Abraxane® (paclitaxel protein-bound particles)
(Intravenous)

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I. Length of Authorization

Coverage is provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Abraxane 100 mg powder for injection single-dose vial: 9 vials per 21 day supply

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

- 900 billable units per 21 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

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

Breast Cancer † [1-3,9,21,16e,18e-20e,22e,30e,121e,126e,130e]

- Used as a single agent after failure on combination chemotherapy for metastatic disease or relapsed within 6 months of adjuvant therapy †; **AND**
  - Previous chemotherapy included an anthracycline unless clinically contraindicated; **OR**
- Patient has recurrent unresectable (local or regional) or metastatic (stage IV [M1]) disease ‡; **AND**
  - Used as a single agent for previously treated disease; **AND**
    - Disease is HER2-negative; **AND**
      - Disease is hormone receptor-negative; **OR**
      - Disease is hormone receptor-positive and patient is refractory to endocrine therapy or has a visceral crisis; **OR**
  - Used in combination with carboplatin as first-line therapy in patients with triple-negative breast cancer (TNBC) with high tumor burden, rapidly progressing disease, and visceral crisis; **AND**

- Patient experienced a hypersensitivity reaction to paclitaxel or docetaxel despite premedication or the patient has contraindications to standard hypersensitivity premedications; **AND**
- Patient has a negative skin test to paclitaxel; **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**

o Used in combination with pertuzumab and trastuzumab as first-line therapy for HER2-positive disease; **AND**

- Patient experienced a hypersensitivity reaction to paclitaxel or docetaxel despite premedication or the patient has contraindications to standard hypersensitivity premedications; **AND**
- Patient has a negative skin test to paclitaxel; **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**

o Used as first-line therapy in combination with pembrolizumab ‡; **AND**

- Used in patients with PD-L1 positive triple-negative disease and a Combined Positive Score (CPS) ≥10; **AND**

▪ Use of albumin-bound paclitaxel in combination with pembrolizumab will be restricted to patients with a contraindication or intolerance to pembrolizumab in combination with either paclitaxel or gemcitabine/carboplatin; **OR**

- Used in neoadjuvant or adjuvant therapy; **AND**
  - Patient experienced a hypersensitivity reaction to paclitaxel or docetaxel despite premedication or the patient has contraindications to standard hypersensitivity premedications; **AND**
  - Patient has a negative skin test to paclitaxel; **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) † [1,2,4,10,26e,27e,30e,43e,122e,129e,131e,134e]

- 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 ✝; **AND**
  - Patient experienced a hypersensitivity reaction to paclitaxel or docetaxel despite premedication or the patient has contraindications to standard hypersensitivity premedications; **AND**

- Patient has a negative skin test to paclitaxel; **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.]; **AND**

- Use of albumin-bound paclitaxel will be restricted to patients with a contraindication or intolerance to an alternative generically available agent/regimen (e.g., carboplatin/gemcitabine, etc. [*see NCCN Non-Small Cell Lung Cancer guidelines for complete list of alternative regimens*]); **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 combination with carboplatin AND pembrolizumab (for squamous cell histology) or atezolizumab (for non-squamous histology); **AND**
      - Used in patients with tumors that have negative actionable molecular biomarkers***** and one of the following:
        - PD-L1 <1% with performance status (PS) score of 0-1
        - PD-L1 expression positive (≥1%) tumors with PS 0-2; **AND**
      - *(In combination with carboplatin and pembrolizumab ONLY):* Patient experienced a hypersensitivity reaction to paclitaxel or docetaxel despite premedication or the patient has contraindications to standard hypersensitivity premedications; **AND**
        - Patient has a negative skin test to paclitaxel; **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.]; **AND**

      PD-L1 ≥50%:
      - Use of albumin-bound paclitaxel will be restricted to patients with a contraindication or intolerance to cemiplimab; **OR**

      - Used in patients with BRAF V600E-mutation, NTRK1/2/3 gene fusion, MET exon 14 skipping mutation, RET rearrangement, KRAS G12C mutation, or EGFR exon 20 mutation AND PS score of 0-1; **AND**
        - *(In combination with carboplatin and pembrolizumab ONLY):* Patient experienced a hypersensitivity reaction to paclitaxel or docetaxel despite premedication or the patient has contraindications to standard hypersensitivity premedications; **AND**

- Patient has a negative skin test to paclitaxel; **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.]; **AND**

PD-L1 ≥50%:

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

- Used in combination with carboplatin in patients with contraindications ¥ to PD-1 or PD-L1 inhibitors (PS score of 0-2) or as a single agent (PS score of 2); **AND**
  - Used for one of the following:
    - Patients with tumors that have negative actionable molecular biomarkers* and PD-L1 ≥1%
    - Patients with tumors that have negative actionable molecular biomarkers* and PD-L1 <1%
    - Patients with BRAF V600E-mutation, NTRK1/2/3 gene fusion, MET exon 14 skipping mutation, KRAS G12C mutation, EGFR exon 20 mutation or RET rearrangement positive tumors; **AND**
  - Patient experienced a hypersensitivity reaction to paclitaxel or docetaxel despite premedication or the patient has contraindications to standard hypersensitivity premedications; **AND**
  - Patient has a negative skin test to paclitaxel; **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.]; **AND**

  - Use of albumin-bound paclitaxel will be restricted to patients with a contraindication or intolerance to an alternative generically available agent/regimen (e.g., carboplatin/gemcitabine, etc. [*see NCCN Non-Small Cell Lung Cancer guidelines for complete list of alternative regimens*]); **OR**

- Used as subsequent therapy; **AND**
  - Used as a single-agent (if not previously given) in patients with a PS 0-2; **AND**
    - Used for first progression after initial systemic therapy; **AND**
    - Patient experienced a hypersensitivity reaction to paclitaxel or docetaxel despite premedication or the patient has contraindications to standard hypersensitivity premedications; **AND**
    - Patient has a negative skin test to paclitaxel; **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.]; **AND**

Patients WITHOUT previous immunotherapy:

- Use of albumin-bound paclitaxel will be restricted to patients with a contraindication or intolerance to one of the following:
  - Nivolumab
  - Pembrolizumab
  - Atezolizumab
  - Pemetrexed *(non-squamous only)*
  - Gemcitabine; **OR**

Patients WITH previous immunotherapy:

- Use of albumin-bound paclitaxel will be restricted to patients with a contraindication or intolerance to one of the following:
  - Pemetrexed *(non-squamous only)*
  - Gemcitabine; **OR**

- Used in combination with carboplatin AND pembrolizumab (for squamous cell histology) or atezolizumab (for non-squamous histology) in patients with PS score of 0-1; **AND**
  - Used for one of the following:
    - Patients with BRAF V600E-mutation, NTRK1/2/3 gene fusion, or MET exon 14 skipping mutation, or RET rearrangement positive tumors
    - Patients with EGFR S768I, L861Q, and/or G719X mutation or ROS1 rearrangement positive tumors who received prior targeted therapy§ for those aberrations; **AND**
  - *(In combination with carboplatin and pembrolizumab ONLY):* Patient experienced a hypersensitivity reaction to paclitaxel or docetaxel despite premedication or the patient has contraindications to standard hypersensitivity premedications; **AND**
    - Patient has a negative skin test to paclitaxel; **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 in combination with carboplatin in patients with contraindications ¥ to PD-1 or PD-L1 inhibitors (PS score of 0-2) or as a single agent (PS score of 2) AND one of the following; **AND**

- Used for one of the following:
  - Patients with BRAF V600E-mutation, NTRK1/2/3 gene fusion, MET exon 14 skipping mutation, or RET rearrangement positive tumors
  - Patients with EGFR exon 19 deletion or L858R tumors, EGFR S768I, L861Q, and/or G719X mutation positive tumors, or ALK or ROS1 rearrangement positive tumors who received prior targeted therapy§ for those aberrations
  - 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-doublet chemotherapy; **AND**
- Patient experienced a hypersensitivity reaction to paclitaxel or docetaxel despite premedication or the patient has contraindications to standard hypersensitivity premedications; **AND**
- Patient has a negative skin test to paclitaxel; **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.]; **AND**

- Use of albumin-bound paclitaxel will be restricted to patients with a contraindication or intolerance to an alternative generically available agent/regimen (e.g., carboplatin/gemcitabine, etc. [*see NCCN Non-Small Cell Lung Cancer guidelines for complete list of alternative regimens*])

** Note: Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET exon 14 skipping mutation, and RET rearrangement. If there is insufficient tissue to allow testing for all of EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, and RET, repeat biopsy and/or plasma testing should be done. If these are not feasible, 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, or presence of an oncogene (e.g., EGFR exon 19 deletion, or L858R, ALK rearrangements), which would predict lack of benefit.

Ovarian Cancer (Epithelial Ovarian/Fallopian Tube/Primary Peritoneal) ‡ [2,8,22,52e,59e,61e]

- 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**
  - Used as a single agent; **AND**

- Patient has platinum-resistant disease and one of the following:
  - Used for progression on primary, maintenance, or recurrence therapy
  - Used for stable or persistent disease if not currently on maintenance therapy
  - Used for relapsed disease <6 months following complete remission from prior chemotherapy; **AND**
    - Patient experienced a hypersensitivity reaction to paclitaxel or docetaxel despite premedication or the patient has contraindications to standard hypersensitivity premedications; **AND**
    - Patient has a negative skin test to paclitaxel; **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.]; **AND**

➢ Use of albumin-bound paclitaxel will be restricted to patients with a contraindication or intolerance to an alternative generically available agent/regimen used for platinum-resistant disease (e.g., carboplatin/gemcitabine, etc. [*see NCCN Ovarian Cancer guidelines for complete list of alternative regimens*]); **OR**

- Patient has platinum-sensitive disease; **AND**
  - Used for radiographic and/or clinical relapse ≥6 months after complete remission from prior chemotherapy; **AND**

➢ Use of albumin-bound paclitaxel will be restricted to patients with a contraindication or intolerance to an alternative generically available agent/regimen with or without bevacizumab used for platinum-sensitive disease (e.g., carboplatin/gemcitabine ± bevacizumab, etc. [*see NCCN Ovarian Cancer guidelines for complete list of alternative regimens*]); **OR**

- Used in combination with carboplatin if platinum-sensitive with confirmed taxane hypersensitivity; **AND**
  - Used for relapse ≥6 months after complete remission from prior chemotherapy; **AND**
  - Patient has a negative skin test to paclitaxel; **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.]; **AND**

▪ Use of albumin-bound paclitaxel will be restricted to patients with a contraindication or intolerance to an alternative generically available

agent/regimen with or without bevacizumab used for platinum-sensitive disease (e.g., carboplatin/gemcitabine ± bevacizumab, etc. [*see NCCN Ovarian Cancer guidelines for complete list of alternative regimens*])

Pancreatic Adenocarcinoma † Φ [1,2,5-7,24,68e,69e,72e]

- Used in combination with gemcitabine; **AND**
  - Patient has locally advanced or metastatic disease; **AND**
    - Used as first-line therapy; **AND**

      ➢ Use of albumin-bound paclitaxel will be restricted to patients who are not candidates for treatment with FOLFORINOX (i.e., has a contraindication, intolerance, or ECOG 2); **OR**
    - Used as induction therapy followed by chemoradiation *(locally advanced disease only)*; **AND**

      ➢ Use of albumin-bound paclitaxel will be restricted to patients who are not candidates for treatment with FOLFORINOX (i.e., has a contraindication, intolerance, or ECOG 2); **OR**
    - Used as subsequent therapy after progression with a fluoropyrimidine-based therapy; **OR**
    - Used as continuation (subsequent) therapy if no disease progression after first-line therapy *(locally advanced disease only)*; **OR**
    - Used as continuation (maintenance) therapy if acceptable tolerance and no disease progression after at least 4-6 months of first-line therapy *(metastatic disease only)*; **OR**
  - Patient has recurrent disease in the pancreatic operative bed or metastatic disease post-resection; **AND**
    - Used ≥6 months after completion of primary therapy; **OR**
    - Used <6 months from completion of primary therapy with a fluoropyrimidine-based regimen; **OR**
  - Used as neoadjuvant therapy; **AND**
    - Patient has resectable with high-risk features (i.e., markedly elevated CA 19-9, large primary tumors, large regional lymph nodes, excessive weight loss, extreme pain); **AND**

      ➢ Use of albumin-bound paclitaxel will be restricted to patients who are not candidates for treatment with FOLFORINOX (i.e., has a contraindication, intolerance, or ECOG 2); **OR**
    - Patient has biopsy positive borderline resectable disease; **AND**

> ➢ Use of albumin-bound paclitaxel will be restricted to patients who are not candidates for treatment with FOLFORINOX (i.e., has a contraindication, intolerance, or ECOG 2); **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; **AND**

> ➢ Use of albumin-bound paclitaxel will be restricted to patients who are not candidates for treatment (i.e., has a contraindication, intolerance, or ECOG 2) with an alternative generically available agent/regimen (e.g., FOLFIRINOX, gemcitabine/erlotinib, etc. [*see NCCN Pancreatic Adenocarcinoma guidelines for complete list of alternative regimens*]); **OR**

    - Used as continuation (maintenance) therapy if acceptable tolerance and no disease progression after at least 4-6 months of first-line therapy

Cutaneous Melanoma ‡ [2,15,16,78e,80e,81e]

- Used as a single agent or in combination with carboplatin for metastatic or unresectable disease; **AND**
- Use for one of the following:
  - Subsequent therapy for disease progression
  - After maximum clinical benefit from BRAF targeted therapy; **AND**
- Patient experienced a hypersensitivity reaction to paclitaxel despite premedication or the patient has contraindications to standard hypersensitivity premedications; **AND**
- Patient has a negative skin test to paclitaxel; **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.]; **AND**

- Patient must demonstrate an inadequate response to an alternative generically available agent/regimen (e.g., temozolomide, dacarbazine, etc. [*see NCCN Cutaneous Melanoma guidelines for complete list of alternative regimens*]), unless there is a contraindication or intolerance, prior to approval of albumin-bound paclitaxel

Hepatobiliary Adenocarcinoma (Intrahepatic/Extrahepatic Cholangiocarcinoma) ‡ [2,11,119e]

- Used in combination with gemcitabine for unresectable or metastatic disease; **AND**
- Used as primary treatment; **AND**

- Use of albumin-bound paclitaxel will be restricted to patients with a contraindication or intolerance to an alternative generically available agent/regimen (e.g.,

gemcitabine/cisplatin, etc. [*see NCCN Hepatobiliary Cancer guidelines for complete list of alternative regimens*])

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.

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

§Genomic Aberration/Mutational Driver Targeted Therapies (Note: *not all inclusive, refer to guidelines for appropriate use*)				
Sensitizing *EGFR* mutation-positive tumors	*ALK* rearrangement-positive tumors	*ROS1* rearrangement-positive tumors	*BRAF* V600E-mutation positive tumors	*NTRK*1/2/3 gene fusion positive tumors
– Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib – Amivantamab *(exon-20 insertion)* – Mobocertinib *(exon-20 insertion)*	– Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib	– Ceritinib – Crizotinib – Entrectinib – Lorlatinib	– Dabrafenib ± trametinib – Vemurafenib	– Larotrectinib – Entrectinib
PD-L1 tumor expression ≥1%	PD-L1 tumor expression ≥ 50%	*MET* exon-14 skipping mutations	*RET* rearrangement-positive tumors	*KRAS G12C* mutation positive tumors
– Pembrolizumab – Atezolizumab – Nivolumab + ipilimumab	– Pembrolizumab – Atezolizumab – Nivolumab + ipilimumab – Cemiplimab	– Capmatinib – Crizotinib – Tepotinib	– Selpercatinib – Cabozantinib – Pralsetinib	– Sotorasib

IV. Renewal Criteria [1,2]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **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), etc.

V. Dosage/Administration [1,11,15,16,19,21,22,25-27]

Indication	Dose
Breast Cancer	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 ***NOTE:** If substituted for weekly paclitaxel or docetaxel, the weekly dose of albumin-bound paclitaxel should not exceed 125 mg/m²*
NSCLC	Administer 100 mg/m² intravenously days 1, 8, and 15 of a 21-day cycle until disease progression or unacceptable toxicity
Cutaneous Melanoma and Ovarian Cancer	Administer 100 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity
Pancreatic Adenocarcinoma & Hepatobiliary Cancer	Administer 125 mg/m² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity
All other indications	Administer 260 mg/m² intravenously every 21 days until disease progression or unacceptable toxicity OR Administer 100 mg/m² intravenously days 1, 8, and 15 of a 21-day cycle until disease progression or unacceptable toxicity

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC:

- Abraxane 100 mg powder for injection; single-dose vial: 68817-0134-xx**

*** Available generically*

VII. References (STANDARD)

1. Abraxane [package insert]. Summit, NJ; Celgene Corporation; August 2020. Accessed August 2022.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) paclitaxel, albumin bound. National Comprehensive Cancer Network, 2022. 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 August 2022.

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 1.2022. National Comprehensive Cancer Network, 2022. 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 August 2022.
21. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Breast Cancer, Version 4.2022. National Comprehensive Cancer Network, 2022. 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 August 2022.
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 1.2022. National Comprehensive Cancer Network, 2022. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.

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26. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Small Bowel Adenocarcinoma, Version 1.2022. National Comprehensive Cancer Network, 2022. 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 August 2022.
27. Von Hoff DD, Ervin T, Arena FP, et al. Increased Survival in Pancreatic Cancer with nab-Paclitaxel plus Gemcitabine. N Engl J Med 2013; 369:1691-1703. DOI: 10.1056/NEJMoa1304369.
28. National Government Services, Inc. Local Coverage Article: Billing and Coding: Paclitaxel (e.g., Taxol®/Abraxane™) (A52450). Centers for Medicare & Medicaid Services, Inc. Updated on 06/24/2022 with effective date of 07/01/2022. Accessed August 2022.

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 3.2022. National Comprehensive Cancer Network, 2022. 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 August 2022.

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4e. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Pancreatic Adenocarcinoma, Version 1.2022. National Comprehensive Cancer Network, 2022. 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 August 2022.

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Network, Inc. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org. Accessed August 2022.

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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. Magellan Health, Magellan Rx Management. Abraxane Clinical Literature Review Analysis. Last updated August 2022. Accessed August 2022.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C22.1	Intrahepatic bile duct carcinoma
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.1	Malignant neoplasm of ampulla of Vater
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
C43.0	Malignant melanoma of lip
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.11	Malignant melanoma of right eyelid, including canthus
C43.12	Malignant melanoma of left eyelid, including canthus
C43.111	Malignant melanoma of right upper eyelid, including canthus

ICD-10	ICD-10 Description
C43.112	Malignant melanoma of right lower eyelid, including canthus
C43.121	Malignant melanoma of left upper eyelid, including canthus
C43.122	Malignant melanoma of left lower eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant neoplasm of right ear and external auricular canal
C43.22	Malignant neoplasm of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified parts of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
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
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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
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
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.43	Personal history of malignant neoplasm of ovary

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

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at:

https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

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

Jurisdiction(s): 6, K	**NCD/LCD/LCA Document (s):** A52450
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a52450&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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