



Paclitaxel Albumin-Bound: **Abraxane®; Paclitaxel Albumin-Bound Ψ** **(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/Paclitaxel albumin-bound 100 mg powder for injection single-dose vial: 9 vials per 21-day supply

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

Kaposi Sarcoma

- 300 billable units per 28 days

All other indications

- 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 † ‡ ^{1-3,9,21,28}

- 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 unresectable (local or regional) or metastatic (stage IV [M1]) disease OR inflammatory breast cancer with no response to preoperative systemic therapy ‡; **AND**
 - Patient has HER2-negative hormone receptor-positive disease; **AND**
 - Patient is refractory to endocrine therapy or has visceral crisis; **AND**
 - Used as one of the following:
 - As a single agent
 - In combination with carboplatin in patients with high tumor burden, rapidly progressing disease, or visceral crisis; **AND**
 - Used in one of the following treatment settings:
 - First-line therapy if no germline BRCA 1/2 mutation
 - Second-line therapy if not a candidate for fam-trastuzumab-deruxtecan-nxki
 - Third-line therapy and beyond; **OR**
 - Patient has triple negative breast cancer (TNBC) Ψ; **AND**
 - Used in combination with pembrolizumab for PD-L1 positive (PD-L1 CPS ≥10) disease; **OR**
 - Used as single agent or in combination with carboplatin (*note: use with carboplatin in select patients with high tumor burden, rapidly progressing disease, or visceral crisis*); **AND**
 - Used as first-line therapy if PD-L1 CPS <10 and no germline BRCA 1/2 mutation; **OR**
 - Used as subsequent therapy; **OR**
 - Patient has HER2-positive disease; **AND**
 - Used as fourth-line therapy and beyond in combination with trastuzumab; **OR**
- May be substituted for paclitaxel or docetaxel if the patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication ‡

Non-Small Cell Lung Cancer (NSCLC) † ‡ 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**
- May be substituted for paclitaxel or docetaxel if the patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication; **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 first-line therapy; **AND**

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- Used in one of the following:
 - Patients with PS of 0-1 who have tumors that are negative for actionable molecular biomarkers* and PD-L1 < 1%
 - Patients with PS 0-2 who have tumors that are negative for actionable molecular biomarkers* and PD-L1 expression positive tumors ($\geq 1\%$)
 - Patients with PS of 0-1 who are positive for one of the following molecular mutations: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, RET rearrangement, or ERBB2 (HER2); **AND**
 - Used in combination with carboplatin and pembrolizumab for squamous cell histology; **OR**
 - Used in combination with carboplatin and atezolizumab for non-squamous histology; **OR**
 - Used in combination with tremelimumab-actl, durvalumab, and carboplatin (*excluding use in patients with PD-L1 $\geq 50\%$*); **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 in patients with tumors that have negative actionable molecular biomarkers* and PD-L1 $\geq 1\%$; **OR**
 - Used in patients with tumors that have negative actionable molecular biomarkers* and PD-L1 <1%; **OR**
 - Used in patients who are positive for one of the following molecular mutations: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); **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; **OR**
 - Used in one of the following:
 - Patients with PS of 0-1 who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, or RET rearrangement
 - Patients with PS 0-1 who are positive for one of the following molecular mutations and have received prior targeted therapy§ for those aberrations: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; **AND**

- Used in combination with carboplatin and pembrolizumab for squamous cell histology; **OR**
- Used in combination with carboplatin and atezolizumab for non-squamous histology; **OR**
- Used in combination with tremelimumab-actl, durvalumab, and carboplatin; **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 in patients who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; **OR**
 - Used in patients who are positive for one of the following molecular mutations and have received prior targeted therapy[§] for those aberrations: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; **OR**
 - Used in patients with PD-L1 expression-positive ($\geq 1\%$) tumors that are negative for actionable molecular biomarkers* with prior PD-1/PD-L1 inhibitor therapy but no prior platinum-containing chemotherapy

** Note: Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2). If there is insufficient tissue to allow testing for all of the EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2) 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, and some oncogenic drivers (e.g., EGFR exon 19 deletion or exon 21 L858R, ALK rearrangements) have been shown to be associated with less benefit from PD-1/PD-L1 inhibitors.

Ovarian, Fallopian Tube, and Primary Peritoneal Cancer ‡^{2,8,22}

- Patient has Grade 1 Endometrioid Carcinoma, Carcinosarcoma (Malignant Mixed Müllerian Tumors), Mucinous Carcinoma of the Ovary, Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer, Clear Cell Carcinoma of the Ovary; **AND**
 - Patient has recurrent or persistent disease; **AND**
 - Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); **AND**
 - Used as one of the following:
 - As a single agent

- In combination with carboplatin in patients with confirmed taxane hypersensitivity; **AND**
- Patient has one of the following:
 - Platinum-resistant disease; **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 <6 months following complete remission from prior chemotherapy; **OR**
 - Platinum-sensitive disease; **AND**
 - Used for relapse ≥6 months after complete remission from prior chemotherapy; **OR**
- Patient has low-grade serous carcinoma; **AND**
 - Patient has recurrent platinum-sensitive or platinum-resistant disease; **AND**
 - Used as a single agent; **OR**
 - Used in combination with carboplatin in patients with confirmed taxane hypersensitivity; **OR**
- May be substituted for paclitaxel if the patient has experienced hypersensitivity reactions despite premedication or the patient has contraindications to standard hypersensitivity premedication

Pancreatic Adenocarcinoma † Φ^{1,2,5-7,24}

- Used in combination with gemcitabine; **AND**
 - Patient has locally advanced or metastatic disease; **AND**
 - Used as first-line therapy; **OR**
 - Used as induction therapy followed by chemoradiation (*locally advanced disease only*); **OR**
 - Used as subsequent therapy after disease progression with a fluoropyrimidine-based therapy; **OR**
 - Patient has 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 disease; **OR**

- Patient has biopsy positive borderline resectable disease; **OR**
- Used in combination with gemcitabine and cisplatin; **AND**
 - Patient has metastatic disease; **AND**
 - Patient has ECOG PS 0-1; **AND**
 - Used as first-line therapy

Cutaneous Melanoma ‡^{2,15,16}

- Patient has metastatic or unresectable disease; **AND**
- Used as subsequent therapy as a single agent or in combination with carboplatin; **AND**
- Used for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.)

Uveal Melanoma ‡^{2,15,16}

- Used as a single agent for metastatic or unresectable disease

Endometrial Carcinoma (Uterine Neoplasms) ‡^{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 subsequent therapy for recurrent disease

Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma) ‡^{2,11}

- Used in combination with gemcitabine for unresectable, resected gross residual (R2), or metastatic disease; **AND**
 - Used as primary treatment; **OR**
 - Use as subsequent treatment for progression on or after systemic therapy

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 subsequent therapy; **OR**
 - Patient has had prior adjuvant oxaliplatin exposure, or a contraindication to oxaliplatin; **AND**
 - Used as initial therapy; **OR**
 - Used as subsequent therapy in patients who previously received initial therapy with nivolumab with or without ipilimumab, pembrolizumab, or dostarlimab-gxly

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Kaposi Sarcoma ‡^{2,19,25}

- Used as subsequent therapy if patient is intolerant to paclitaxel; **AND**
- Patient has relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease; **AND**
- Disease has progressed on or not responded to first-line systemic therapy; **AND**
- Disease has progressed on alternate first-line systemic therapy; **AND**
 - Used as a single agent for patients that do not have HIV; **OR**
 - Used in combination with antiretroviral therapy (ART) for patients with HIV

Ampullary Adenocarcinoma ‡^{2,27}

- Used in combination with gemcitabine; **AND**
- Patient has pancreatobiliary or mixed type disease; **AND**
 - Used as neoadjuvant therapy for localized disease in high-risk patients (i.e., imaging findings, markedly elevated CA 19-9, markedly elevated carcinoembryonic antigen [CEA], large primary tumors, large regional lymph nodes, excessive weight loss, extreme pain); **OR**
 - Used as first-line therapy for unresectable localized or metastatic disease; **OR**
 - Used as subsequent therapy for disease progression

Cervical Cancer ‡^{2,29}

- Used as a single agent as subsequent therapy; **AND**
 - Patient has persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervix (NECC); **OR**
 - Patient has recurrent or metastatic disease

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

Ψ ER Scoring Interpretation (following ER testing by validated IHC assay)	
Results	Interpretation
– 0% – <1% of nuclei stain	– ER-negative
– 1%–10% of nuclei stain	– ER-low–positive*
– >10% of nuclei stain	– ER-positive
<i>*Note: Patients with cancers with ER-low–positive (1%–10%) results are a heterogeneous group with reported biologic behavior often similar to ER-negative cancers; thus, as such these cancers inherently behave aggressively and may be treated similar to triple-negative disease. Individualized consideration of risks versus benefits should be incorporated into decision-making.</i>	

§ Genomic Aberration/Mutational Driver Targeted Therapies (Note: not all inclusive, refer to guidelines for appropriate use)

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Sensitizing <i>EGFR</i> mutation-positive tumors	<i>ALK</i> rearrangement-positive tumors	<i>ROS1</i> rearrangement-positive tumors	<i>BRAF</i> V600E-mutation positive tumors	<i>NTRK1/2/3</i> gene fusion positive tumors
<ul style="list-style-type: none"> – Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib – Amivantamab (<i>exon-20 insertion</i>) – Mobocertinib (<i>exon-20 insertion</i>) 	<ul style="list-style-type: none"> – Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib 	<ul style="list-style-type: none"> – Ceritinib – Crizotinib – Entrectinib – Lorlatinib 	<ul style="list-style-type: none"> – Dabrafenib ± trametinib – Vemurafenib 	<ul style="list-style-type: none"> – Larotrectinib – Entrectinib
PD-L1 tumor expression ≥ 1%	<i>MET</i> exon-14 skipping mutations	<i>RET</i> rearrangement-positive tumors	<i>KRAS</i> G12C mutation positive tumors	<i>ERBB2</i> (<i>HER2</i>) mutation positive tumors
<ul style="list-style-type: none"> – Pembrolizumab – Atezolizumab – Nivolumab + ipilimumab – Cemiplimab – Tremelimumab + durvalumab 	<ul style="list-style-type: none"> – Capmatinib – Crizotinib – Tepotinib 	<ul style="list-style-type: none"> – Selpercatinib – Cabozantinib – Pralsetinib 	<ul style="list-style-type: none"> – Sotorasib – Adagrasib 	<ul style="list-style-type: none"> – Fam-trastuzumab deruxtecan-nxki – Ado-trastuzumab emtansine

IV. Renewal Criteria ^{1,2}

Coverage may 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: severe myelosuppression (e.g., severe neutropenia [absolute neutrophil count < 1,500 cell/mm³] or thrombocytopenia), sensory neuropathy, sepsis, pneumonitis, severe hypersensitivity reactions (including anaphylactic reactions), etc.

V. Dosage/Administration ^{1,11,15,16,19,21,22,25-29}

Indication	Dose
Breast Cancer	Administer 260 mg/m ² intravenously every 21 days until disease progression or unacceptable toxicity OR Administer 100 mg/m ² OR 125 mg/m ² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity <i>**Note: If being used as a substitute for weekly paclitaxel or docetaxel, the weekly dose of albumin-bound paclitaxel should not exceed 125 mg/m²</i>

NSCLC	Administer 100 mg/m ² intravenously days 1, 8, and 15 of a 21-day cycle until disease progression or unacceptable toxicity
Cutaneous Melanoma, Uveal Melanoma, & Ovarian Cancer	Administer 100 mg/m ² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity
Kaposi Sarcoma	Administer 100 mg (fixed dose) intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity
Pancreatic Adenocarcinoma, Cervical Cancer, Biliary Tract Cancers, & Ampullary Adenocarcinoma	Administer 125 mg/m ² intravenously days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity
Small Bowel Adenocarcinoma	Administer 220 – 260 mg/m ² intravenously every 21 days as a single agent until disease progression or unacceptable toxicity OR Administer 125 mg/m ² intravenously days 1, 8, and 15 of a 28-day cycle in combination with gemcitabine until disease progression or unacceptable toxicity
All other indications	Administer 260 mg/m ² intravenously every 21 days until disease progression or unacceptable toxicity OR Administer 100 mg/m ² 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
- J9259 – Injection, paclitaxel protein-bound particles (american reagent) not therapeutically equivalent to J9264, 1 mg; 1 billable unit = 1 mg **Ψ**
- J9999 – Not otherwise classified, antineoplastic **Ψ**

NDC:

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

***Multiple manufacturers produce ANDA generics**

Ψ Designated products approved by the FDA as a 505(b)(2) NDA of the innovator product. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book and are therefore considered single source products based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. For a complete list of all approved 505(b)(2) NDA products please reference the latest edition of the Orange Book: [Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book | FDA](#)

VII. References

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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

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ICD-10	ICD-10 Description
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C22.1	Intrahepatic bile duct carcinoma
C23	Malignant neoplasm of the gallbladder
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.1	Malignant neoplasm of ampulla of Vater
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

PACLITAXEL ALBUMIN-BOUND
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ICD-10	ICD-10 Description
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
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

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ICD-10	ICD-10 Description
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
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

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ICD-10	ICD-10 Description
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
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
C53.0	Malignant neoplasm of endocervix
C53.1	Malignant neoplasm of exocervix
C53.8	Malignant neoplasm of overlapping sites of cervix uteri
C53.9	Malignant neoplasm of cervix uteri, unspecified
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

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ICD-10	ICD-10 Description
C55	Malignant neoplasm of uterus, part unspecified
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
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
Z85.068	Personal history of other malignant neoplasm of small intestine
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.09	Personal history of malignant neoplasm of other digestive organs
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.42	Personal history of malignant neoplasm of other parts of uterus

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ICD-10	ICD-10 Description
Z85.43	Personal history of malignant neoplasm of ovary
Z85.820	Personal history of malignant melanoma of skin

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 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%2CMD%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

PreferredOne Community Health Plan Nondiscrimination Notice

PreferredOne Community Health Plan (“PCHP”) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PCHP does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PCHP:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, taiaajiila qarqaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

ໂບດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສຍຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው፡ 763.847.4013) .

ဟ်သ့ဟ်သး- နမာ်ကတိ၊ ကညီ ကိုက်အယံ၊ နမာ် ကိုက်အတၢ်မၤစၢၤလၢ တလၢ်ဘျၣ်လၢ်စၢၤ နီတမံၤဘၣ်သန့လီၤ. ကိ: 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតល្បួល គឺអាចមានសំរាប់បំរើអ្នក។ ចរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013)។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013), 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).

PreferredOne Insurance Company Nondiscrimination Notice

PreferredOne Insurance Company ("PIC") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PIC does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PIC:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PIC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Insurance Company
PO Box 59212
Minneapolis, MN 55459-0212
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

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XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

បំពេញ: ប្រសិនបើ អ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፡ በነጻ ሊያገኙበት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (ማስማት ለተሳናቸው: 763.847.4013) .

ဟံသာဝတီ: နမူနာတို့ ကညီ ကျိအသိ, နမူနာ ကျိအတိအကျတို့ တလက်ကွက်လက်စွာ နှိတ်မိသည့်သို့လည်း ကိ: 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន: បើសិនជាអ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).