Clinical Policy: Nivolumab (Opdivo)

Reference Number: LA.PHAR.121
Effective Date:
Last Review Date: 01.21
Line of Business: Medicaid

Coding Implications Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Nivolumab (Opdivo®) is a programmed death receptor-1 (PD-1) blocking antibody.

FDA Approved Indication(s)
Opdivo is indicated for the treatment of:

- Melanoma
  - Patients with unresectable or metastatic melanoma, as a single agent or in combination with ipilimumab.
  - Patients with melanoma with lymph node involvement or metastatic disease who have undergone complete resection, in the adjuvant setting.
- Non-small cell lung cancer (NSCLC)
  - Adult patients with metastatic non-small cell lung cancer expressing PD-L1 (≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, as first-line treatment in combination with ipilimumab.
  - Adult patients with metastatic or recurrent non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations as first-line treatment, in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy.
  - Patients with metastatic NSCLC and progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Opdivo.
- Small cell lung cancer (SCLC)
  - Patients with metastatic SCLC with progression after platinum based chemotherapy and at least one other line of therapy.*
- Malignant pleural mesothelioma
  - Adult patients with unresectable malignant pleural mesothelioma, as first-line treatment in combination with ipilimumab.
- Renal cell carcinoma (RCC)
  - Patients with advanced renal cell carcinoma (RCC) who have received prior antiangiogenic therapy.
  - Patients with intermediate or poor risk, previously untreated advanced RCC, in combination with ipilimumab.
- Classical Hodgkin lymphoma (cHL)
  - Adult patients with cHL that has relapsed or progressed after:*

  - autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin, or
  - 3 or more lines of systemic therapy that includes autologous HSCT.
- Squamous cell carcinoma of the head and neck (SCCHN)
  - Patients with recurrent or metastatic SCCHN with disease progression on or after a platinum-based therapy.
- Urothelial carcinoma (UC)
  - Patients with locally advanced or metastatic UC who:*
    - have disease progression during or following platinum-containing chemotherapy, or
    - have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
- Colorectal cancer
  - Adult and pediatric (12 years and older) patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, as a single agent or in combination with ipilimumab.*
- Hepatocellular carcinoma (HCC)
  - Patients with HCC who have been previously treated with sorafenib, as a single agent or in combination with ipilimumab.*
- Esophageal squamous cell carcinoma (ESCC)
  - Patients with unresectable advanced, recurrent or metastatic ESCC after prior fluoropyrimidine- and platinum-based chemotherapy.*

*This indication is approved under accelerated approval based on overall or tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Policy/Criteria

Prior authorization is required. Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Opdivo is medically necessary when the following criteria are met:

I. Initial Approval Criteria

A. Melanoma (must meet all):

1. Diagnosis of unresectable, metastatic, or lymph node positive melanoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a, b, or c):*
   a. Monotherapy (unresectable or metastatic disease, or adjuvant treatment): Dose does not exceed 240 mg every 2 weeks or 480 mg every 4 weeks;

b. In combination with Yervoy® (unresectable or metastatic disease): Dose does not exceed 1 mg/kg every 3 weeks for 4 doses, followed by 240 mg every 2 weeks or 480 mg every 4 weeks (*see Appendix E for dose rounding guidelines*);
c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Non-Small Cell Lung Cancer (must meet all):
1. Diagnosis of recurrent, advanced, or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Member has not previously progressed on a PD-1/PD-L1 inhibitor (e.g., Keytruda®, Tecentriq®, Imfinzi®);
5. Opdivo is prescribed in one of the following ways (a, b, or c):
   a. For use as a single agent, and disease has progressed on or after systemic therapy;
   b. For use as a single agent or in combination with Yervoy for tumors positive for the Tumor Mutation Burden (TMB) biomarker;
   c. For use in combination with Yervoy, and both of the following (i and ii):
      i. Request meets one of the following (a, b, or c):
         a) Disease mutation status is unknown or negative for EGFR, ALK, ROS1, BRAF, MET exon 14 skipping, and RET, and member has not received prior systemic therapy for advanced disease;
         b) Disease mutation status is positive for EGFR, ALK, ROS1, BRAF, MET exon 14 skipping, RET, or NTRK gene fusion, and member has received mutation-specific treatment;
         c) Disease is positive for a RET rearrangement;
      ii. Request meets one of the following (a or b):
         a) Member has PD-L1 tumor expression of ≥ 1%;
         b) Opdivo is being used in combination with Yervoy ± a platinum-based regimen (*see Appendix B*);

   **Prior authorization may be required for Yervoy*
6. Request meets one of the following (a, b, c, or d):*
   a. Monotherapy: Dose does not exceed 240 mg every 2 weeks or 480 mg every 4 weeks;
   b. In combination with Yervoy: Dose does not exceed 3 mg/kg every 2 weeks (*see Appendix E for dose rounding guidelines*);
   c. In combination with Yervoy and platinum-doublet chemotherapy: Dose does not exceed 360 mg every 3 weeks;
   d. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

C. Small Cell Lung Cancer (must meet all):

1. Diagnosis of SCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Failure of platinum-containing regimen (e.g. cisplatin, carboplatin), unless clinically significant adverse effects are experienced or all are contraindicated;
5. Prescribed as single agent or in combination with Yervoy;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 240 mg every 2 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

D. Malignant Pleural Mesothelioma (must meet all):
1. Diagnosis of unresectable malignant pleural mesothelioma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in one of the following ways (a or b):
   a. As first-line therapy in combination with Yervoy;
   b. If not administered first-line, as subsequent therapy in combination with Yervoy or as a single agent;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 360 mg every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

E. Renal Cell Carcinoma (must meet all):
1. Diagnosis of RCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a, b, or c):*
   a. Monotherapy: Dose does not exceed 240 mg every 2 weeks or 480 mg every 4 weeks;
   b. In combination with Yervoy: Dose does not exceed 3 mg/kg every 3 weeks for 4 doses, followed by 240 mg every 2 weeks or 480 mg every 4 weeks (*see Appendix E for dose rounding guidelines*);
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

F. Classical Hodgkin Lymphoma (must meet all):
1. Diagnosis of relapsed, refractory or progressive cHL;

2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as subsequent therapy;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 240 mg every 2 weeks or 480 mg every 4 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

G. Squamous Cell Carcinoma of the Head and Neck (must meet all):
1. Diagnosis of SCCHN;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease has progressed on or after a platinum-containing regimen (e.g., cisplatin, carboplatin);
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 240 mg every 2 weeks or 480 mg every 4 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

H. Urothelial Carcinoma (must meet all):
1. Diagnosis of UC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Failure of a platinum-containing regimen (e.g., cisplatin, carboplatin), unless clinically significant adverse effects are experienced or all are contraindicated;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 240 mg every 2 weeks or 480 mg every 4 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

I. Colorectal Cancer (must meet all):
1. Diagnosis of unresectable or metastatic CRC;
2. Tumor is characterized as MSI-H or dMMR;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 12 years;
5. Dose does not exceed one of the following (a, b, or c):*
   a. Monotherapy: 240 mg every 2 weeks;

b. In combination with Yervoy: 3 mg/kg every 3 weeks for 4 doses, then 240 mg every 2 weeks or 480 mg every 4 weeks (*see Appendix E for dose rounding guidelines*);
c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

J. Hepatocellular Carcinoma (must meet all):
1. Diagnosis of HCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Member has had disease progression following treatment with Nexavar® or Lenvima®;
   **Prior authorization may be required for Nexavar and Lenvima.*
5. Member has not had previous treatment with a checkpoint inhibitor (e.g., Yervoy, Keytruda, Tecentriq, Imfinzi);
6. Dose does not exceed one of the following (a, b, or c):*
   a. Monotherapy: 240 mg every 2 weeks or 480 mg every 4 weeks;
   b. In combination with Yervoy: 1 mg/kg every 3 weeks for 4 doses, then 240 mg every 2 weeks or 480 mg every 4 weeks (*see Appendix E for dose rounding guidelines*);
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

K. Esophageal Squamous Cell Carcinoma (must meet all):
1. Diagnosis of unresectable advanced, recurrent, or metastatic ESCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Member has had previous treatment with a fluoropyrimidine-based (e.g., 5-fluorouracil, capecitabine) and platinum-based (e.g., carboplatin, cisplatin, oxaliplatin) chemotherapy;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 240 mg every 2 weeks or 480 mg every 4 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

L. Off-label NCCN Compendium Recommended Indications (must meet all):
1. Diagnosis of one of the following (a, b, c, d, e, f, or g):
   a. Metastatic squamous cell anal carcinoma;
   b. Metastatic Merkel cell carcinoma;

c. Gestational trophoblastic neoplasia;
d. Uveal melanoma;
e. Small bowel adenocarcinoma;
f. Extranodal NK/T-cell lymphoma, nasal type;
g. Pediatric Hodgkin lymphoma;
h. Vulvar cancer - HPV-related advanced, recurrent, or metastatic disease;

2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. For anal carcinoma: prescribed as second line or subsequent therapy (examples of prior therapy include 5-FU/cisplatin, carboplatin/paclitaxel, FOLFOX, FOLFCIS);
5. For gestational trophoblastic neoplasia: prescribed as one of the following (a or b):
   a. Following treatment with a platinum/etoposide-containing regimen;
   b. Disease is methotrexate-resistant and high-risk (*see Appendix D*);
6. For uveal melanoma: prescribed as a single agent or in combination with Yervoy;
   **Prior authorization may be required for Yervoy.*
7. For pediatric Hodgkin lymphoma and vulvar cancer: prescribed as subsequent therapy;
8. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

M. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all):

1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Opdivo for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b, or c):*
   a. NSCLC in combination with Yervoy: New dose does not exceed 3 mg/kg every 2 weeks;
   b. Malignant pleural mesothelioma in combination with Yervoy: New dose does not exceed 360 mg every 3 weeks;
   c. Other indications: New dose does not exceed 480 mg every 4 weeks;
   d. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):
1. Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALK: anaplastic lymphoma kinase
BRAF: B-Raf proto-oncogene, serine/threonine kinase
CHL: classic Hodgkin lymphoma
CRC: colorectal cancer
dMMR: mismatch repair deficient
EGFR: epidermal growth factor receptor
ESCC: esophageal squamous cell carcinoma
FDA: Food and Drug Administration
HCC: hepatocellular carcinoma
HSCT: hematopoietic stem cell transplantation
MET: mesenchymal-epithelial transition
MSI-H: microsatellite instability-high
NSCLC: non-small cell lung cancer
PD-1: programmed death receptor-1
PD-L1: programmed death-ligand 1
RCC: renal cell carcinoma
ROS1: ROS proto-oncogene 1
SCLC: small cell lung cancer
TMB: Tumor Mutational Burden
UC: urothelial carcinoma

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Nexavar (sorafenib)	HCC: 400 mg PO BID until clinical benefit ceases or unacceptable toxicity occurs	800 mg/day
Lenvima (lenvatinib)	HCC: 12 mg PO QD (patients ≥ 60 kg) or 8 mg PO QD (patients < 60 kg) until disease progression or unacceptable toxicity	12 mg/day
Cisplatin- or carboplatin-containing chemotherapy	SCLC, UC, SCCHN: Varies	Varies
First-line therapies (e.g., 5-FU/cisplatin,	Metastatic anal carcinoma: Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
carboplatin/paclitaxel, FOLFOX, FOLFCIS)		
First-line therapies (e.g., platinum/etoposide-containing regimen)	Gestational trophoblastic neoplasia: Varies	Varies
platinum-containing regimens	NSCLC – squamous cell carcinoma: paclitaxel + carboplatin dose varies NSCLC – nonsquamous cell carcinoma: pemetrexed + [carboplatin or cisplatin] dose varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information
- High-risk disease in gestational trophoblastic neoplasia is defined as having a FIGO stage II to III and ≥ 7 prognostic score or stage IV
  - FIGO staging system:

Stage	Criteria
I	Tumor confined to uterus
II	Tumor extends to other genital structures (ovary, tube, vagina, broad ligaments) by metastasis or direct extension
III	Lung metastasis
IV	All other distant metastases

  - Prognostic Scoring Index
    - The total score is obtained by adding the individual scores for each prognostic factor (low risk is indicated by a score < 7 and high risk is indicated by a score ≥ 7)

Prognostic factor	Risk score			
	0	1	2	4
Age (years)	< 40	≥ 40	--	--
Antecedent pregnancy	Hydatidiform mole	Abortion	Term pregnancy	--
Interval from index	< 4	4 to 6	7 to 12	>12

Prognostic factor	Risk score			
pregnancy (months)				
Pretreatment hCG (IU/L)	$< 10^3$	10^3 to $< 10^4$	10^4 to 10^5	$\geq 10^5$
Largest tumor size, including uterus (cm)	< 3	3 to 5	> 5	
Site of metastases	Lung	Spleen, kidney	Gastrointestinal tract	Brain, liver
Number of metastases identified	0	1 to 4	5 to 8	> 8
Previous failed chemotherapy	--	--	Single drug	Two or more drugs
Total score	--	--	--	--

*Appendix E: Dose Rounding Guidelines**

Weight-based Dose Range	Vial Quantity Recommendation
≤ 41.99 mg	1 vial of 40 mg/4 mL
42 mg-104.99 mg	1 vial of 100 mg/10 mL
105 mg-146.99 mg	1 vial of 40 mg/4 mL and 100 mg/10 mL
147 mg-209.99 mg	2 vials of 100 mg/10 mL
210 mg-251.99 mg	1 vial of 240 mg/24 mL
260 mg-293.99 mg	1 vial of 40 mg/4 mL and 240 mg/24 mL
294 mg-356.99 mg	1 vial of 100 mg/4 mL and 240 mg/24 mL
357 mg-503.99 mg	2 vials of 240 mg/24 mL

**This is part of a dose rounding guideline on select drug classes as part of an initiative conducted on a larger scale with multiple references and prescriber feedback.*

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Melanoma (unresectable or metastatic)	Monotherapy: 240 mg IV every 2 weeks or 480 mg IV every 4 weeks With ipilimumab: 1 mg/kg IV, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then nivolumab 240 mg IV every 2 weeks or 480 mg IV every 4 weeks	480 mg/dose

Indication	Dosing Regimen	Maximum Dose
Melanoma (adjuvant treatment) RCC - advanced with previous anti-angiogenic therapy, cHL, SCCHN, UC	240 mg IV every 2 weeks or 480 mg IV every 4 weeks	480 mg/dose
MSI-H/dMMR CRC	Monotherapy: 240 mg IV every 2 weeks or 480 mg IV every 4 weeks With ipilimumab: 3 mg/kg IV, followed by ipilimumab 1 mg/kg on the same day every 3 weeks for 4 doses, then nivolumab 240 mg IV every 2 weeks or 480 mg IV every 4 weeks	Monotherapy: 480 mg/dose With ipilimumab: 3 mg/kg/dose
RCC - advanced previously untreated	Monotherapy: 240 mg IV every 2 weeks or 480 mg every 4 weeks With ipilimumab: 3 mg/kg IV, followed by ipilimumab 1 mg/kg IV on the same day every 3 weeks for 4 doses, then nivolumab 240 mg IV every 2 weeks or 480 mg IV every 4 weeks	480 mg/dose
HCC	Monotherapy: 240 mg IV every 2 weeks or 480 mg every 4 weeks until disease progression or unacceptable toxicity With ipilimumab: nivolumab 1 mg/kg IV, followed by ipilimumab 3 mg/kg IV on the same day, every 3 weeks for a maximum of 4 doses, then as single-agent nivolumab 240 mg IV every 2 weeks or 480 mg IV every 4 weeks until disease progression or unacceptable toxicity	480 mg/dose
NSCLC	Monotherapy: 240 mg IV every 2 weeks or 480 mg IV every 4 weeks until disease progression or unacceptable toxicity With ipilimumab: nivolumab 3 mg/kg IV every 2 weeks and ipilimumab 1 mg/kg IV every 6 weeks until disease progression, unacceptable toxicity, or for up to 2 years in patients without disease progression With ipilimumab and platinum-doublet chemotherapy: nivolumab 360 mg IV every 3 weeks and ipilimumab 1 mg/kg IV every 6	Monotherapy: 480 mg/dose With ipilimumab: 3 mg/kg/dose With ipilimumab and platinum-doublet: 360 mg/dose

Indication	Dosing Regimen	Maximum Dose
	weeks and histology-based platinum-doublet chemotherapy every 3 weeks for 2 cycles until disease progression, unacceptable toxicity, or up to 2 years in patients without disease progression	
SCLC	240 mg IV every 2 weeks until disease progression or unacceptable toxicity	240 mg/dose
ESCC	240 mg IV every 2 weeks or 480 mg IV every 4 weeks until disease progression or unacceptable toxicity	480 mg/dose
Malignant pleural mesothelioma	With ipilimumab: nivolumab 360 mg every 3 weeks and ipilimumab 1 mg/kg every 6 weeks	With ipilimumab: 360 mg/dose

VI. Product Availability
Single-dose vials: 40 mg/4 mL, 100 mg/10 mL, 240 mg/24 mL

VII. References

1. Opdivo Prescribing Information. Princeton, NJ: Bristol-Myers Squibb; November 2020. Available at https://www.opdivo.com/. Accessed November 17, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at http://www.nccn.org. Accessed November 17, 2020.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 8.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed November 17, 2020.
4. Hellman MD, Paz-Ares L, Bernabe Caro R, et al. Nivolumab plus ipilimumab in advanced non-small-cell lung cancer. N Engl J Med. 2019 November; 381(21):2020-2031.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9299	Injection, nivolumab, 1 mg

Reviews, Revisions, and Approvals	Date
	01.21

Important Reminder
Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program

approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

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