

Opdivo® (nivolumab) (Intravenous)

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I. Length of Authorization

Coverage will be provided for six months and may be renewed.

- Adjuvant use in the treatment of melanoma patients can be authorized up to a maximum of 12 months of therapy.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Opdivo 40 mg/4 mL single-use vial: 2 vials per 14 days
- Opdivo 100 mg/10 mL single-use vial: 2 vials per 14 days
- Opdivo 240mg/24 mL single-use vial: 1 vial per 14 days

B. Max Units (per dose and over time) [Medical Benefit]:

| Indication | Billable Units (BU) | Per unit time (days) |
|---|---------------------|----------------------|
| Merkel Cell, Anal Carcinoma | 340 BU | 14 days |
| Melanoma (in combination with ipilimumab) | Initial: 140 BU | 21 days x 4 doses |
| | Followed by: 480 BU | 28 days |
| Melanoma/RCC (as a single agent), NSCLC, cHL, SCCHN, MSI-H/dMMR, HCC & Urothelial Carcinoma | 480 BU | 28 days |
| Gestational Trophoblastic Tumor | 240 BU | 14 days |
| CRC and SCLC (as a single agent) | 240 BU | 14 days |
| CRC (in combination with ipilimumab) | Initial: 340 BU | 21 days x 4 doses |
| | Followed by: 240 BU | 14 days |
| RCC (in combination with ipilimumab) | Initial: 340 BU | 21 days x 4 doses |
| | Followed by: 480 BU | 28 days |
| SCLC (in combination with ipilimumab) | Initial: 340 BU | 21 days x 4 doses |
| | Followed by: 340 BU | 14 days |
| CNS Metastases (in combination with ipilimumab) | Initial: 140 BU | 21 days x 4 doses |
| | Followed by: 340 BU | 14 days |

III. Initial Approval Criteria

Coverage is provided for the following conditions:

- Patient must be 18 years of age or older (unless otherwise specified); **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, etc.) unless otherwise specified; **AND**

Melanoma †

- Patient's disease is unresectable or metastatic; **AND**
 - Used as a single agent or in combination with ipilimumab; **OR**
 - Used in combination with ipilimumab in patients who previously progressed on single-agent checkpoint inhibitor immunotherapy
- Patient has unresectable or metastatic uveal melanoma; **AND**
 - Used as a single agent or in combination with ipilimumab; **OR**
- Used as adjuvant treatment as a single agent; **AND**
 - Patient has lymph node involvement or metastatic disease and has undergone complete resection; **OR**
- Used for retreatment of disease (*see Section IV for criteria*)

Hepatocellular Carcinoma (HCC) †

- Used as a single agent; **AND**
- Patient progressed on or was intolerant to sorafenib; **AND**
- Patient has a laboratory confirmed diagnosis of hepatocellular carcinoma; **AND**
- Patient has Child-Pugh Class A or B7 disease

Non-Small Cell Lung Cancer (NSCLC) †

- Patient has disease with a high tumor mutational burden (TMB) (i.e., ≥ 10 mutations per megabase); **AND**
 - Used as a single-agent or in combination with ipilimumab; **OR**
- Used as subsequent therapy in patients with metastatic disease; **AND**
 - Must be used as a single agent; **AND**
 - Disease has progressed during or following cytotoxic therapy; **AND**
 - Patients with genomic tumor aberrations must have progressed following systemic therapy for those aberrations (e.g., EGFR, ALK, etc.)

Renal Cell Carcinoma (RCC) †

- Used in combination with ipilimumab; **AND**
 - Used as initial therapy in patients with advanced or metastatic disease with intermediate or poor risk; **OR**
 - Used as subsequent therapy in patients with relapsed, unresectable metastatic disease with clear cell histology; **OR**

- Used as a single agent; **AND**
 - Patient has advanced disease with intermediate or poor risk; **OR**
 - Patient has relapsed, unresectable metastatic disease; **AND**
 - Used as subsequent therapy for clear cell histology; **OR**
 - Patient has non-clear cell histology

Classical Hodgkin Lymphoma (cHL) †

- Must be used as a single agent; **AND**
- Patient has relapsed or progressive disease; **AND**
 - Patient had an autologous hematopoietic stem cell transplantation (HSCT) and post-transplantation brentuximab vedotin; **OR**
 - Patient has received 3 or more lines of systemic therapy that includes autologous HSCT

Squamous Cell Carcinoma of the Head and Neck (SCCHN) †

- Used as single-agent therapy; **AND**
- Patient has unresectable, recurrent, persistent or metastatic disease; **AND**
- Disease has progressed on or after platinum-based therapy

Urothelial Carcinoma †

- Must be used as a single agent; **AND**
- Must be used as subsequent systemic therapy after previous platinum treatment*; **AND**
- Patient has one of the following:
 - Locally advanced or metastatic disease; **OR**
 - Disease recurrence post-cystectomy ‡; **OR**
 - Recurrent or metastatic Primary Carcinoma of the Urethra ‡; **AND**
 - Patient does not have recurrent stage T3-4 disease or palpable inguinal lymph nodes; **OR**
 - Metastatic Upper GU Tract Tumors ‡; **OR**
 - Metastatic Urothelial Carcinoma of the Prostate ‡

**If platinum treatment occurred greater than 12 months ago, the patient should be re-treated with platinum-based therapy. Patients with comorbidities (e.g., hearing loss, neuropathy, poor PS, renal insufficiency, etc.) may not be eligible for cisplatin. Carboplatin may be substituted for cisplatin particularly in those patients with a GFR <60 mL/min or a PS of 2.*

Small Cell Lung Cancer (SCLC) †

- Used as subsequent systemic therapy; **AND**
 - Used as single agent therapy for metastatic disease after previous platinum-based treatment and at least one other line of therapy †; **OR**
 - Used as single agent or in combination with ipilimumab in patients with a ECOG performance status score of 0-2 ‡; **AND**
 - Primary progressive disease; **OR**

- Relapsed within 6 months following complete response, partial response, or stable disease following initial treatment

Microsatellite Instability-High (MSI-H)/Mismatch Repair Deficient (dMMR) Colorectal Cancer †

- Patient must be at least 12 years old; **AND**
- Patient's disease must be microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); **AND**
- Patients must not have a diagnosis of MSI-H central nervous system metastases; **AND**
- Patient has one of the following:
 - Patient has progressed following treatment with a fluoropyrimidine-, oxaliplatin-, and/or irinotecan based chemotherapy; **AND**
 - Used as a single agent for unresectable advanced or metastatic disease; **OR**
 - Used in combination with ipilimumab for metastatic disease †; **OR**
 - Used as primary treatment for patients who failed adjuvant treatment with FOLFOX (fluorouracil, leucovorin and oxaliplatin) or CapeOX (capecitabine-oxaliplatin) in the previous 12 months †; **AND**
 - Used as a single agent or in combination with ipilimumab for unresectable metastatic disease; **OR**
 - Used as initial therapy for patients who are not candidates for intensive therapy †; **AND**
Used as a single agent for unresectable advanced or metastatic disease

Merkel Cell Carcinoma †

- Used as a single agent; **AND**
- Patient has disseminated metastatic disease

Central Nervous System Cancer †

- Used for the treatment of melanoma brain metastases; **AND**
- Nivolumab must have been active against the primary melanoma tumor; **AND**
- Used in combination with ipilimumab

Anal Carcinoma †

- Patient has metastatic squamous cell disease; **AND**
- Used as a single agent for second-line therapy

Gestational Trophoblastic Neoplasia †

- Used as single-agent therapy; **AND**
 - Patient has recurrent or progressive disease; **AND**
 - Patient has intermediate placental or epithelioid trophoblastic tumor; **AND**
 - Patient was previously treated with a platinum/etoposide containing regimen; **OR**
 - Patient has methotrexate-resistant high risk disease

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

IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet the criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe infusion reactions, complications of allogeneic HSCT, severe immune-mediated adverse reactions such as pneumonitis, colitis, hepatitis, endocrinopathies, nephritis/renal dysfunction, rash, encephalitis, etc.; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- For the following indication (s), the patient has not exceeded a maximum of twelve (12) months of therapy:
 - Adjuvant treatment of melanoma

Retreatment for Melanoma (metastatic or unresectable disease) ‡

- Used for re-treatment of patients who experienced disease control (i.e, complete or partial response or stable disease), but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **OR**
- Used as subsequent therapy, in combination with ipilimumab, in patients who experienced disease relapse and/or progression within 3 months after initial monotherapy with an immune checkpoint-inhibitor

V. Dosage/Administration

| Indication | Dose |
|-------------|---|
| Merkel Cell | 3 mg/kg every 2 weeks |
| CRC | <u>Single agent:</u> <ul style="list-style-type: none"> • 240 mg every 2 weeks, until disease progression or unacceptable toxicity. <u>In combination with ipilimumab:</u> <ul style="list-style-type: none"> • 3 mg/kg every 3 weeks for 4 doses, then 240 mg every 2 weeks until disease progression or unacceptable toxicity. |
| Anal Cancer | 240 mg every 2 weeks or 3 mg/kg every 2 weeks, until disease progression or unacceptable toxicity. |
| Melanoma | <u>Single agent:</u> <ul style="list-style-type: none"> • 240 mg every 2 weeks OR 480 mg every 4 weeks <u>Adjuvant single-agent treatment:</u> <ul style="list-style-type: none"> • 240 mg every 2 weeks or 480 mg every 4 weeks, until disease recurrence or unacceptable toxicity for up to 1 year <u>In combination with ipilimumab:</u> |

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|---|--|
| | <ul style="list-style-type: none"> 1 mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then 240 mg every 2 weeks or 480 mg every 4 weeks |
| NSCLC, MSI-H/dMMR, cHL, SCCHN, HCC and Urothelial Carcinoma | 240 mg every 2 weeks or 480 mg every 4 weeks, until disease progression or unacceptable toxicity. |
| SCLC | <p><u>Single agent:</u></p> <ul style="list-style-type: none"> 240 mg every 2 weeks until disease progression or unacceptable toxicity <p><u>In combination with ipilimumab:</u></p> <ul style="list-style-type: none"> 1 mg/kg to 3 mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then 3 mg/kg every 2 weeks |
| Renal Cell Carcinoma | <p><u>Single-agent:</u></p> <ul style="list-style-type: none"> 240 mg every 2 weeks or 480 mg every 4 weeks, until disease progression or unacceptable toxicity. <p><u>In combination with ipilimumab:</u></p> <ul style="list-style-type: none"> 3 mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then follow single-agent regimen |
| Gestational Trophoblastic Neoplasia (GTN) | 240 mg on days 1, 15, 29 (every 2 weeks) of a 42 day cycle repeated until disease progression or unacceptable toxicity |
| CNS Metastases | <u>1 mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then 3 mg/kg every 2 weeks</u> |

Dosing should be calculated using actual body weight and not flat dosing (as applicable) based on the following:

Weight ≥ 74 kg:

- Standard dose 240 mg IV every 2 weeks OR 480 mg IV every 4 weeks

Weight is 67 kg to 73 kg:

- Use 440 mg IV every 4 weeks

Weight is ≤ 66kg:

- Use 400 mg IV every 4 weeks

Note: This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide. Patient-specific variables should be taken into account.

VI. Billing Code/Availability Information

Jcode:

J9299 - Injection, nivolumab, 1 mg; 1 billable unit = 1 mg

NDC:

- Opdivo 40 mg/4 mL single-use vial: 00003-3772-xx
- Opdivo 100 mg/10 mL single-use vial: 00003-3774-xx
- Opdivo 240 mg/24 mL single-use vial: 00003-3734-xx

VII. References

1. Opdivo [package insert]. Princeton, NJ; Bristol-Myers Squibb Company; August 2018. Accessed November 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) nivolumab. National Comprehensive Cancer Network, 2018. 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 2018.
3. Scherpereel A, Mazieres J, Greillier L, et al. Second- or third-line nivolumab (Nivo) versus nivo plus ipilimumab (Ipi) in malignant pleural mesothelioma (MPM) patients: Results of the IFCT-1501 MAPS2 randomized phase II trial. [Abstract]. J Clin Oncol 2017;35: Abstract LBA 8507.
4. Walocko FM, Scheier BY, Harms PW, et al. Metastatic Merkel cell carcinoma response to nivolumab. J Immunother Cancer. 2016 Nov 15;4:79.
5. Tawbi HA-H, Forsyth PAJ, Algazi AP, et al. Efficacy and safety of nivolumab (NIVO) plus ipilimumab (IPI) in patients with melanoma (MEL) metastatic to the brain: Results of the phase II study CheckMate 204. J Clin Oncol 2017;35(15_suppl):abstr 9507.
6. Morris VK, Salem ME, Nimeiri H, et al. Nivolumab for previously treated unresectable metastatic anal cancer (NCI9673): a multicentre, single-arm, phase 2 study. Lancet Oncol. 2017 Apr;18(4):446-453. doi: 10.1016/S1470-2045(17)30104-3. Epub 2017 Feb 18.
7. Zhao X, Ivaturi V, Gopalakrishnan M, et al. Abstract CT 101: A model-based exposure-response (E-R) assessment of a nivolumab (NIVO) 4-weekly (Q4W) dosing schedule across multiple tumor types. Cancer Res July 1 2017 (77) (13 Supplement) CT101; DOI: 10.1158/1538-7445.AM2017-CT101
8. National Government Services, Inc. Local Coverage Article: Nivolumab (Opdivo®) – Related to LCD L33394 (A54862). Centers for Medicare & Medicaid Services, Inc. Updated on 9/21/2018 with effective date 10/1/2018. Accessed November 2018.

Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|--------|--|
| C00.0 | Malignant neoplasm of external upper lip |
| C00.1 | Malignant neoplasm of external lower lip |
| C00.2 | Malignant neoplasm of external lip, unspecified |
| C00.3 | Malignant neoplasm of upper lip, inner aspect |
| C00.4 | Malignant neoplasm of lower lip, inner aspect |
| C00.5 | Malignant neoplasm of lip, unspecified, inner aspect |
| C00.6 | Malignant neoplasm of commissure of lip, unspecified |

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| C00.8 | Malignant neoplasm of overlapping sites of lip |
| C01 | Malignant neoplasm of base of tongue |
| C02.0 | Malignant neoplasm of dorsal surface of tongue |
| C02.1 | Malignant neoplasm of border of tongue |
| C02.2 | Malignant neoplasm of ventral surface of tongue |
| C02.3 | Malignant neoplasm of anterior two-thirds of tongue, part unspecified |
| C02.4 | Malignant neoplasm of lingual tonsil |
| C02.8 | Malignant neoplasm of overlapping sites of tongue |
| C02.9 | Malignant neoplasm of tongue, unspecified |
| C03.0 | Malignant neoplasm of upper gum |
| C03.1 | Malignant neoplasm of lower gum |
| C03.9 | Malignant neoplasm of gum, unspecified |
| C04.0 | Malignant neoplasm of anterior floor of mouth |
| C04.1 | Malignant neoplasm of lateral floor of mouth |
| C04.8 | Malignant neoplasm of overlapping sites of floor of mouth |
| C04.9 | Malignant neoplasm of floor of mouth, unspecified |
| C05.0 | Malignant neoplasm of hard palate |
| C05.1 | Malignant neoplasm of soft palate |
| C06.0 | Malignant neoplasm of cheek mucosa |
| C06.2 | Malignant neoplasm of retromolar area |
| C06.80 | Malignant neoplasm of overlapping sites of unspecified parts of mouth |
| C06.89 | Malignant neoplasm of overlapping sites of other parts of mouth |
| C06.9 | Malignant neoplasm of mouth, unspecified |
| C09.0 | Malignant neoplasm of tonsillar fossa |
| C09.1 | Malignant neoplasm of tonsillar pillar (anterior) (posterior) |
| C09.8 | Malignant neoplasm of overlapping sites of tonsil |
| C09.9 | Malignant neoplasm of tonsil, unspecified |
| C10.3 | Malignant neoplasm of posterior wall of oropharynx |
| C11.0 | Malignant neoplasm of superior wall of nasopharynx |
| C11.1 | Malignant neoplasm of posterior wall of nasopharynx |
| C11.2 | Malignant neoplasm of lateral wall of nasopharynx |
| C11.3 | Malignant neoplasm of anterior wall of nasopharynx |
| C11.8 | Malignant neoplasm of overlapping sites of nasopharynx |
| C11.9 | Malignant neoplasm of nasopharynx, unspecified |
| C12 | Malignant neoplasm of pyriform sinus |
| C13.0 | Malignant neoplasm of postcricoid region |

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| C13.1 | Malignant neoplasm of aryepiglottic fold, hypopharyngeal aspect |
| C13.2 | Malignant neoplasm of posterior wall of hypopharynx |
| C13.8 | Malignant neoplasm of overlapping sites of hypopharynx |
| C13.9 | Malignant neoplasm of hypopharynx, unspecified |
| C14.0 | Malignant neoplasm of pharynx, unspecified |
| C14.2 | Malignant neoplasm of Waldeyer's ring |
| C14.8 | Malignant neoplasm of overlapping sites of lip, oral cavity and pharynx |
| C17.0 | Malignant neoplasm of duodenum |
| C17.1 | Malignant neoplasm of jejunum |
| C17.2 | Malignant neoplasm of ileum |
| C17.8 | Malignant neoplasm of overlapping sites of small intestine |
| C17.9 | Malignant neoplasm of small intestine, unspecified |
| C18.0 | Malignant neoplasm of cecum |
| C18.1 | Malignant neoplasm of appendix |
| C18.2 | Malignant neoplasm of ascending colon |
| C18.3 | Malignant neoplasm of hepatic flexure |
| C18.4 | Malignant neoplasm of transverse colon |
| C18.5 | Malignant neoplasm of splenic flexure |
| C18.6 | Malignant neoplasm of descending colon |
| C18.7 | Malignant neoplasm of sigmoid colon |
| C18.8 | Malignant neoplasm of overlapping sites of colon |
| C18.9 | Malignant neoplasm of colon, unspecified |
| C19 | Malignant neoplasm of rectosigmoid junction |
| C20 | Malignant neoplasm of rectum |
| C21.0 | Malignant neoplasm of anus, unspecified |
| C21.1 | Malignant neoplasm of anal canal |
| C21.2 | Malignant neoplasm of cloacogenic zone |
| C21.8 | Malignant neoplasm of overlapping sites of rectum, anus and anal canal |
| C22.0 | Liver cell carcinoma |
| C22.9 | Malignant neoplasm of liver, not specified as primary or secondary |
| C31.0 | Malignant neoplasm of maxillary sinus |
| C31.1 | Malignant neoplasm of ethmoidal sinus |
| C32.0 | Malignant neoplasm of glottis |
| C32.1 | Malignant neoplasm of supraglottis |
| C32.2 | Malignant neoplasm of subglottis |
| C32.3 | Malignant neoplasm of laryngeal cartilage |

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| C32.8 | Malignant neoplasm of overlapping sites of larynx |
| C32.9 | Malignant neoplasm of larynx, 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 and lung |
| C34.81 | Malignant neoplasm of overlapping sites of right bronchus and lung |
| C34.82 | Malignant neoplasm of overlapping sites of left bronchus and lung |
| C34.90 | Malignant neoplasm of unspecified part of unspecified bronchus or lung |
| C34.91 | Malignant neoplasm of unspecified part of right bronchus or lung |
| C34.92 | Malignant neoplasm of unspecified part of left bronchus or lung |
| C43.0 | Malignant melanoma of lip |
| C43.10 | Malignant melanoma of unspecified eyelid, including canthus |
| C43.11 | Malignant melanoma of right eyelid, including canthus |
| C43.12 | Malignant melanoma of left eyelid, including canthus |
| C43.20 | Malignant melanoma of unspecified ear and external auricular canal |
| C43.21 | Malignant melanoma of right ear and external auricular canal |
| C43.22 | Malignant melanoma of left ear and external auricular canal |
| C43.30 | Malignant melanoma of unspecified part 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 |

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| 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 |
| C44.00 | Unspecified malignant neoplasm of skin of lip |
| C44.02 | Squamous cell carcinoma of skin of lip |
| C44.09 | Other specified malignant neoplasm of skin of lip |
| C4A.0 | Merkel cell carcinoma of lip |
| C4A.10 | Merkel cell carcinoma of eyelid, including canthus |
| C4A.11 | Merkel cell carcinoma of right eyelid, including canthus |
| C4A.12 | Merkel cell carcinoma of left eyelid, including canthus |
| C4A.20 | Merkel cell carcinoma of unspecified ear and external auricular canal |
| C4A.21 | Merkel cell carcinoma of right ear and external auricular canal |
| C4A.22 | Merkel cell carcinoma of left ear and external auricular canal |
| C4A.30 | Merkel cell carcinoma of unspecified part of face |
| C4A.31 | Merkel cell carcinoma of nose |
| C4A.39 | Merkel cell carcinoma of other parts of face |
| C4A.4 | Merkel cell carcinoma of scalp and neck |
| C4A.51 | Merkel cell carcinoma of anal skin |
| C4A.52 | Merkel cell carcinoma of skin of breast |
| C4A.59 | Merkel cell carcinoma of other part of trunk |
| C4A.60 | Merkel cell carcinoma of unspecified upper limb, including shoulder |
| C4A.61 | Merkel cell carcinoma of right upper limb, including shoulder |
| C4A.62 | Merkel cell carcinoma of left upper limb, including shoulder |
| C4A.70 | Merkel cell carcinoma of unspecified lower limb, including hip |
| C4A.71 | Merkel cell carcinoma of right lower limb, including hip |
| C4A.72 | Merkel cell carcinoma of left lower limb, including hip |
| C4A.8 | Merkel cell carcinoma of overlapping sites |
| C4A.9 | Merkel cell carcinoma, unspecified |
| C61 | Malignant neoplasm of prostate |
| C64.1 | Malignant neoplasm of right kidney, except renal pelvis |
| C64.2 | Malignant neoplasm of left kidney, except renal pelvis |
| C64.9 | Malignant neoplasm of unspecified kidney, except renal pelvis |
| C65.1 | Malignant neoplasm of right renal pelvis |
| C65.2 | Malignant neoplasm of left renal pelvis |
| C65.9 | Malignant neoplasm of unspecified renal pelvis |

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| C66.1 | Malignant neoplasm of right ureter |
| C66.2 | Malignant neoplasm of left ureter |
| C66.9 | Malignant neoplasm of unspecified ureter |
| C67.0 | Malignant neoplasm of trigone of bladder |
| C67.1 | Malignant neoplasm of dome of bladder |
| C67.2 | Malignant neoplasm of lateral wall of bladder |
| C67.3 | Malignant neoplasm of anterior wall of bladder |
| C67.4 | Malignant neoplasm of posterior wall of bladder |
| C67.5 | Malignant neoplasm of bladder neck |
| C67.6 | Malignant neoplasm of ureteric orifice |
| C67.7 | Malignant neoplasm of urachus |
| C67.8 | Malignant neoplasm of overlapping sites of bladder |
| C67.9 | Malignant neoplasm of bladder, unspecified |
| C68.0 | Malignant neoplasm of urethra |
| 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 |
| C69.90 | Malignant neoplasm of unspecified site of unspecified eye |
| C69.91 | Malignant neoplasm of unspecified site of right eye |
| C69.92 | Malignant neoplasm of unspecified site of left eye |
| C76.0 | Malignant neoplasm of head, face and neck |
| C77.0 | Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck |
| C78.00 | Secondary malignant neoplasm of unspecified lung |
| C78.01 | Secondary malignant neoplasm of right lung |
| C78.02 | Secondary malignant neoplasm of left lung |
| C78.6 | Secondary malignant neoplasm of retroperitoneum and peritoneum |
| C78.7 | Secondary malignant neoplasm of liver and intrahepatic bile duct |
| C78.89 | Secondary malignant neoplasm of other digestive organs |
| C79.31 | Secondary malignant neoplasm of brain |
| C79.51 | Secondary malignant neoplasm of bone |

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| C79.52 | Secondary malignant neoplasm of bone marrow |
| C7A.1 | Malignant poorly differentiated neuroendocrine tumors |
| C7B.1 | Secondary Merkel cell carcinoma |
| C80.0 | Disseminated malignant neoplasm, unspecified |
| C80.1 | Malignant (primary) neoplasm, unspecified |
| C81.10 | Nodular sclerosis Hodgkin lymphoma, unspecified site |
| C81.11 | Nodular sclerosis Hodgkin lymphoma, lymph nodes of head, face, and neck |
| C81.12 | Nodular sclerosis Hodgkin lymphoma, intrathoracic lymph nodes |
| C81.13 | Nodular sclerosis Hodgkin lymphoma, intra-abdominal lymph nodes |
| C81.14 | Nodular sclerosis Hodgkin lymphoma, lymph nodes of axilla and upper limb |
| C81.15 | Nodular sclerosis Hodgkin lymphoma, lymph nodes of inguinal region and lower limb |
| C81.16 | Nodular sclerosis Hodgkin lymphoma, intrapelvic lymph nodes |
| C81.17 | Nodular sclerosis Hodgkin lymphoma, spleen |
| C81.18 | Nodular sclerosis Hodgkin lymphoma, lymph nodes of multiple sites |
| C81.19 | Nodular sclerosis Hodgkin lymphoma, extranodal and solid organ sites |
| C81.20 | Mixed cellularity Hodgkin lymphoma, unspecified site |
| C81.21 | Mixed cellularity Hodgkin lymphoma, lymph nodes of head, face, and neck |
| C81.22 | Mixed cellularity Hodgkin lymphoma, intrathoracic lymph nodes |
| C81.23 | Mixed cellularity Hodgkin lymphoma, intra-abdominal lymph nodes |
| C81.24 | Mixed cellularity Hodgkin lymphoma, lymph nodes of axilla and upper limb |
| C81.25 | Mixed cellularity Hodgkin lymphoma, lymph nodes of inguinal region and lower limb |
| C81.26 | Mixed cellularity Hodgkin lymphoma, intrapelvic lymph nodes |
| C81.27 | Mixed cellularity Hodgkin lymphoma, spleen |
| C81.28 | Mixed cellularity Hodgkin lymphoma, lymph nodes of multiple sites |
| C81.29 | Mixed cellularity Hodgkin lymphoma, extranodal and solid organ sites |
| C81.30 | Lymphocyte depleted Hodgkin lymphoma, unspecified site |
| C81.31 | Lymphocyte depleted Hodgkin lymphoma, lymph nodes of head, face, and neck |
| C81.32 | Lymphocyte depleted Hodgkin lymphoma, intrathoracic lymph nodes |
| C81.33 | Lymphocyte depleted Hodgkin lymphoma, intra-abdominal lymph nodes |
| C81.34 | Lymphocyte depleted Hodgkin lymphoma, lymph nodes of axilla and upper limb |
| C81.35 | Lymphocyte depleted Hodgkin lymphoma, lymph nodes of inguinal region and lower limb |
| C81.36 | Lymphocyte depleted Hodgkin lymphoma, intrapelvic lymph nodes |
| C81.37 | Lymphocyte depleted Hodgkin lymphoma, spleen |
| C81.38 | Lymphocyte depleted Hodgkin lymphoma, lymph nodes of multiple sites |
| C81.39 | Lymphocyte depleted Hodgkin lymphoma, extranodal and solid organ sites |
| C81.40 | Lymphocyte-rich Hodgkin lymphoma, unspecified site |

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| C81.41 | Lymphocyte-rich Hodgkin lymphoma, lymph nodes of head, face, and neck |
| C81.42 | Lymphocyte-rich Hodgkin lymphoma, intrathoracic lymph nodes |
| C81.43 | Lymphocyte-rich Hodgkin lymphoma, intra-abdominal lymph nodes |
| C81.44 | Lymphocyte-rich Hodgkin lymphoma, lymph nodes of axilla and upper limb |
| C81.45 | Lymphocyte-rich Hodgkin lymphoma, lymph nodes of inguinal region and lower limb |
| C81.46 | Lymphocyte-rich Hodgkin lymphoma, intrapelvic lymph nodes |
| C81.47 | Lymphocyte-rich Hodgkin lymphoma, spleen |
| C81.48 | Lymphocyte-rich Hodgkin lymphoma, lymph nodes of multiple sites |
| C81.49 | Lymphocyte-rich Hodgkin lymphoma, extranodal and solid organ sites |
| C81.70 | Other Hodgkin lymphoma unspecified site |
| C81.71 | Other Hodgkin lymphoma lymph nodes of head, face, and neck |
| C81.72 | Other Hodgkin lymphoma intrathoracic lymph nodes |
| C81.73 | Other Hodgkin lymphoma intra-abdominal lymph nodes |
| C81.74 | Other Hodgkin lymphoma lymph nodes of axilla and upper limb |
| C81.75 | Other Hodgkin lymphoma lymph nodes of inguinal region and lower limb |
| C81.76 | Other Hodgkin lymphoma intrapelvic lymph nodes |
| C81.77 | Other Hodgkin lymphoma spleen |
| C81.78 | Other Hodgkin lymphoma lymph nodes of multiple sites |
| C81.79 | Other Hodgkin lymphoma extranodal and solid organ sites |
| C81.90 | Hodgkin lymphoma, unspecified site |
| C81.91 | Hodgkin lymphoma, unspecified lymph nodes of head, face, and neck |
| C81.92 | Hodgkin lymphoma, unspecified intrathoracic lymph nodes |
| C81.93 | Hodgkin lymphoma, unspecified intra-abdominal lymph nodes |
| C81.94 | Hodgkin lymphoma, unspecified lymph nodes of axilla and upper limb |
| C81.95 | Hodgkin lymphoma, unspecified lymph nodes of inguinal region and lower limb |
| C81.96 | Hodgkin lymphoma, unspecified intrapelvic lymph nodes |
| C81.97 | Hodgkin lymphoma, unspecified spleen |
| C81.98 | Hodgkin lymphoma, unspecified lymph nodes of multiple sites |
| C81.99 | Hodgkin lymphoma, unspecified extranodal and solid organ sites |
| D09.0 | Carcinoma in situ of bladder |
| D37.01 | Neoplasm of uncertain behavior of lip |
| D37.02 | Neoplasm of uncertain behavior of tongue |
| D37.05 | Neoplasm of uncertain behavior of pharynx |
| D37.09 | Neoplasm of uncertain behavior of other specified sites of the oral cavity |
| D38.0 | Neoplasm of uncertain behavior of larynx |
| D38.5 | Neoplasm of uncertain behavior of other respiratory organs |

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| D38.6 | Neoplasm of uncertain behavior of respiratory organ, unspecified |
| D39.2 | Neoplasm of uncertain behavior of placenta |
| D39.8 | Neoplasm of uncertain behavior of other specified female genital organs |
| D39.9 | Neoplasm of uncertain behavior of female genital organ, unspecified |
| Z85.038 | Personal history of other malignant neoplasm of large intestine |
| Z85.068 | Personal history of other malignant neoplasm of small intestine |
| Z85.118 | Personal history of other malignant neoplasm of bronchus and lung |
| Z85.21 | Personal history of malignant neoplasm of larynx |
| Z85.22 | Personal history of malignant neoplasm of nasal cavities, middle ear, and accessory sinuses |
| Z85.51 | Personal history of malignant neoplasm of bladder |
| Z85.528 | Personal history of other malignant neoplasm of kidney |
| Z85.59 | Personal history of malignant neoplasm of other urinary tract organ |
| Z85.71 | Personal history of Hodgkin lymphoma |
| Z85.810 | Personal history of malignant neoplasm of tongue |
| Z85.818 | Personal history of malignant neoplasm of other sites of lip, oral cavity and pharynx |
| Z85.819 | Personal history of malignant neoplasm of unspecified site of lip, oral cavity and pharynx |
| Z85.820 | Personal history of malignant melanoma of skin |
| Z85.821 | Personal history of Merkel cell carcinoma |

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) and Local Coverage Determinations (LCDs) 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):

| | |
|---|-------------------------------------|
| Jurisdiction(s): 6, K | NCD/LCD Document (s): A54862 |
| https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A54862&bc=gAAAAAAAAAAAAA== | |

| 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) |

Medicare Part B Administrative Contractor (MAC) Jurisdictions

| Jurisdiction | Applicable State/US Territory | Contractor |
|---------------------|---|---|
| 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 |