Libtayo® (cemiplimab-rwlc)
(Intravenous)

-E-

Document Number: IC-0473

Last Review Date: 01/04/2024
Date of Origin: 07/01/2019
Dates Reviewed: 07/2019, 10/2019, 01/2020, 04/2020, 07/2020, 10/2020, 01/2021, 04/2021, 07/2021, 10/2021, 02/2022, 05/2022, 07/2022, 10/2022, 01/2023, 04/2023, 07/2023, 10/2023, 01/2024

I. Length of Authorization Δ [1,12,14]

Coverage will be provided for 6 months and may be renewed, unless otherwise specified.

- Neoadjuvant therapy in Cutaneous Squamous Cell Carcinoma (cSCC) can be authorized up to a maximum of 4 doses and cannot be renewed.
- Treatment for metastatic, locally advanced, or recurrent cSCC and Basal Cell Carcinoma (BCC) can be renewed up to a maximum of twenty-four (24) months of therapy (35 doses).
- Treatment for recurrent or metastatic Cervical Cancer can be authorized up to a maximum of ninety-six (96) weeks of therapy (32 doses).

II. Dosing Limits

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

- Libtayo 350 mg/7 mL single-dose vial: 1 vial per 21 days

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

All Indications –

- 350 billable units (350 mg) every 21 days

III. Initial Approval Criteria [1]

Coverage is provided for the following conditions:

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

Universal Criteria [1]

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, pembrolizumab, atezolizumab, durvalumab, nivolumab,

dostarlimab, nivolumab/relatlimab-rmbw, retifanlimab, etc.), unless otherwise specified [Δ]; **AND**

Cutaneous Squamous Cell Carcinoma (cSCC) † ‡ [1-5,8,12]

- Used as a single agent; **AND**
  - Patient has metastatic, locally advanced, or recurrent disease [Δ]; **AND**
    - Patient is not a candidate for curative surgery or curative radiation therapy; **OR**
  - Used as neoadjuvant therapy; **AND**
    - Patient has resectable stage II, III, or IV (M0) disease

Cervical Cancer ‡ [2,14,7e]

- Used as a single agent as subsequent therapy; **AND**
- Patient has recurrent or metastatic disease [Δ]; **AND**
- Patient has received a prior platinum-based chemotherapy regimen

Basal Cell Carcinoma (BCC) † ‡ [1,2,6,9,13]

- Patient has previously been treated with a hedgehog pathway inhibitor (HHI) (e.g., vismodegib, sonidegib, etc.) or for whom HHI treatment is not appropriate; **AND**
- Used as a single agent; **AND**
  - Patient has locally advanced or metastatic disease [Δ]; **OR**
  - Patient has nodal disease and surgery is not feasible [Δ]

Non-Small Cell Lung Cancer (NSCLC) † ‡ [1,2,7,10,15,16]

- Patient has 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 in combination with platinum-based chemotherapy (e.g., paclitaxel and either carboplatin or cisplatin OR pemetrexed and either carboplatin or cisplatin); **AND**
    - Used as first-line therapy for one of the following:
      - Patients with a performance status (PS) 0-1 who have tumors that are negative for actionable molecular biomarkers* and PD-L1 expression <1%
      - Patients with a PS 0-1 who are positive for one of the following molecular biomarkers: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2)
      - PD-L1 expression-positive (PD-L1 ≥1%) tumors that are negative for actionable molecular biomarkers*; **OR**
    - Used as subsequent therapy for one of the following:

- Patients with a PS 0-1 who are positive for one of the following molecular biomarkers and have received prior targeted therapy§: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X, ALK rearrangement, or ROS1 rearrangement
- Patients with a PS 0-1 who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; **OR**

- Used in combination with pemetrexed; **AND**
  - Used as continuation maintenance therapy in patients who have achieved a tumor response or stable disease after first-line therapy with cemiplimab, pemetrexed, and either carboplatin or cisplatin for non-squamous cell histology; **OR**
- Used as a single agent; **AND**
  - Patient has tumors that are negative for actionable molecular biomarkers* and high PD-L1 expression (Tumor Proportion Score [TPS] ≥ 50%) as determined by an FDA-approved or CLIA compliant test❖; **AND**
    - Used as first-line therapy †; **OR**
    - Used as continuation maintenance therapy in patients who achieved a tumor response or stable disease after first-line therapy with cemiplimab as monotherapy or as part of combination therapy; **OR**
  - Patient has tumors with PD-L1 expression <1% or ≥1%-49%; **AND**
    - Used as continuation maintenance therapy in patients who have achieved a tumor response or stable disease following initial therapy with cemiplimab combination therapy

** Note: Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET exon 14 skipping mutation, RET rearrangement and ERBB2 (HER2). If there is insufficient tissue to allow testing for all of 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.*

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.

❖ *If confirmed using an FDA approved assay – http://www.fda.gov/companiondiagnostics*

† 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	*NTRK1/2/3* gene fusion positive tumors
– Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib – Amivantamab *(exon-20 insertion)*	– Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib	– Ceritinib – Crizotinib – Entrectinib – Lorlatinib	– Dabrafenib ± trametinib – Encorafenib + binimetinib – Vemurafenib	– Larotrectinib – Entrectinib
PD-L1 tumor expression ≥ 1%	*MET* exon-14 skipping mutations	*RET* rearrangement-positive tumors	*KRAS G12C* mutation positive tumors	*ERBB2 (HER2)* mutation positive tumors
– Pembrolizumab – Atezolizumab – Nivolumab + ipilimumab – Cemiplimab – Tremelimumab + durvalumab	– Capmatinib – Crizotinib – Tepotinib	– Selpercatinib – Cabozantinib – Pralsetinib	– Sotorasib – Adagrasib	– Fam-trastuzumab deruxtecan-nxki – Ado-trastuzumab emtansine

IV. Renewal Criteria Δ [1,12]

Coverage may be renewed based on the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, severe and fatal immune-mediated adverse reactions (e.g., pneumonitis, colitis, hepatitis, endocrinopathies, nephritis with renal dysfunction, dermatological adverse reactions, etc.), complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**

Non-Small Cell Lung Cancer (continuation maintenance therapy)

- *Refer to Section III for criteria*

Cutaneous Squamous Cell Carcinoma (cSCC) (neoadjuvant therapy):

- Coverage may not be renewed

Cutaneous Squamous Cell Carcinoma (cSCC) (metastatic, locally advanced, or recurrent disease)

- Patient has not exceeded a maximum of twenty-four (24) months of therapy

Cervical Cancer

- Patient has not exceeded a maximum of ninety-six (96) weeks of therapy

Basal Cell Carcinoma

- Patient has not exceeded a maximum of twenty-four (24) months of therapy

Δ Notes:

- Patients responding to therapy who relapse ≥ 6 months after discontinuation due to duration are eligible to re-initiate PD-directed therapy.
- Patients previously presenting with aggressive disease who are exhibiting stable disease on treatment as their best response (or if therapy improved performance status) may be eligible for continued therapy without interruption or discontinuation.
- Patients who complete adjuvant therapy and progress ≥ 6 months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
- Patients whose tumors, upon re-biopsy, demonstrate a change in actionable mutation (e.g., MSS initial biopsy; MSI-H subsequent biopsy) may be eligible to re-initiate PD-directed therapy and will be evaluated on a case-by-case basis.

V. Dosage/Administration Δ [1,12]

Indication	Dose
cSCC	Metastatic, locally advanced, or recurrent disease: Administer 350 mg intravenously every 3 weeks for up to a maximum of 24 months in patients without disease progression or unacceptable toxicity Neoadjuvant therapy: Administer 350 mg intravenously every 3 weeks for up to 4 doses in patients without disease progression or unacceptable toxicity
Cervical Cancer	Administer 350 mg intravenously every 3 weeks up to a maximum of 96 weeks in patients without disease progression or unacceptable toxicity
BCC	Administer 350 mg intravenously every 3 weeks up to a maximum of 24 months in patients without disease progression or unacceptable toxicity
NSCLC	Administer 350 mg intravenously every 3 weeks until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code:

- J9119 – Injection, cemiplimab-rwlc, 1 mg; 1 billable units = 1 mg

NDC:

- Libtayo 350 mg/7 mL single-dose vial: 61755-0008-xx

VII. References (STANDARD)

1. Libtayo [package insert]. Tarrytown, NY; Regeneron Pharmaceuticals, Inc.; April 2023. Accessed November 2023.

2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) cemiplimab-rwlc. National Comprehensive Cancer Network, 2023. 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 November 2023.
3. Falchook GS, Leidner R, Stankevich E, et al. Responses of metastatic basal cell and cutaneous squamous cell carcinomas to anti-PD1 monoclonal antibody REGN2810. J Immunother Cancer. 2016 Nov 15;4:70. doi: 10.1186/s40425-016-0176-3. eCollection 2016.
4. Migden MR, Rischin D, Schmults CD, et al. PD-1 Blockade with Cemiplimab in Advanced Cutaneous Squamous-Cell Carcinoma. N Engl J Med. 2018 Jul 26;379(4):341-351. doi: 10.1056/NEJMoa1805131. Epub 2018 Jun 4.
5. Migden MR, Khushalani NI, Chang ALS, et al. Cemiplimab in locally advanced cutaneous squamous cell carcinoma: results from an open-label, phase 2, single-arm trial. Lancet Oncol. 2020 Feb;21(2):294-305. doi: 10.1016/S1470-2045(19)30728-4. Epub 2020 Jan 14.
6. Lewis KD, Fury MG, Stankevich, et al. Phase II study of cemiplimab, a human monoclonal anti-PD-1, in patients with advanced basal cell carcinoma (BCC) who experienced progression of disease on, or were intolerant of prior hedgehog pathway inhibitor (HHI) therapy. Annals of Oncology. 2018 Oct 01; Volume 29, Supplement 8,VII440.
7. 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.
8. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Squamous Cell Skin Cancer. Version 3.2023. National Comprehensive Cancer Network, 2023. 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 November 2023.
9. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Basal Cell Skin Cancer. Version 2.2024. National Comprehensive Cancer Network, 2023. 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 November 2023.
10. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Non-Small Cell Lung Cancer. Version 5.2023. National Comprehensive Cancer Network, 2023. 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 November 2023.

11. Gogishvili M, Melkadze T, Makharadze T, et al. LBA51 EMPOWER-Lung 3: Cemiplimab in combination with platinum doublet chemotherapy for first-line (1L) treatment of advanced non-small cell lung cancer (NSCLC). Annals of Oncology, ISSN: 0923-7534, Vol: 32, SUPPLEMENT 5, S1328, SEPTEMBER 01, 2021. DOI10.1016/j.annonc.2021.08.2130.
12. Gross N, Miller D, Khushalani N, et al. Neoadjuvant Cemiplimab for Stage II to IV Cutaneous Squamous-Cell Carcinoma N Engl J Med 2022; 387:1557-1568. doi: 10.1056/NEJMoa2209813
13. Stratigos AJ, Sekulic A, Peris K, et al. Cemiplimab in locally advanced basal cell carcinoma after hedgehog inhibitor therapy: an open-label, multicentre, single-arm, phase 2 trial. Lancet Oncol 2021;22:848-857.
14. Tewari KS, Monk BJ, Vergote I, et al. Survival with Cemiplimab in Recurrent Cervical Cancer. N Engl J Med 2022;386:544-555.
15. Gogishvili M, Melkadze T, Makharadze T, et al. Cemiplimab plus chemotherapy versus chemotherapy alone in non-small cell lung cancer: a randomized, controlled, double-blind phase 3 trial. Nat Med. 2022 Nov;28(11):2374-2380. doi: 10.1038/s41591-022-01977-y. Epub 2022 Aug 25. PMID: 36008722; PMCID: PMC9671806.
16. Özgüroğlu M, Kilickap S, Sezer A, et al. First-line cemiplimab monotherapy and continued cemiplimab beyond progression plus chemotherapy for advanced non-small-cell lung cancer with PD-L1 50% or more (EMPOWER-Lung 1): 35-month follow-up from a multicentre, open-label, randomised, phase 3 trial. Lancet Oncol 2023; 24: 989–1001.

VIII. References (ENHANCED)

1e. Maubec E1, Petrow P, Scheer-Senyarich I, et al. Phase II study of cetuximab as first-line single-drug therapy in patients with unresectable squamous cell carcinoma of the skin. J Clin Oncol. 2011 Sep 1;29(25):3419-26. doi: 10.1200/JCO.2010.34.1735. Epub 2011 Aug 1.

2e. Jarkowski A 3rd, Hare R, Loud P, et al. Systemic Therapy in Advanced Cutaneous Squamous Cell Carcinoma (CSCC): The Roswell Park Experience and a Review of the Literature. Am J Clin Oncol. 2016 Dec;39(6):545-548.

3e. Lu SM, Lien WW. Concurrent Radiotherapy With Cetuximab or Platinum-based Chemotherapy for Locally Advanced Cutaneous Squamous Cell Carcinoma of the Head and Neck. Am J Clin Oncol. 2018 Jan;41(1):95-99.

4e. Grob J, Gonzalez Mendoza R, Basset-Seguin N, et al. Pembrolizumab for recurrent/metastatic cutaneous squamous cell carcinoma (cSCC): Efficacy and safety results from the phase II KEYNOTE-629 study. Ann Oncol. 2019;30(suppl_5):v908. doi: 10.1093/annonc/mdz394.069.

5e. 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 Nov 10;375(19):1823-1833. Epub 2016 Oct 8.

6e. Spigel DR, De Marinis F, Giaccone G, et al. IMpower110: Interim overall survival (OS) analysis of a phase III study of atezolizumab (atezo) vs platinum-based chemotherapy (chemo) as first-line (1L) treatment (tx) in PD-L1–selected NSCLC [abstract]. Ann Oncol 2019;30(suppl_5):Abstract 6256.

7e. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Cervical Cancer. Version 1.2024. National Comprehensive Cancer Network, 2023. 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 December 2023.

8e. Coleman RL, Lorusso D, Gennigens C, et al; innovaTV 204/GOG-3023/ENGOT-cx6 Collaborators. Efficacy and safety of tisotumab vedotin in previously treated recurrent or metastatic cervical cancer (innovaTV 204/GOG-3023/ENGOT-cx6): a multicentre, open-label, single-arm, phase 2 study. Lancet Oncol. 2021 May;22(5):609-619. doi: 10.1016/S1470-2045(21)00056-5. Epub 2021 Apr 9.

9e. Chung HC, Ros W, Delord JP, et al. Efficacy and Safety of Pembrolizumab in Previously Treated Advanced Cervical Cancer: Results From the Phase II KEYNOTE-158 Study. J Clin Oncol. 2019 Jun 10;37(17):1470-1478. Doi: 10.1200/JCO.18.01265. Epub 2019 Apr 3.

10e. Magellan Rx Management. Libtayo Clinical Literature Review Analysis. Last updated December 2023. Accessed December 2023.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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 and lung

ICD-10	ICD-10 Description
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
C44.01	Basal cell carcinoma of skin of lip
C44.02	Squamous cell carcinoma of skin of lip
C44.111	Basal cell carcinoma of skin of unspecified eyelid, including canthus
C44.1121	Basal cell carcinoma of skin of right upper eyelid, including canthus
C44.1122	Basal cell carcinoma of skin of right lower eyelid, including canthus
C44.1191	Basal cell carcinoma of skin of left upper eyelid, including canthus
C44.1192	Basal cell carcinoma of skin of left lower eyelid, including canthus
C44.121	Squamous cell carcinoma of skin of unspecified eyelid, including canthus
C44.1221	Squamous cell carcinoma of skin of right upper eyelid, including canthus
C44.1222	Squamous cell carcinoma of skin of right lower eyelid, including canthus
C44.1291	Squamous cell carcinoma of skin of left upper eyelid, including canthus
C44.1292	Squamous cell carcinoma of skin of left lower eyelid, including canthus
C44.211	Basal cell carcinoma of skin of unspecified ear and external auricular canal
C44.212	Basal cell carcinoma of skin of right ear and external auricular canal
C44.219	Basal cell carcinoma of skin of left ear and external auricular canal
C44.221	Squamous cell carcinoma of skin of unspecified ear and external auricular canal
C44.222	Squamous cell carcinoma of skin of right ear and external auricular canal
C44.229	Squamous cell carcinoma of skin of left ear and external auricular canal
C44.310	Basal cell carcinoma of skin of unspecified parts of face
C44.311	Basal cell carcinoma of skin of nose
C44.319	Basal cell carcinoma of skin of other parts of face
C44.320	Squamous cell carcinoma of skin of unspecified parts of face
C44.321	Squamous cell carcinoma of skin of nose
C44.329	Squamous cell carcinoma of skin of other parts of face
C44.41	Basal cell carcinoma of skin of scalp and neck
C44.42	Squamous cell carcinoma of skin of scalp and neck
C44.510	Basal cell carcinoma of anal skin
C44.511	Basal cell carcinoma of skin of breast
C44.519	Basal cell carcinoma of skin of other part of trunk
C44.520	Squamous cell carcinoma of anal skin
C44.521	Squamous cell carcinoma of skin of breast
C44.529	Squamous cell carcinoma of skin of other part of trunk

ICD-10	ICD-10 Description
C44.611	Basal cell carcinoma of skin of unspecified upper limb, including shoulder
C44.612	Basal cell carcinoma of skin of right upper limb, including shoulder
C44.619	Basal cell carcinoma of skin of left upper limb, including shoulder
C44.621	Squamous cell carcinoma of skin of unspecified upper limb, including shoulder
C44.622	Squamous cell carcinoma of skin of right upper limb, including shoulder
C44.629	Squamous cell carcinoma of skin of left upper limb, including shoulder
C44.711	Basal cell carcinoma of skin of unspecified lower limb, including hip
C44.712	Basal cell carcinoma of skin of right lower limb, including hip
C44.719	Basal cell carcinoma of skin of left lower limb, including hip
C44.721	Squamous cell carcinoma of skin of unspecified lower limb, including hip
C44.722	Squamous cell carcinoma of skin of right lower limb, including hip
C44.729	Squamous cell carcinoma of skin of left lower limb, including hip
C44.81	Basal cell carcinoma of overlapping sites of skin
C44.82	Squamous cell carcinoma of overlapping sites of skin
C44.91	Basal cell carcinoma of skin, unspecified
C44.92	Squamous cell carcinoma of skin, unspecified
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
Z85.118	Personal history of other malignant neoplasm of bronchus and lung

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

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

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

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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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