Independent Health

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 240 mg/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
Small Bowel Adenocarcinoma (as a single agent)	340 BU	14 days
Small Bowel Adenocarcinoma (in combination with ipilimumab)	Initial: 340 BU	21 days x 4 doses
	Followed by: 340 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

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MPM (as a single agent or in combination with ipilimumab)	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**
- Patient has uveal melanoma with distant metastatic disease; **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 as re-induction OR subsequent to progression on single agent checkpoint inhibitor therapy or maximum clinical benefit from BRAF-targeted therapy (*refer to Section IV for criteria)*

Hepatocellular Carcinoma (HCC) †

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

Non-Small Cell Lung Cancer (NSCLC) †

- Patient has metastatic 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 as first-line therapy**; OR**
- Used as subsequent therapy in patients with recurrent (excluding locoregional recurrent without evidence of disseminated disease), advanced, or metastatic disease; **AND**
  - Must be used as a single agent; **AND**
  - Disease has progressed during or following cytotoxic (e.g., platinum-based) therapy; **AND**
  - Patients with genomic tumor aberrations must have progressed following systemic therapy for those aberrations (i.e., EGFR, ALK, etc.) ; **AND**

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- Patient did not progress on prior PD-1/PD-L1 inhibitor therapy

**TMB is an evolving biomarker that may be helpful in selecting patients for immunotherapy. There is no consensus on how to measure TMB.*

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 first-line therapy for clear cell histology and favorable or poor/intermediate risk; **OR**
  - Used as subsequent therapy in patients with relapsed or stage IV disease with clear cell histology; **OR**
- Used as a single agent; **AND**
  - Patient has advanced disease and received prior antiangiogenic therapy (e.g., everolimus) †; **OR**
  - Patient has relapsed or stage IV 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 †; **OR**
  - Patient is transplant ineligible based on comorbidities or failure of second-line therapies; **OR**
  - Patient had an allogeneic stem-cell transplant

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**

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        - Patient does not have recurrence of 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 for metastatic disease with progression after 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 performance status of 0-2 ‡; **AND**
        - Primary progressive disease; **OR**
        - Relapse within 6 months following complete response, partial response, or stable disease with initial treatment

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 unresectable advanced or metastatic disease that progressed following treatment with a fluoropyrimidine-, oxaliplatin-, and/or irinotecan based chemotherapy; **AND**
        - Used as a single agent if nivolumab or pembrolizumab were not previously used; **OR**
        - Used in combination with ipilimumab if patient had no previous treatment with a checkpoint-inhibitor; **OR**
    - Used as primary treatment for patients with previous adjuvant FOLFOX (fluorouracil, leucovorin and oxaliplatin) or CapeOX (capecitabine-oxaliplatin) in the past 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 ‡

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

Central Nervous System Cancer ‡

- Used for the treatment of brain metastases in patients with melanoma; **AND**
- Used as a single-agent or in combination with ipilimumab; **AND**
  - Patient has recurrent disease with limited brain metastases; **OR**
  - Used for newly-diagnosed-limited or recurrent-extensive brain metastases in patients with stable disease or reasonable systemic treatment options

Anal Carcinoma ‡

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

Gestational Trophoblastic Neoplasia ‡

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

Malignant Pleural Mesothelioma ‡

- Used as a single agent or in combination with ipilimumab as subsequent therapy

Small Bowel Adenocarcinoma ‡

- Patient has advanced or metastatic disease that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR): **AND**
- Used as single agent or in combination with ipilimumab (in one of the following settings):
  - As subsequent therapy; **OR**
  - As initial therapy in patients with prior oxaliplatin exposure in the adjuvant setting or contraindication.

† 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**

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- 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 as re-induction therapy as a single agent or in combination with ipilimumab in 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 patients who experienced disease progression, in combination with ipilimumab after monotherapy with an immune checkpoint-inhibitor or as a single-agent if a checkpoint-inhibitor was not previously used

V. Dosage/Administration

Indication	Dose
Merkel Cell	3 mg/kg every 2 weeks
Anal Cancer	240 mg every 2 weeks or 3 mg/kg every 2 weeks, until disease progression or unacceptable toxicity.
Melanoma	Single agent: • 240 mg every 2 weeks OR 480 mg every 4 weeks until disease progression or unacceptable toxicity Adjuvant treatment: • 240 mg every 2 weeks or 480 mg every 4 weeks, until disease recurrence or unacceptable toxicity for up to 1 year In combination with ipilimumab: • 1 mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then follow single agent regimen
NSCLC, cHL, SCCHN, HCC and Urothelial Carcinoma	240 mg every 2 weeks or 480 mg every 4 weeks, until disease progression or unacceptable toxicity.
MSI-H/dMMR CRC	Adult patients and for pediatric patients ≥ 12 years and ≥ 40 kg • As a single agent, 240 mg every 2 weeks or 480 mg every 4 weeks, until disease progression or unacceptable toxicity. • In combination with ipilimumab, nivolumab 3 mg/kg, followed by ipilimumab 1 mg/kg on the same day, every 3 weeks for 4 doses. After completing 4 doses of the combination, follow the single agent regimen thereafter. Pediatric patients ≥ 12 years and < 40 kg • As a single agent, 3 mg/kg every 2 weeks, intravenously until disease progression or unacceptable toxicity. • In combination with ipilimumab, nivolumab 3 mg/kg, followed by ipilimumab 1 mg/kg on the same day, every 3

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	weeks for 4 doses. After completing 4 doses of the combination, follow the single agent regimen thereafter.
SCLC	Single agent: • 240 mg every 2 weeks until disease progression or unacceptable toxicity In combination with ipilimumab: • 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	Single-agent: • 240 mg every 2 weeks or 480 mg every 4 weeks, until disease progression or unacceptable toxicity. In combination with ipilimumab: • 3 mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then follow single-agent regimen
Malignant Pleural Mesothelioma (MPM)	Single agent: • 3 mg/kg every 2 weeks In combination with ipilimumab: • 3 mg/kg every 2 weeks, followed by ipilimumab 1mg/kg every 6 weeks, until disease progression or unacceptable toxicity
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	1 mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then 3 mg/kg every 2 weeks
Small Bowel Adenocarcinoma	Single agent: • 3 mg/kg every 2 weeks, or 240 mg every 2 weeks, or 480 mg every 4 weeks In combination with ipilimumab: • 3 mg/kg with ipilimumab at 1 mg/kg every 3 weeks for 4 doses, then nivolumab 3 mg/kg or 240 mg every 2 weeks
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.*	

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VI. Billing Code/Availability Information

HCPCS code:

- 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; May 2019. Accessed July 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) nivolumab. National Comprehensive Cancer Network, 2019. 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 July 2019.
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 – Related to LCD L33394 (A54862). Centers for Medicare & Medicaid Services, Inc. Updated on 9/21/2018 with effective date 10/1/2018. Accessed July 2019.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description

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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
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
C06.8	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

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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
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
C17.3	Meckel's diverticulum, malignant
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

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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
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
C38.4	Malignant neoplasm of pleura
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

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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
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
C45.0	Mesothelioma of pleura
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

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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
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

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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
C79.52	Secondary malignant neoplasm of bone marrow
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7B.1	Secondary Merkel cell carcinoma
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

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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
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

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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
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

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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)
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

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