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

Document Number: IC-0001

Last Review Date: 06/02/2020
Date of Origin: 10/17/2008
Dates Reviewed: 06/2009, 12/2009, 07/2010, 09/2010, 12/2010, 03/2011, 06/2011, 09/2011, 12/2011, 03/2012, 06/2012, 09/2012, 11/2012, 12/2012, 03/2013, 06/2013, 09/2013, 12/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 05/2015, 08/2015, 11/2015, 02/2016, 05/2016, 08/2016, 11/2016, 02/2017, 05/2017, 08/2017, 11/2017, 02/2018, 04/2018, 05/2018, 09/2018, 12/2018, 03/2019, 06/2019, 09/2019, 12/2019, 03/2020, 06/2020

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 SDV: 9 vials per 21 day supply

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

All indications

- 900 billable units per 21 days

III. Initial Approval Criteria[1]

Coverage is provided in the following conditions:

- Patient is 18 years of age or older; **AND**

Breast cancer † [1,2,3,9,21]

- Patient failed 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 or metastatic (stage IV [M1]) disease ‡; **AND**
  - Used in combination with carboplatin in patients with high tumor burden, rapidly progressing disease, and visceral crisis or used as single agent therapy; **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 trastuzumab for disease that is HER2-positive; **AND**
  - Disease is hormone receptor negative; **OR**
  - Disease is hormone receptor positive and used with or without endocrine therapy; **OR**

- Used in combination with atezolizumab for PD-L1 positive triple negative recurrent or stage IV (M1) disease ‡; **OR**
- May be substituted for paclitaxel or docetaxel if patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication ‡

Non-small cell lung cancer † [1,2,4,10]

- 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**
- Used for recurrent, advanced or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as a single agent in patients with a performance status (PS) score of 2; **OR**
  - Used in combination with carboplatin for patients with contraindications to PD-1 or PD-L1 inhibitors; **AND**
    - Patient has a PS score of 0-1 with non-squamous histology; **OR**
    - Patient has a PS score of 0-2 with squamous cell histology; **OR**
  - Used in combination with pembrolizumab AND carboplatin with a PS score of ≤1 in patients with squamous cell histology; **AND**
    - Used as first-line therapy for patients with EGFR, ALK, ROS1, BRAF, MET exon 14 skipping mutation, and RET rearrangement negative tumors and PD-L1 <1%; **OR**
    - Used as first line or subsequent therapy for patients with BRAF V600E-mutation, NTRK gene fusion, MET exon 14 skipping mutation, or RET rearrangement positive tumors; **OR**
    - Used as subsequent therapy for patients with EGFR, ALK, or ROS1 positive tumors who received prior targeted therapy§ for those aberrations; **OR**
    - Used as subsequent therapy for PD-L1 expression-positive (≥1%) tumors that are EGFR, ALK, ROS1, BRAF, MET exon 14 skipping mutation, and RET rearrangement negative with no prior platinum-doublet chemotherapy; **OR**
  - Used in combination with atezolizumab and carboplatin PS score of ≤1 in patients with nonsquamous cell histology; **AND**
    - Used as first-line therapy for patients with EGFR, ALK, ROS1, BRAF, MET exon 14 skipping mutation, and RET rearrangement negative tumors and PD-L1 <1%; **OR**
    - Used as first line or subsequent therapy for patients with BRAF V600E-mutation, NTRK gene fusion, MET exon-14 skipping mutation, or RET rearrangement positive tumors; **OR**

        - Used as subsequent therapy for patients with EGFR, ALK, or ROS1 positive tumors who received prior targeted therapy§ for those aberrations; **OR**
        - Used as subsequent therapy for PD-L1 expression-positive (≥1%) tumors that are EGFR, ALK, ROS1, BRAF, MET exon-14 skipping mutation, and RET rearrangement negative with no prior platinum-doublet chemotherapy; **OR**
    - Used as first-line therapy for PD-L1 expression positive (≥1%) tumors that are EGFR, ALK, ROS1, BRAF, MET exon-14 skipping mutation, and RET rearrangement negative; **AND**
        - Used in combination with pembrolizumab AND carboplatin in patients with a PS score of ≤2 and squamous cell histology; **OR**
        - Used in combination with atezolizumab AND carboplatin in patients with a PS score of ≤2 in patients with nonsquamous cell histology; **OR**
- May be substituted for paclitaxel or docetaxel if patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication

Ovarian cancer (Epithelial/Fallopian Tube/Primary Peritoneal) ‡ [2,8,22]

- 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**
        - 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 relapsed disease; **OR**
    - Used in combination with carboplatin for platinum-sensitive disease with confirmed taxane hypersensitivity; **AND**
        - Used for relapse ≥6 months after complete remission from prior chemotherapy

Pancreatic Adenocarcinoma † Φ [1,2,5,6,7,24]

- Used in combination with gemcitabine; **AND**
    - Patient's disease is locally advanced or metastatic; **AND**
        - Patient has good performance status (defined as an ECOG PS ≤2); **AND**
            - Used as first-line or induction therapy; **OR**
            - Used as second-line therapy after progression with a fluoropyrimidine-based therapy; **OR**
    - Patient's disease is recurrent; **AND**
        - Used as second-line therapy in patients with an ECOG PS ≤2; **OR**
    - Used as neoadjuvant therapy; **AND**
        - Patient has resectable disease with high-risk features (i.e., very highly elevated CA 19-9, large primary tumors, large regional lymph nodes, excessive weight loss, extreme pain); **OR**

- Patient has biopsy positive borderline resectable disease

Melanoma ‡ [2,15,16]

- Used as a single agent; **AND**
  - Patient has cutaneous melanoma; **AND**
    - Disease is metastatic or unresectable; **AND**
      - Used as second-line or subsequent therapy for disease progression; **OR**
      - Used after maximum clinical benefit from BRAF targeted therapy; **OR**
  - Patient has uveal melanoma; **AND**
    - Used for distant metastatic disease

Uterine Cancer ‡ [2,20]

- Used as single agent therapy; **AND**
- Patient has tried paclitaxel and treatment with paclitaxel was not tolerated due to a documented hypersensitivity reaction, despite use of recommended premedication or there is a documented medical contraindication to recommended premedication; **AND**
  - Used as primary treatment of endometrioid adenocarcinoma for one of the following:
    - Distant metastatic disease; **OR**
    - Unresectable disease excluding patients using chemotherapy alone for disease not suitable for primary surgery with suspected or gross cervical involvement; **OR**
    - Used preoperatively for patients with abdominal/pelvic confined disease that is suitable for primary surgery; **OR**
  - Adjuvant treatment for stage IB histologic grade 3 tumors or stage III-IV endometrioid adenocarcinoma; **OR**
  - Used as treatment of local-regional recurrent or disseminated metastatic endometrioid adenocarcinoma; **OR**
  - Used for non-adenocarcinomas (carcinosarcoma, clear cell carcinoma, serous carcinoma, un-/de-differentiated carcinoma) as additional treatment of disease suitable for primary surgery OR as primary treatment for disease not suitable for primary surgery

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

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

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

- Patient has advanced or metastatic disease; **AND**
- Used as single agent or in combination with gemcitabine; **AND**
  - Used as initial therapy in patients with disease that is microsatellite stable or proficient mismatch repair [MSS or pMMR] who have had prior adjuvant oxaliplatin exposure, or a contraindication to oxaliplatin; **OR**
  - Used as subsequent therapy; **AND**

- Patient has disease that is microsatellite stable or proficient mismatch repair [MSS or pMMR] in which intensive therapy is appropriate; **OR**
- Patient has disease that is microsatellite stable or proficient mismatch repair [MSS or pMMR] in which intensive therapy is NOT appropriate and has progressed through FOLFOX, irinotecan, or clinical trial; **OR**
- Patient has disease that is deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H); **AND**
  - Patient has progressed through pembrolizumab, nivolumab, or clinical trial; **OR**
  - Patient has had prior adjuvant oxaliplatin exposure, or a contraindication to oxaliplatin, and has also progressed through pembrolizumab, nivolumab, or clinical trial

AIDS-related Kaposi Sarcoma ‡ [2,19,25]

- Used as subsequent therapy in combination with antiretroviral therapy (ART); **AND**
- Patient has relapsed/refractory advanced, cutaneous, oral, visceral, or nodal disease; **AND**
- Disease has progressed on or not responded to first-line therapy; **AND**
- Disease has progressed on alternate first-line therapy

† 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 – Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib
ALK rearrangement-positive tumors – Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib
ROS1 rearrangement-positive tumors – Ceritinib – Crizotinib – Entrectinib
BRAF V600E-mutation positive tumors – Dabrafenib ± Trametinib – Vemurafenib
NTRK Gene Fusion positive tumors – Larotrectinib – Entrectinib
PD-1/PD-L1 expression-positive tumors (≥1%) – Pembrolizumab – Atezolizumab – Nivolumab ± ipilimumab

MET Exon-14 skipping mutations – Capmatinib – Crizotinib
RET rearrangement-positive tumors – Selpercatinib – Cabozantinib – Vandetanib

IV. Renewal Criteria [1,2]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet 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: bone marrow suppression (primarily neutropenia with absolute neutrophil counts of < 1,500 cell/mm^3), sensory neuropathy, sepsis, pneumonitis, severe hypersensitivity reactions including anaphylactic reactions, hepatic impairment, etc.

V. Dosage/Administration [1,3,9,11,15-23,25,26]

Indication	Dose
Breast Cancer	260 mg/m² every 21 days OR 100 mg/m² OR 125 mg/m² days 1, 8, and 15 of a 28-day cycle
NSCLC	100 mg/m² days 1, 8, and 15 of a 21-day cycle
AIDS-related Kaposi Sarcoma, Melanoma, and Ovarian Cancer	100 mg/m² days 1, 8, and 15 of a 28-day cycle
Pancreatic Adenocarcinoma and Hepatobiliary Cancer	125 mg/m² days 1, 8, and 15 of a 28-day cycle
Small Bowel Adenocarcinoma	260 mg/m² every 21 days as a single agent OR 125 mg/m² days 1, 8, and 15 of a 28-day cycle in combination with gemcitabine
All other indications	260 mg/m² every 21 days OR 100 mg/m² days 1, 8, and 15 of a 21-day cycle

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-use vial: 68817-0134-xx

VII. References

1. Abraxane [package insert]. Summit, NJ; Celgene Corporation; December 2019. Accessed May 2020.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) paclitaxel, albumin bound. National Comprehensive Cancer Network, 2020. 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 May 2020.
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 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 Metastat*ic Breast Ca*ncer," *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 1.2020. National Comprehensive Cancer Network, 2020. 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 May 2020.
21. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer Version 4.2020. National Comprehensive Cancer Network, 2020. 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 May 2020.

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®) for AIDS-Related Kaposi Sarcoma Version 1.2020. National Comprehensive Cancer Network, 2020. 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 May 2020.
26. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Small Bowel Adenocarcinoma Version 2.2020. National Comprehensive Cancer Network, 2020. 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 May 2020.
27. National Government Services, Inc. Local Coverage Article: Billing and Coding: Paclitaxel (e.g., Taxol®/Abraxane™) (A52450). Centers for Medicare & Medicaid Services, Inc. Updated on 12/20/2019 with effective date of 01/01/2020. Accessed May 2020.
28. CGS Administrators, LLC. Local Coverage Article: Billing and Coding: Paclitaxel protein-bound particles; Abraxane -J9264 (A57354). Centers for Medicare & Medicaid Services, Inc. Updated on 09/24/2019 with effective date of 10/03/2019. Accessed May 2020.

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

ICD-10	ICD-10 Description
C22.1	Intrahepatic bile duct carcinoma
C24.0	Malignant neoplasm of extrahepatic bile duct
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
C43.111	Malignant melanoma of right upper eyelid, including canthus
C43.112	Malignant melanoma of right lower eyelid, including canthus
C43.121	Malignant melanoma of left upper eyelid, including canthus

ICD-10	ICD-10 Description
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
C46.0	Kaposi's sarcoma of skin
C46.1	Kaposi's sarcoma of soft tissue
C46.2	Kaposi's sarcoma of palate
C46.3	Kaposi's sarcoma of lymph nodes
C46.4	Kaposi's sarcoma of gastrointestinal sites
C46.50	Kaposi's sarcoma of unspecified lung
C46.51	Kaposi's sarcoma of right lung
C46.52	Kaposi's sarcoma of left lung
C46.7	Kaposi's sarcoma of other sites
C46.9	Kaposi's sarcoma, 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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
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

ICD-10	ICD-10 Description
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
C69.30	Malignant neoplasm of unspecified choroid
C69.31	Malignant neoplasm of right choroid
C69.32	Malignant neoplasm of left choroid
C69.40	Malignant neoplasm of unspecified ciliary body
C69.41	Malignant neoplasm of right ciliary body
C69.42	Malignant neoplasm of left ciliary body
C69.60	Malignant neoplasm of unspecified orbit
C69.61	Malignant neoplasm of right orbit
C69.62	Malignant neoplasm of left orbit
Z85.07	Personal history of malignant neoplasm of pancreas
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)

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: http://www.cms.gov/medicare-coverage-database/search/advanced-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 Document (s): A52450
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52450&bc=gAAAAAAAAAAAAA==	

Jurisdiction(s): 15	NCD/LCD Document (s): A57354
https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=57354&ver=3&DocID=A57354&bc=gAAAABAAAAAA&	

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