancer: The HERNATA Study. Journal of Clinical Oncology 2011 29:3, 264-271.

20e. Anthony Ellis P, Barrios CH, Eiermann W, et al. Phase III, randomized study of trastuzumab emtansine (T-DM1) ± pertuzumab (P) vs trastuzumab + taxane (HT) for first-line treatment of HER2-positive MBC: Primary results from the MARIANNE study. Journal of Clinical Oncology 2015 33:15_suppl, 507-507.

21e. Verma S, Miles D, Gianni L, et al. Trastuzumab emtansine for HER2-positive advanced breast cancer. N Engl J Med. 2012;367(19):1783-91.

22e. Mirtsching, Barry, Cosgriff T, Harker G, et al. A Phase II Study of Weekly Nanoparticle Albumin-Bound Paclitaxel With or Without Trastuzumab in Metastatic Breast Cancer. Clinical Breast Cancer 2011 11:2, 121 – 128.

23e. Untch M, Jackisch C, Schneeweiss A, et al. Nab-paclitaxel versus solvent-based paclitaxel in neoadjuvant chemotherapy for early breast cancer (GeparSepto-GBG 69): a randomised, phase 3 trial. Lancet Oncol. 2016 Mar;17(3):345-56. doi: 10.1016/S1470-2045(15)00542-2. Epub 2016 Feb 8.

24e. Loibl S, Jackisch C, Schneeweiss A, et al. Dual HER2-blockade with pertuzumab and trastuzumab in HER2-positive early breast cancer: a subanalysis of data from the randomized phase III GeparSepto trial. Annals of Oncology 2017 28:3, 497–504.

25e. Gianni L, Mansutti M, Anton A, et al. Comparing Neoadjuvant Nab-paclitaxel vs Paclitaxel Both Followed by Anthracycline Regimens in Women With ERBB2/HER2-Negative Breast Cancer-The Evaluating Treatment With Neoadjuvant Abraxane (ETNA) Trial: A Randomized Phase 3 Clinical Trial. JAMA Oncol. 2018 Mar 1;4(3):302-308. doi: 10.1001/jamaoncol.2017.4612.

26e. Paz-Ares L, Luft A, Vicente D, et al. Pembrolizumab plus Chemotherapy for Squamous Non–Small-Cell Lung Cancer. N Engl J Med 2018; 379:2040-2051.

27e. Gandhi L, Rodríguez-Abreu D, Gadgeel S, et al. Pembrolizumab plus Chemotherapy in Metastatic Non–Small-Cell Lung Cancer. N Engl J Med 2018; 378:2078-2092.

28e. Socinski MA, Jotte RM, Cappuzzo F, et al. Atezolizumab for First-Line Treatment of Metastatic Nonsquamous NSCLC. N Engl J Med 2018; 378:2288-2301

29e. Sandler A, Gray R, Perry MC, et al. Paclitaxel–Carboplatin Alone or with Bevacizumab for Non–Small-Cell Lung Cancer. N Engl J Med 2006; 355:2542-2550.

30e. Picard M, Pur L, Caiado J, et al. Risk stratification and skin testing to guide re-exposure in taxane-induced hypersensitivity reactions. J Allergy Clin Immunol. 2016 Apr;137(4):1154-1164.e12. doi: 10.1016/j.jaci.2015.

31e. Fossella F, Pereira JR, von Pawel J, et al. Randomized, multinational, phase III study of docetaxel plus platinum combinations versus vinorelbine plus cisplatin for advanced non-small-cell lung cancer: the TAX 326 study group. J Clin Oncol. 2003 Aug 15;21(16):3016-24. Epub 2003 Jul 1.

32e. Klastersky J, Sculier JP, Lacroix H, et al. A randomized study comparing cisplatin or carboplatin with etoposide in patients with advanced non-small-cell lung cancer: European Organization for Research and Treatment of Cancer Protocol 07861. J Clin Oncol. 1990 Sep;8(9):1556-62.

33e. Danson S, Middleton MR, O'Byrne KJ, et al. Phase III trial of gemcitabine and carboplatin versus mitomycin, ifosfamide, and cisplatin or mitomycin, vinblastine, and cisplatin in patients with advanced nonsmall cell lung carcinoma. Cancer 2003;98:542–53.

34e. Ohe Y, Ohashi Y, Kubota K, et al. Randomized phase III study of cisplatin plus irinotecan versus carboplatin plus paclitaxel, cisplatin plus gemcitabine, and cisplatin plus vinorelbine for advanced non-small-cell lung cancer: Four-Arm Cooperative Study in Japan. Annals of Oncology 2007 18:2, 317–323.

35e. Scagliotti GV, Kortsik C, Dark GG, et al. Pemetrexed Combined with Oxaliplatin or Carboplatin as First-Line Treatment in Advanced Non–Small Cell Lung Cancer: A Multicenter, Randomized, Phase II Trial. Clin Cancer Res January 15 2005; 11(2); 690-696.

36e. Cardenal F, López-Cabrerizo MP, Antón A, et al. Randomized phase III study of gemcitabine-cisplatin versus etoposide-cisplatin in the treatment of locally advanced or metastatic non-small-cell lung cancer. J Clin Oncol. 1999 Jan;17(1):12-8.

37e. Scagliotti GV, Parikh P, von Pawel J, et al. Phase III Study Comparing Cisplatin Plus Gemcitabine With Cisplatin Plus Pemetrexed in Chemotherapy-Naive Patients With Advanced-Stage Non–Small-Cell Lung Cancer. Journal of Clinical Oncology 2008 26:21, 3543-3551.

38e. Schiller JH, Harrington D, Belani CP, et al. Comparison of Four Chemotherapy Regimens for Advanced Non–Small-Cell Lung Cancer. N Engl J Med 2002; 346:92-98.

39e. Pujol JL, Breton JL, Gervais R, et al. Gemcitabine–docetaxel versus cisplatin–vinorelbine in advanced or metastatic non-small-cell lung cancer: a phase III study addressing the case for cisplatin. Annals of Oncology, Volume 16, Issue 4, 1 April 2005, 602–610.

40e. Tan EH, Szczesna A, Krzakowski M, et al. Randomized study of vinorelbine--gemcitabine versus vinorelbine--carboplatin in patients with advanced non-small cell lung cancer. Lung Cancer. 2005 Aug;49(2):233-40.

41e. Barlesi F, Scherpereel A, Rittmeyer A, et al. Randomized Phase III Trial of Maintenance Bevacizumab With or Without Pemetrexed After First-Line Induction With Bevacizumab, Cisplatin, and Pemetrexed in Advanced Nonsquamous Non–Small-Cell Lung Cancer: AVAPERL (MO22089). Journal of Clinical Oncology 2013 31:24, 3004-3011.

42e. Zatloukal P, Kanitz E, Magyar P, et al. Gemcitabine in locally advanced and metastatic non-small cell lung cancer: the Central European phase II study. Lung Cancer. 1998 Dec;22(3):243-50.

43e. Green MR, Manikhas GM, Orlov S, et al. Abraxane®, a novel Cremophor®-free, albumin-bound particle form of paclitaxel for the treatment of advanced non-small-cell lung cancer. Annals of Oncology, Volume 17, Issue 8, 1 August 2006, 1263–1268.

44e. Borghaei H, Paz-Ares L, Horn L, et al. Nivolumab versus Docetaxel in Advanced Nonsquamous Non-Small-Cell Lung Cancer. N Engl J Med. 2015;373(17):1627-39.

45e. Brahmer J, Reckamp KL, Baas P, et al. Nivolumab versus Docetaxel in Advanced Squamous-Cell Non-Small-Cell Lung Cancer. N Engl J Med. 2015;373(2):123-35.

46e. Herbst RS, Baas P, Kim DW, et al. Pembrolizumab versus docetaxel for previously treated, PD-L1-positive, advanced non-small-cell lung cancer (KEYNOTE-010): a randomised controlled trial. Lancet. 2016 Apr 9;387(10027):1540-50.

47e. Barlesi F, Park K, Ciardiello F, et al. Primary analysis from OAK, a randomized phase III study comparing atezolizumab with docetaxel in 2L/3L NSCLC. Annals of Oncology, Volume 27, Issue suppl_6, 1 October 2016, LBA44_PR.

48e. Shepherd FA, Dancey J, Ramlau R, et al. Prospective randomized trial of docetaxel versus best supportive care in patients with non-small-cell lung cancer previously treated with platinum-based chemotherapy. J Clin Oncol. 2000 May;18(10):2095-103.

49e. Fossella FV, DeVore R, Kerr RN, et al. Randomized phase III trial of docetaxel versus vinorelbine or ifosfamide in patients with advanced non-small-cell lung cancer previously treated with platinum-containing chemotherapy regimens. The TAX 320 Non-Small Cell Lung Cancer Study Group. J Clin Oncol. 2000 Jun;18(12):2354-62.

50e. Hanna N, Shepherd FA, Fossella FV, et al. Randomized Phase III Trial of Pemetrexed Versus Docetaxel in Patients With Non–Small-Cell Lung Cancer Previously Treated With Chemotherapy. Journal of Clinical Oncology 2004 22:9, 1589-1597.

51e. Anderson H, Hopwood P, Stephens RJ, et al. Gemcitabine plus best supportive care (BSC) vs BSC in inoperable non-small cell lung cancer - a randomized trial with quality of life as the primary outcome. British Journal of Cancer (2000) 83(4), 447–453.

52e. Pfisterer J, Plante M, Vergote I, et al. Gemcitabine Plus Carboplatin Compared With Carboplatin in Patients With Platinum-Sensitive Recurrent Ovarian Cancer: An Intergroup Trial of the AGO-OVAR, the NCIC CTG, and the EORTC GCG. Journal of Clinical Oncology 2006 24:29, 4699-4707.

53e. Pujade-Lauraine E, Wagner U, Aavall-Lundqvist E, et al. Pegylated Liposomal Doxorubicin and Carboplatin Compared With Paclitaxel and Carboplatin for Patients With Platinum-Sensitive Ovarian Cancer in Late Relapse. Journal of Clinical Oncology 2010 28:20, 3323-3329.

54e. Parmar MK, Ledermann JA, Colombo N, et al. Paclitaxel plus platinum-based chemotherapy versus conventional platinum-based chemotherapy in women with relapsed ovarian cancer: the ICON4/AGO-OVAR-2.2 trial. Lancet. 2003 Jun 21;361(9375):2099-106.

55e. Aghajanian C, Blank SV, Goff BA, et al. OCEANS: a randomized, double-blind, placebo-controlled phase III trial of chemotherapy with or without bevacizumab in patients with platinum-sensitive

recurrent epithelial ovarian, primary peritoneal, or fallopian tube cancer. J Clin Oncol. 2012;30(17):2039-45.

56e. Coleman RL, Brady MF, Herzog TJ, et al. Bevacizumab and paclitaxel-carboplatin chemotherapy and secondary cytoreduction in recurrent, platinum-sensitive ovarian cancer (NRG Oncology/Gynecologic Oncology Group study GOG-0213): a multicentre, open-label, randomised, phase 3 trial. Lancet Oncol. 2017;18(6):779-791.

57e. Strauss HG, Henze A, Teichmann A, et al. Phase II trial of docetaxel and carboplatin in recurrent platinum-sensitive ovarian, peritoneal and tubal cancer. Gynecol Oncol. 2007 Mar;104(3):612-6.

58e. Rose PG, Blessing JA, Mayer AR, et al. Prolonged oral etoposide as second-line therapy for platinum-resistant and platinum-sensitive ovarian carcinoma: a Gynecologic Oncology Group study. J Clin Oncol. 1998 Feb;16(2):405-10.

59e. Gordon AN, Tonda M, Sun S, et al. Long-term survival advantage for women treated with pegylated liposomal doxorubicin compared with topotecan in a phase 3 randomized study of recurrent and refractory epithelial ovarian cancer. Gynecol Oncol. 2004 Oct;95(1):1-8.

60e. Gordon AN, Fleagle JT, Guthrie D, et al. Recurrent epithelial ovarian carcinoma: a randomized phase III study of pegylated liposomal doxorubicin versus topotecan. J Clin Oncol. 2001 Jul 15;19(14):3312-22.

61e. Mutch DG, Orlando M, Goss T, et al. Randomized Phase III Trial of Gemcitabine Compared With Pegylated Liposomal Doxorubicin in Patients With Platinum-Resistant Ovarian Cancer. Journal of Clinical Oncology 2007 25:19, 2811-2818.

62e. Ferrandina G, Ludovisi M, Lorusso D, et al. Phase III Trial of Gemcitabine Compared With Pegylated Liposomal Doxorubicin in Progressive or Recurrent Ovarian Cancer. Journal of Clinical Oncology 2008 26:6, 890-896.

63e. Pujade-Lauraine E, Hilpert F, Weber B, et al. Bevacizumab Combined With Chemotherapy for Platinum-Resistant Recurrent Ovarian Cancer: The AURELIA Open-Label Randomized Phase III Trial. Journal of Clinical Oncology 2014 32:13, 1302-1308.

64e. Pignata S, Lorusso D, Scambia G, et al. Pazopanib plus weekly paclitaxel versus weekly paclitaxel alone for platinum-resistant or platinum-refractory advanced ovarian cancer (MITO 11): a randomised, open-label, phase 2 trial. Lancet Oncol. 2015 May;16(5):561-8.

65e. Markman M, Blessing J, Rubin SC, et al. Phase II trial of weekly paclitaxel (80 mg/m2) in platinum and paclitaxel-resistant ovarian and primary peritoneal cancers: a Gynecologic Oncology Group study. Gynecol Oncol. 2006 Jun;101(3):436-40. Epub 2005 Dec 2.

66e. Rose PG, Blessing JA, Ball HG, et al. A phase II study of docetaxel in paclitaxel-resistant ovarian and peritoneal carcinoma: a Gynecologic Oncology Group study. Gynecol Oncol. 2003 Feb;88(2):130-5.

67e. Burger RA, Sill MW, Monk BJ, et al. Phase II Trial of Bevacizumab in Persistent or Recurrent Epithelial Ovarian Cancer or Primary Peritoneal Cancer: A Gynecologic Oncology Group Study. Journal of Clinical Oncology 2007 25:33, 5165-5171.

68e. Katz MH, Shi Q, Ahmad SA, et al. Preoperative Modified FOLFIRINOX Treatment Followed by Capecitabine-Based Chemoradiation for Borderline Resectable Pancreatic Cancer: Alliance for Clinical Trials in Oncology Trial A021101. JAMA Surg. 2016;151(8):e161137.

69e. Conroy T, Desseigne F, Ychou M, et al. FOLFIRINOX versus Gemcitabine for Metastatic Pancreatic Cancer. N Engl J Med 2011; 364:1817-1825.

70e. Moore MJ, Goldstein D, Hamm J, et al. Erlotinib Plus Gemcitabine Compared With Gemcitabine Alone in Patients With Advanced Pancreatic Cancer: A Phase III Trial of the National Cancer Institute of Canada Clinical Trials Group. Journal of Clinical Oncology 2007 25:15, 1960-1966.

71e. Burris HA 3rd, Moore MJ, Andersen J, et al. Improvements in survival and clinical benefit with gemcitabine as first-line therapy for patients with advanced pancreas cancer: a randomized trial. J Clin Oncol. 1997 Jun;15(6):2403-13.

72e. Portal A, Pernot S, Tougeron D, et al. Nab-paclitaxel plus gemcitabine for metastatic pancreatic adenocarcinoma after Folfirinox failure: an AGEO prospective multicentre cohort. Br J Cancer. 2015;113(7):989-95.

73e. Le DT, Durham JN, Smith KN, et al. Mismatch repair deficiency predicts response of solid tumors to PD-1 blockade. Science. 2017;357(6349):409-413.

74e. Hodi FS, O'Day SJ, McDermott DF, et al. Improved survival with ipilimumab in patients with metastatic melanoma. N Engl J Med. 2010;363(8):711-23.

75e. Larkin J, Del Vecchio M, Ascierto PA, et al. Vemurafenib in patients with BRAF(V600) mutated metastatic melanoma: an open-label, multicentre, safety study. Lancet Oncol. 2014 Apr;15(4):436-44.

76e. Ascierto PA, Minor D, Ribas A, et al. Phase II Trial (BREAK-2) of the BRAF Inhibitor Dabrafenib (GSK2118436) in Patients With Metastatic Melanoma. Journal of Clinical Oncology 2013 31:26, 3205-3211.

77e. Robert C, Schachter J, Long GV, et al. Pembrolizumab versus Ipilimumab in Advanced Melanoma. N Engl J Med 2015; 372:2521-2532.

78e. Agarwala SS, Keilholz U, Hogg D, et al. Randomized phase III study of paclitaxel plus carboplatin with or without sorafenib as second-line treatment in patients with advanced melanoma. Journal of Clinical Oncology 2007 25:18_suppl, 8510-8510.

79e. Rao RD, Holtan SG, Ingle JN, et al. Combination of paclitaxel and carboplatin as second-line therapy for patients with metastatic melanoma. Cancer. 2006 Jan 15;106(2):375-82.

80e. Middleton MR, Grob JJ, Aaronson N, et al. Randomized phase III study of temozolomide versus dacarbazine in the treatment of patients with advanced metastatic malignant melanoma. J Clin Oncol. 2000 Jan;18(1):158-66.

81e. Einzig AI, Hochster H, Wiernik PH, et al. A phase II study of taxol in patients with malignant melanoma. Invest New Drugs. 1991 Feb;9(1):59-64.

82e. Kottschade LA, McWilliams RR, Markovic SN, et al. The use of pembrolizumab for the treatment of metastatic uveal melanoma. Melanoma Res. 2016 Jun;26(3):300-3.

83e. Algazi AP, Tsai KK, Shoushtari AN, et al. Clinical outcomes in metastatic uveal melanoma treated with PD-1 and PD-L1 antibodies. Cancer. 2016;122(21):3344-3353.

84e. Piulats Rodriguez JM, De La Cruz Merino L, Espinosa E, et al. Phase II multicenter, single arm, open label study of Nivolumab in combination with Ipilimumab in untreated patients with metastatic uveal melanoma. Annals of Oncology (2018) 29 (suppl_8): viii442-viii466.

85e. Zimmer L, Vaubel J, Mohr P, et al. Phase II DeCOG-study of ipilimumab in pretreated and treatment-naïve patients with metastatic uveal melanoma. PLoS One. 2015;10(3):e0118564. Published 2015 Mar 11. doi:10.1371/journal.pone.0118564.

86e. Bedikian AY, Papadopoulos N, Plager C, et al. Phase II evaluation of temozolomide in metastatic choroidal melanoma. Melanoma Res. 2003 Jun;13(3):303-6.

87e. Bellmunt J, de Wit R, Vaughn DJ, et al. Pembrolizumab as Second-Line Therapy for Advanced Urothelial Carcinoma. N Engl J Med. 2017;376(11):1015-1026.

88e. Rosenberg JE, Hoffman-Censits J, Powles T, et al. Atezolizumab in patients with locally advanced and metastatic urothelial carcinoma who have progressed following treatment with platinum-based chemotherapy: a single-arm, multicentre, phase 2 trial. Lancet. 2016;387(10031):1909-20.

89e. Sharma P, Retz M, Siefker-Radtke A, et al. Nivolumab in metastatic urothelial carcinoma after platinum therapy (CheckMate 275): a multicentre, single-arm, phase 2 trial. Lancet Oncol. 2017 Mar;18(3):312-322.

90e. Massard C, Gordon MS, Sharma S, et al. Safety and Efficacy of Durvalumab (MEDI4736), an Anti-Programmed Cell Death Ligand-1 Immune Checkpoint Inhibitor, in Patients With Advanced Urothelial Bladder Cancer. J Clin Oncol. 2016;34(26):3119-25.

91e. Massard C, Gordon MS, Sharma S, et al. Safety and Efficacy of Durvalumab (MEDI4736), an Anti-Programmed Cell Death Ligand-1 Immune Checkpoint Inhibitor, in Patients With Advanced Urothelial Bladder Cancer. J Clin Oncol. 2016;34(26):3119-25.

92e. Patel MR, Ellerton J, Infante JR, et al. Avelumab in metastatic urothelial carcinoma after platinum failure (JAVELIN Solid Tumor): pooled results from two expansion cohorts of an open-label, phase 1 trial. Lancet Oncol. 2018 Jan;19(1):51-64.

93e. Lorusso V, Pollera CF, Antimi M, et al. A phase II study of gemcitabine in patients with transitional cell carcinoma of the urinary tract previously treated with platinum. Italian Co-operative Group on Bladder Cancer. Eur J Cancer. 1998 Jul;34(8):1208-12.

94e. Meluch AA, Greco FA, Burris HA 3rd, et al. Paclitaxel and gemcitabine chemotherapy for advanced transitional-cell carcinoma of the urothelial tract: a phase II trial of the Minnie pearl cancer research network. J Clin Oncol. 2001 Jun 15;19(12):3018-24.

95e. von der Maase H, Hansen SW, Roberts JT, et al. Gemcitabine and Cisplatin Versus Methotrexate, Vinblastine, Doxorubicin, and Cisplatin in Advanced or Metastatic Bladder Cancer: Results of a Large, Randomized, Multinational, Multicenter, Phase III Study. Journal of Clinical Oncology 2000 18:17, 3068-3077.

96e. McCaffrey JA, Hilton S, Mazumdar M, et al. Phase II trial of docetaxel in patients with advanced or metastatic transitional-cell carcinoma. J Clin Oncol. 1997 May;15(5):1853-7.

97e. Vaughn DJ, Broome CM, Hussain M, et al. Phase II trial of weekly paclitaxel in patients with previously treated advanced urothelial cancer. J Clin Oncol. 2002 Feb 15;20(4):937-40.

98e. Petrylak DP, de Wit R, Chi KN, et al. Ramucirumab plus docetaxel versus placebo plus docetaxel in patients with locally advanced or metastatic urothelial carcinoma after platinum-based therapy (RANGE): a randomised, double-blind, phase 3 trial. Lancet. 2017 Nov 18;390(10109):2266-2277.

99e. Sweeney CJ, Roth BJ, Kabbinavar FF, et al. Phase II Study of Pemetrexed for Second-Line Treatment of Transitional Cell Cancer of the Urothelium. Journal of Clinical Oncology 2006 24:21, 3451-3457.

100e. Witte RS, Elson P, Bono B, et al. Eastern Cooperative Oncology Group phase II trial of ifosfamide in the treatment of previously treated advanced urothelial carcinoma. J Clin Oncol. 1997 Feb;15(2):589-93.

101e. Siefker-Radtke AO, Dinney CP, Shen Y, et al. A phase 2 clinical trial of sequential neoadjuvant chemotherapy with ifosfamide, doxorubicin, and gemcitabine followed by cisplatin, gemcitabine, and ifosfamide in locally advanced urothelial cancer: final results. Cancer. 2012;119(3):540-7.

102e. Sternberg CN, de Mulder PH, Schornagel JH, et al. Randomized phase III trial of high-dose-intensity methotrexate, vinblastine, doxorubicin, and cisplatin (MVAC) chemotherapy and recombinant human granulocyte colony-stimulating factor versus classic MVAC in advanced urothelial tract tumors: European Organization for Research and Treatment of Cancer Protocol no. 30924. J Clin Oncol. 2001 May 15;19(10):2638-46.

103e. Miller D, Filiaci V, Gleming G, et al. Late-Breaking Abstract 1: Randomized phase III noninferiority trial of first line chemotherapy for metastatic or recurrent endometrial carcinoma: A Gynecologic Oncology Group study. Gynecologic Oncology 2012;125(3):771-3.

104e. Fleming GF, Brunetto VL, Cella D, et al. Phase III Trial of Doxorubicin Plus Cisplatin With or Without Paclitaxel Plus Filgrastim in Advanced Endometrial Carcinoma: A Gynecologic Oncology Group Study. Journal of Clinical Oncology 2004 22:11, 2159-2166

105e. Muggia FM, Blessing JA, Sorosky J, et al. Phase II trial of the pegylated liposomal doxorubicin in previously treated metastatic endometrial cancer: a Gynecologic Oncology Group study. J Clin Oncol. 2002 May 1;20(9):2360-4.

106e. Ott PA, Bang YJ, Berton-Rigaud D, et al. Safety and Antitumor Activity of Pembrolizumab in Advanced Programmed Death Ligand 1–Positive Endometrial Cancer: Results From the KEYNOTE-028 Study. Journal of Clinical Oncology 2017 35:22, 2535-2541.

107e. Aghajanian C, Sill MW, Darcy KM, et al. Phase II trial of bevacizumab in recurrent or persistent endometrial cancer: a Gynecologic Oncology Group study. J Clin Oncol. 2011;29(16):2259-65.

108e. Oza AM, Elit L, Tsao MS, et al. Phase II study of temsirolimus in women with recurrent or metastatic endometrial cancer: a trial of the NCIC Clinical Trials Group. J Clin Oncol. 2011;29(24):3278-85.

109e. Homesley, HD, Filiaci V, Markman M, et al. Phase III Trial of Ifosfamide With or Without Paclitaxel in Advanced Uterine Carcinosarcoma: A Gynecologic Oncology Group Study. Journal of Clinical Oncology 2007 25:5, 526-531.

110e. Rose PG, Ali S, Moslemi-Kebria M, et al. Paclitaxel, Carboplatin, and Bevacizumab in Advanced and Recurrent Endometrial Carcinoma. Int J Gynecol Cancer. 2017 Mar;27(3):452-458.

111e. Northfelt DW, Dezube BJ, Thommes JA, et al. Efficacy of pegylated-liposomal doxorubicin in the treatment of AIDS-related Kaposi's sarcoma after failure of standard chemotherapy. J Clin Oncol. 1997 Feb;15(2):653-9.

112e. Polizzotto MN, Uldrick TS, Wyvill KM, et al. Pomalidomide for Symptomatic Kaposi's Sarcoma in People With and Without HIV Infection: A Phase I/II Study. J Clin Oncol. 2016;34(34):4125-4131.

113e. Stebbing J, Wildfire A, Portsmouth S, et al. Paclitaxel for anthracycline-resistant AIDS-related Kaposi's sarcoma: clinical and angiogenic correlations. Ann Oncol. 2003 Nov;14(11):1660-6.

114e. Uldrick TS, Wyvill KM, Kumar P, et al. Phase II study of bevacizumab in patients with HIV-associated Kaposi's sarcoma receiving antiretroviral therapy. J Clin Oncol. 2012;30(13):1476-83.

115e. Evans SR, Krown SE, Testa MA, et al. Phase II evaluation of low-dose oral etoposide for the treatment of relapsed or progressive AIDS-related Kaposi's sarcoma: an AIDS Clinical Trials Group clinical study. J Clin Oncol. 2002 Aug 1;20(15):3236-41.

116e. Busakhala NW, Waako PJ, Strother MR, et al. Randomized Phase IIA Trial of Gemcitabine Compared With Bleomycin Plus Vincristine for Treatment of Kaposi's Sarcoma in Patients on Combination Antiretroviral Therapy in Western Kenya. J Glob Oncol. 2018;4(4):1-9.

117e. Koon HB, Krown SE, Lee JY, et al. Phase II trial of imatinib in AIDS-associated Kaposi's sarcoma: AIDS Malignancy Consortium Protocol 042. J Clin Oncol. 2013;32(5):402-8.

118e. Shepherd FA, Beaulieu R, Gelmon K, et al. Prospective randomized trial of two dose levels of interferon alfa with zidovudine for the treatment of Kaposi's sarcoma associated with human immunodeficiency virus infection: a Canadian HIV Clinical Trials Network study. J Clin Oncol. 1998 May;16(5):1736-42.

119e. Little RF, Wyvill KM, Pluda JM, et al. Activity of thalidomide in AIDS-related Kaposi's sarcoma. J Clin Oncol. 2000 Jul;18(13):2593-602.

120e. Nasti G, Errante D, Talamini R, et al. Vinorelbine is an effective and safe drug for AIDS-related Kaposi's sarcoma: results of a phase II study. J Clin Oncol. 2000 Apr;18(7):1550-7.

121e. Valle J, Wasan H, Palmer DH, et al. Cisplatin plus gemcitabine versus gemcitabine for biliary tract cancer. N Engl J Med. 2010 Apr 8;362(14):1273-81.

122e. Knox JJ, Hedley D, Oza A, et al. Combining gemcitabine and capecitabine in patients with advanced biliary cancer: a phase II trial. J Clin Oncol. 2005 Apr 1;23(10):2332-8.

123e. Schmid P, Adams S, Rugo HS, et al. Atezolizumab and Nab-Paclitaxel in Advanced Triple-Negative Breast Cancer. N Engl J Med 2018; 379:2108-2121.

124e. Reck M, Rodríguez-Abreu D, Robinson AG, et al. Pembrolizumab versus Chemotherapy for PD-L1–Positive Non–Small-Cell Lung Cancer. N Engl J Med 2016; 375:1823-1833.

125e. Zaanan A, Gauthier M, Malka D, et al. Second-line chemotherapy with fluorouracil, leucovorin, and irinotecan (FOLFIRI regimen) in patients with advanced small bowel adenocarcinoma after failure of first-line platinum-based chemotherapy: a multicenter AGEO study. Cancer. 2011 Apr 1;117(7):1422-8. doi: 10.1002/cncr.25614.

126e. Suenaga M, Mizunuma N, Chin K, et al. Chemotherapy for small-bowel Adenocarcinoma at a single institution. Surg Today. 2009;39(1):27-31. doi: 10.1007/s00595-008-3843-2.

127e. Drilon A, Laetsch TW, Kummar S, et al. Efficacy of Larotrectinib in TRK Fusion–Positive Cancers in Adults and Children. N Engl J Med 2018; 378:731-739.

128e. Yardley DA, Coleman R, Conte P, et al. nab-Paclitaxel plus carboplatin or gemcitabine versus gemcitabine plus carboplatin as first-line treatment of patients with triple-negative metastatic breast cancer: results from the tnAcity trial. Ann Oncol. 2018;29(8):1763–1770. doi:10.1093/annonc/mdy201.

129e. Mavroudis D, Papakotoulas P, Ardavanis A, et al. Randomized phase III trial comparing docetaxel plus epirubicin versus docetaxel plus capecitabine as first-line treatment in women with advanced breast cancer. Ann Oncol. 2010 Jan;21(1):48-54. doi: 10.1093/annonc/mdp498.

130e. Albain KS, Nag SM, Calderillo-Ruiz G, et al. Gemcitabine plus Paclitaxel versus Paclitaxel monotherapy in patients with metastatic breast cancer and prior anthracycline treatment. J Clin Oncol. 2008 Aug 20;26(24):3950-7. doi: 10.1200/JCO.2007.11.9362.

131e. West H, McCleod M, Hussein M, et al. Atezolizumab in combination with carboplatin plus nab-paclitaxel chemotherapy compared with chemotherapy alone as first-line treatment for metastatic non-squamous non-small-cell lung cancer (IMpower130): a multicentre, randomised, open-label, phase 3 trial. Lancet Oncol. 2019 Jul;20(7):924-937. doi: 10.1016/S1470-2045(19)30167-6.

132e. Bachelot T, Ciruelos E, Schneeweiss A, et al. Preliminary safety and efficacy of first-line pertuzumab combined with trastuzumab and taxane therapy for HER2-positive locally recurrent or metastatic breast cancer (PERUSE). Ann Oncol. 2019;30(5):766-773. doi:10.1093/annonc/mdz061.

133e. Spigel D et al. IMpower110: Interim OS Analysis of a Phase III Study of Atezolizumab (atezo) vs Platinum-Based Chemotherapy (chemo) as 1L Treatment (tx) in PD-L1–selected NSCLC [ESMO 2019 Abstract LBA78].

134e. Cortes J, Cescon DW, Rugo HS, et al. Pembrolizumab plus chemotherapy versus placebo plus chemotherapy for previously untreated locally recurrent inoperable or metastatic triple-negative breast cancer (KEYNOTE-355): a randomised, placebo-controlled, double-blind, phase 3 clinical trial. Lancet. 2020 Dec 5;396(10265):1817-1828. doi: 10.1016/S0140-6736(20)32531-9.

135e. Reid EG, Suazo A, Lensing SY, et al. Pilot Trial AMC-063: Safety and Efficacy of Bortezomib in AIDS-associated Kaposi Sarcoma. Clin Cancer Res. 2020;26(3):558-565. doi:10.1158/1078-0432.CCR-19-1044.

136e. Sezer A, Kilickap S, Gümüş M, et al. Cemiplimab monotherapy for first-line treatment of advanced non-small-cell lung cancer with PD-L1 of at least 50%: a multicentre, open-label, global, phase 3, randomised, controlled trial. Lancet. 2021 Feb 13;397(10274):592-604.

137e. Miles D, Gligorov J, André F, et al. Primary results from IMpassion131, a double-blind, placebo-controlled, randomised phase III trial of first-line paclitaxel with or without atezolizumab for unresectable locally advanced/metastatic triple-negative breast cancer. Ann Oncol. 2021;32(8):994-1004. doi:10.1016/j.annonc.2021.05.801.

138e. Morgensztern D, Cobo M, Ponce Aix S, et al. ABOUND.2L+: A randomized phase 2 study of nanoparticle albumin-bound paclitaxel with or without CC-486 as second-line treatment for advanced nonsquamous non-small cell lung cancer (NSCLC). Cancer. 2018 Dec 15;124(24):4667-4675. doi: 10.1002/cncr.31779. Epub 2018 Nov 1.

139e. Jameson GS, Borazanci E, Babiker HM, et al. Response Rate Following Albumin-Bound Paclitaxel Plus Gemcitabine Plus Cisplatin Treatment Among Patients With Advanced Pancreatic Cancer: A Phase 1b/2 Pilot Clinical Trial. JAMA Oncol. 2019 Oct 3;6(1):125–32. doi: 10.1001/jamaoncol.2019.3394. Epub ahead of print. Erratum in: JAMA Oncol. 2019 Nov 1;5(11):1643. PMID: 31580386; PMCID: PMC6777241.

140e. Yoneshima Y, Morita S, Ando M, et al. Phase 3 Trial Comparing Nanoparticle Albumin-Bound Paclitaxel With Docetaxel for Previously Treated Advanced NSCLC. J Thorac Oncol. 2021 Sep;16(9):1523-1532. doi: 10.1016/j.jtho.2021.03.027. Epub 2021 Apr 27.

141e. Wang-Gillam A, Li CP, Bodky G, NAPOLI-1 study group. Nanoliposomal irinotecan with fluorouracil and folinic acid in metastatic pancreatic cancer after previous gemcitabine-based therapy (NAPOLI-1): a global, randomised, open-label, phase 3 trial. Lancet. 2016 Feb 6;387(10018):545-557. doi: 10.1016/S0140-6736(15)00986-1. Epub 2015 Nov 29.

142e. Cunningham D, Chau I, Stocken DD, et al. Phase III randomized comparison of gemcitabine versus gemcitabine plus capecitabine in patients with advanced pancreatic cancer. J Clin Oncol. 2009 Nov 20;27(33):5513-8. doi: 10.1200/JCO.2009.24.2446. Epub 2009 Oct 26.

143e. Moore MJ, Goldstein D, Hamm J, et al. Erlotinib plus gemcitabine compared with gemcitabine alone in patients with advanced pancreatic cancer: a phase III trial of the National Cancer

Institute of Canada Clinical Trials Group. J Clin Oncol. 2007 May 20;25(15):1960-6. doi: 10.1200/JCO.2006.07.9525. Epub 2007 Apr 23.

144e. Sohal DPS, Duong M, Ahmad SA, et al. Efficacy of Perioperative Chemotherapy for Resectable Pancreatic Adenocarcinoma: A Phase 2 Randomized Clinical Trial. JAMA Oncol. 2021 Mar 1;7(3):421-427.

145e. Wiernik PH, Einzig AI. Taxol in malignant melanoma. J Natl Cancer Inst Monogr. 1993;(15):185-7.

146e. Fountzilas G, Kalofonos HP, Dafni U, et al. Paclitaxel and epirubicin versus paclitaxel and carboplatin as first-line chemotherapy in patients with advanced breast cancer: a phase III study conducted by the Hellenic Cooperative Oncology Group. Ann Oncol. 2004 Oct;15(10):1517-26.

147e. Johnson ML, Cho BC, Luft A, et al; POSEIDON investigators. Durvalumab With or Without Tremelimumab in Combination With Chemotherapy as First-Line Therapy for Metastatic Non-Small-Cell Lung Cancer: The Phase III POSEIDON Study. J Clin Oncol. 2022 Nov 3:JCO2200975. doi: 10.1200/JCO.22.00975.

148e. Gogishvili M, Melkadze T, Makharadze T, et al. LBA51 EMPOWER-Lung 3: Cemiplimab in combination with platinum doublet chemotherapy for first-line (1L) treatment of advanced non-small cell lung cancer (NSCLC). Annals of Oncology, ISSN: 0923-7534, Vol: 32, SUPPLEMENT 5, S1328, SEPTEMBER 01, 2021. DOI10.1016/j.annonc.2021.08.2130.

149e. Zaibet S, Hautefeuille V, Auclin E, et al. Gemcitabine + Nab-paclitaxel or Gemcitabine alone after FOLFIRINOX failure in patients with metastatic pancreatic adenocarcinoma: a real-world AGEO study. Br J Cancer. 2022 Jun;126(10):1394-1400. doi: 10.1038/s41416-022-01713-w. Epub 2022 Jan 29.

150e. Novello S, Mazières J, Oh IJ, et al. Alectinib versus chemotherapy in crizotinib-pretreated anaplastic lymphoma kinase (ALK)-positive non-small-cell lung cancer: results from the phase III ALUR study. Ann Oncol. 2018;29(6):1409-1416. doi:10.1093/annonc/mdy121.

151e. Kim DW, Tiseo M, Ahn MJ, et al. Brigatinib in Patients With Crizotinib-Refractory Anaplastic Lymphoma Kinase-Positive Non-Small-Cell Lung Cancer: A Randomized, Multicenter Phase II Trial. J Clin Oncol. 2017 Aug 1;35(22):2490-2498. doi: 10.1200/JCO.2016.71.5904.

152e. Solomon BJ, Besse B, Bauer TM, et al. Lorlatinib in patients with ALK-positive non-small-cell lung cancer: results from a global phase 2 study. Lancet Oncol. 2018 Dec;19(12):1654-1667. doi: 10.1016/S1470-2045(18)30649-1.

153e. Shaw AT, Kim DW, Nakagawa K, et al. Crizotinib versus chemotherapy in advanced ALK-positive lung cancer. N Engl J Med. 2013 Jun 20;368(25):2385-94. doi: 10.1056/NEJMoa1214886.

154e. Nabholtz JM, Falkson C, Campos D, et al. Docetaxel and doxorubicin compared with doxorubicin and cyclophosphamide as first-line chemotherapy for metastatic breast cancer: results of a randomized, multicenter, phase III trial [published correction appears in J Clin Oncol. 2003 May 15;21(10):2048]. J Clin Oncol. 2003;21(6):968-975. doi:10.1200/JCO.2003.04.040.

155e. Langley RE, Carmichael J, Jones AL, et al. Phase III trial of epirubicin plus paclitaxel compared with epirubicin plus cyclophosphamide as first-line chemotherapy for metastatic breast cancer: United Kingdom National Cancer Research Institute trial AB01. J Clin Oncol. 2005;23(33):8322-8330. doi:10.1200/JCO.2005.01.1817.

156e. Yamamoto Y, Iwata H, Taira N, et al. Pertuzumab retreatment for HER2-positive advanced breast cancer: A randomized, open-label phase III study (PRECIOUS). Cancer Sci. 2022;113(9):3169-3179. doi:10.1111/cas.15474.

157e. Nathan P, Hassel JC, Rutkowski P, et al. Overall Survival Benefit with Tebentafusp in Metastatic Uveal Melanoma. *New England Journal of Medicine*. 2021;385(13):1196-1206. doi:https://doi.org/10.1056/nejmoa2103485

158e. Brown J, Smith JA, Ramondetta LM, et al. Combination of gemcitabine and cisplatin is highly active in women with endometrial carcinoma: results of a prospective phase 2 trial. *Cancer*. 2010;116(21):4973-4979. doi:https://doi.org/10.1002/cncr.25498

159e. Oh DY, He AR, Qin S, et al. A phase 3 randomized, double-blind, placebo-controlled study of durvalumab in combination with gemcitabine plus cisplatin (GemCis) in patients (pts) with advanced biliary tract cancer (BTC): TOPAZ-1. *Journal of Clinical Oncology*. 2022;40(4_suppl):378-378. doi:https://doi.org/10.1200/jco.2022.40.4_suppl.378

160e. Kelley RK, Ueno M, Yoo C, et al. Pembrolizumab in combination with gemcitabine and cisplatin compared with gemcitabine and cisplatin alone for patients with advanced biliary tract cancer (KEYNOTE-966): a randomised, double-blind, placebo-controlled, phase 3 trial. *The Lancet*. 2023;0(0). doi:https://doi.org/10.1016/S0140-6736(23)00727-4

161e. Kim ST, Oh SY, Lee J, et al. Capecitabine plus Oxaliplatin as a Second-Line Therapy for Advanced Biliary Tract Cancers: A Multicenter, Open-Label, Phase II Trial. *Journal of Cancer*. 2019;10(25):6185-6190. doi:https://doi.org/10.7150/jca.37610

162e. Thierry André, Christophe Tournigand, Olivier Rosmorduc, et al. Gemcitabine combined with oxaliplatin (GEMOX) in advanced biliary tract adenocarcinoma: a GERCOR study. *Annals of Oncology*. 2004;15(9):1339-1343. doi:https://doi.org/10.1093/annonc/mdh351

163e. Lamarca A, Palmer DH, Wasan HS, et al. Second-line FOLFOX chemotherapy versus active symptom control for advanced biliary tract cancer (ABC-06): a phase 3, open-label, randomised, controlled trial. *The Lancet Oncology*. 2021;0(0). doi:https://doi.org/10.1016/S1470-2045(21)00027-9

164e. Nehls O, Oettle H, Hartmann J, et al. Capecitabine plus oxaliplatin as first-line treatment in patients with advanced biliary system adenocarcinoma: a prospective multicentre phase II trial. *British Journal of Cancer*. 2008;98(2):309-315. doi:https://doi.org/10.1038/sj.bjc.6604178

165e. Aydin D, Sendur MA, Kefeli U, et al. Evaluation of Bevacizumab in Advanced Small Bowel Adenocarcinoma. *Clinical Colorectal Cancer*. 2017;16(1):78-83. doi:https://doi.org/10.1016/j.clcc.2016.04.013

166e. Pourcher V, Desnoyer A, Assoumou L, et al. Phase II Trial of Lenalidomide in HIV-Infected Patients with Previously Treated Kaposi's Sarcoma: Results of the ANRS 154 Lenakap Trial. *AIDS Research and Human Retroviruses*. 2017;33(1):1-10. doi:https://doi.org/10.1089/aid.2016.0069

167e. Zer A, Icht O, Yosef L, et al. Phase II single-arm study of nivolumab and ipilimumab (Nivo/Ipi) in previously treated classical Kaposi sarcoma (cKS). *Annals of Oncology*. 2022;33(7):720-727. doi:https://doi.org/10.1016/j.annonc.2022.03.012

168e. Delyon J, Biard L, Renaud M, et al. PD-1 blockade with pembrolizumab in classic or endemic Kaposi's sarcoma: a multicentre, single-arm, phase 2 study. *The Lancet Oncology*. 2022;23(4):491-500. doi:https://doi.org/10.1016/S1470-2045(22)00097-3

169e. Chung HC, Ros W, Delord JP, et al. Efficacy and Safety of Pembrolizumab in Previously Treated Advanced Cervical Cancer: Results From the Phase II KEYNOTE-158 Study. *Journal of* Clinical Oncology. 2019;37(17):1470-1478. doi:https://doi.org/10.1200/jco.18.01265

170e. Coleman RL, Lorusso D, Gennigens C, et al. Efficacy and safety of tisotumab vedotin in previously treated recurrent or metastatic cervical cancer (innovaTV 204/GOG-3023/ENGOT-cx6): a multicentre, open-label, single-arm, phase 2 study. The Lancet Oncology. 2021;22(5):609-619. doi:https://doi.org/10.1016/s1470-2045(21)00056-5

171e. Tewari KS, Monk BJ, Vergote I, et al. Survival with Cemiplimab in Recurrent Cervical Cancer. New England Journal of Medicine. 2022;386(6):544-555. doi:https://doi.org/10.1056/nejmoa2112187

172e. Monk BJ, Sill MW, Burger RA, Gray HJ, Buekers TE, Roman LD. Phase II Trial of Bevacizumab in the Treatment of Persistent or Recurrent Squamous Cell Carcinoma of the Cervix: A Gynecologic Oncology Group Study. Journal of Clinical Oncology. 2009;27(7):1069-1074. doi:https://doi.org/10.1200/jco.2008.18.9043

173e. Curtin JP, Blessing JA, Webster KD, et al. Paclitaxel, an Active Agent in Nonsquamous Carcinomas of the Uterine Cervix: A Gynecologic Oncology Group Study. Journal of Clinical Oncology. 2001;19(5):1275-1278. doi:https://doi.org/10.1200/jco.2001.19.5.1275

174e. Bookman MA, Blessing JA, Hanjani P, Herzog TJ, Andersen WA. Topotecan in Squamous Cell Carcinoma of the Cervix: A Phase II Study of the Gynecologic Oncology Group. Gynecologic Oncology. 2000;77(3):446-449. doi:https://doi.org/10.1006/gyno.2000.5807

175e. Muggia FM, Blessing JA, Method M, et al. Evaluation of vinorelbine in persistent or recurrent squamous cell carcinoma of the cervix: a Gynecologic Oncology Group study. Gynecologic Oncology. 2004;92(2):639-643. doi:https://doi.org/10.1016/j.ygyno.2003.10.045

176e. Lorusso D, G. Ferrandina, S. Pignata, et al. Evaluation of pemetrexed (Alimta, LY231514) as second-line chemotherapy in persistent or recurrent carcinoma of the cervix: the CERVIX 1 study of the MITO (Multicentre Italian Trials in Ovarian Cancer and Gynecologic Malignancies) Group. Annals of Oncology. 2009;21(1):61-66. doi:https://doi.org/10.1093/annonc/mdp266

177e. Bardia A, Hurvitz SA, Tolaney SM, et al. Sacituzumab Govitecan in Metastatic Triple-Negative Breast Cancer. New England Journal of Medicine. 2021;384(16):1529-1541. doi:https://doi.org/10.1056/nejmoa2028485

178e. O'Shaughnessy J, Schwartzberg L, Danso MA, et al. Phase III Study of Iniparib Plus Gemcitabine and Carboplatin Versus Gemcitabine and Carboplatin in Patients With Metastatic Triple-Negative Breast Cancer. Journal of Clinical Oncology. 2014;32(34):3840-3847. doi:https://doi.org/10.1200/jco.2014.55.2984

179e. Prime Therapeutics Management. Paclitaxel Albumin-Bound Clinical Literature Review Analysis. Last updated September 2025. Accessed September 2025.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C22.1	Intrahepatic bile duct carcinoma
C23	Malignant neoplasm of the gallbladder
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.1	Malignant neoplasm of ampulla of Vater

ICD-10	ICD-10 Description
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C24.9	Malignant neoplasm of biliary tract, unspecified
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of the pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast

ICD-10	ICD-10 Description
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast

ICD-10	ICD-10 Description
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C52	Malignant neoplasm of vagina
C53.0	Malignant neoplasm of endocervix
C53.1	Malignant neoplasm of exocervix
C53.8	Malignant neoplasm of overlapping sites of cervix uteri
C53.9	Malignant neoplasm of cervix uteri, unspecified
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament

ICD-10	ICD-10 Description
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
Z85.068	Personal history of other malignant neoplasm of small intestine
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.09	Personal history of malignant neoplasm of other digestive organs
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.3	Personal history of malignant neoplasm of breast
Z85.43	Personal history of malignant neoplasm of ovary

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
6, K	A52450	National Government Services, Inc. (NGS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC