CLINICAL MEDICATION POLICY	
Policy Name:	Opdivo® (Nivolumab)
Policy Number:	MP-015-MD-PA
Responsible Departments:	Medical Management Medical Policy; Clinical Pharmacy
Provider Notice Date:	06/01/2017
Original Effective Date:	07/01/2017
Annual Approval Date:	12/29/2017
Revision Date:	12/13/2016
Products:	Pennsylvania Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 11

Disclaimer

Gateway Health℠ (Gateway) clinical medication policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Gateway Health℠ may provide coverage under the medical or pharmacy benefits of the Company's Medicaid products for medically necessary intravenous infusions of Opdivo® (nivolumab).

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

DEFINITIONS

Medical Necessity: A service or benefit is medically necessary if it is compensable under the Medical Assistance program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition, or disability
- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental, or developmental effects of an illness, condition, injury, or disability.
- The service or benefit will assist the patient to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the patient and those functional capacities that are appropriate for patients of the same age.

PROCEDURES

1. The administration of Opdivo is provided for the following indications and criteria:

    A. Coverage may be provided when the diagnosis is unresectable or metastatic melanoma and the member meets the following criteria:
        1) The member is 18 years of age or older; AND
        2) Treatment is prescribed by an oncologist/hematologist; AND
        3) The member has Stage III (unresectable) or IV (metastatic) disease; AND
        4) Treatment will be used for BRAF V600 mutation positive or wild-type, as a single agent; OR
        5) Treatment will be used in combination with Yervoy (ipilimumab); AND
        6) The dosing is within the following prescribing-supported parameters:
            a) Monotherapy: Does not exceed 240 mg every 2 weeks; OR
            b) Opdivo is used in combination with Yervoy: Does not exceed 1 mg/kg (Opdivo), followed by 3 mg/kg (Yervoy) on the same day, every 3 weeks for 4 doses, then 240 mg (Opdivo) every 2 weeks

    B. Coverage may be provided when the diagnosis is metastatic squamous OR non-squamous non-small cell lung cancer and the member meets the following criteria:
        1) The member is 18 years of age or older; AND
        2) Treatment is prescribed by an oncologist/hematologist; AND
        3) Treatment will be used for progression on or after platinum-based chemotherapy; members with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Opdivo; AND
        4) The dosing is within the following prescribing-supported parameters: dose does not exceed 240 mg every 2 weeks

    C. Coverage may be provided when the diagnosis is renal cell carcinoma and the member meets the following criteria:
        1) The member is 18 years of age or older; AND
        2) Treatment is prescribed by an oncologist/hematologist; AND

3) The treatment will be used for advanced disease; AND
4) Treatment will be used in members who have received prior anti-angiogenic; AND
5) The dosing is within the following prescribing-supported parameters: dose does not exceed 240 mg every 2 weeks

D. Coverage may be provided when the diagnosis is classical Hodgkin lymphoma (cHL) and the member meets the following criteria:
1) The member is aged 18 years or older; AND
2) Treatment is prescribed by an oncologist/hematologist; AND
3) The member has relapsed or has progressed disease after autologous hematopoietic stem cell transplant AND post-transplant brentuximab vedotin (Adcetris®); AND
4) The dosing is within the following prescribing-supported parameters: dose does not exceed 3 mg/kg every 2 weeks

E. Coverage may be provided when the diagnosis is recurrent or metastatic squamous cell carcinoma of the head and neck and the member meets the following criteria:
1) The member is aged 18 years or older; AND
2) Treatment is prescribed by an oncologist/hematologist; AND
3) Treatment will be used for members with disease progression on or after a platinum-based therapy; AND
4) The dosing is within the following prescribing-supported parameters: dose does not exceed 3 mg/kg every 2 weeks

2. Warnings and Precautions
Members with active autoimmune disease or medical conditions requiring systemic immunosuppression or with symptomatic interstitial lung disease

3. When Opdivo services are not covered
Opdivo is not covered for conditions other than those listed above because the scientific evidence has not been established.

Coverage may be provided for any non-FDA labeled indication or a medically accepted indication that is supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis for which it is prescribed and will be reviewed on a case-by-case basis to determine medical necessity.

When non-formulary criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must over ride criteria when, in their professional judgment, the requested medication is medically necessary.

4. Post-payment Audit Statement
The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health℠ at any time pursuant to the terms of your provider agreement.

5. Place of Service
   The place of service for the administration of Opdivo is outpatient.

Governing Bodies Approval
On December 22, 2014, Opdivo was approved for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. This indication was approved under the accelerated approval based on tumor response rate and durability of response.

On March 4, 2015, the FDA granted approval for Opdivo for the treatment of patients with metastatic squamous non-small cell lung cancer with progression on or after platinum-based chemotherapy.

On November 23, 2015, the FDA granted approval of Opdivo for the treatment of patients with advanced (metastatic) renal cell carcinoma who have received a prior therapy.

On May 16, 2016, the FDA granted accelerated approval to nivolumab (Opdivo) for the treatment of patients with classical Hodgkin lymphoma (cHL) that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and post-transplantation brentuximab vedotin (Adcetris®).

CODING REQUIREMENTS

Procedure Codes:

HCPCS Code	Description
J9299	Injection, Nivolumab, 1 mg

Diagnosis Codes:

ICD-10 Codes	Description
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C31.01	Malignant neoplasm of right main bronchus
C31.02	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
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
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, expect renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
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
C79.31	Secondary malignant neoplasm of brain
C80.0	Disseminated malignant neoplasm, unspecified
C80.1	Malignant (primary) neoplasm, unspecified
C81.00	Nodular lymphocyte predominate Hodgkin lymphoma, unspecified site
C81.01	Nodular lymphocyte predominate Hodgkin lymphoma, lymph nodes of head, face and neck
C81.02	Nodular lymphocyte predominate Hodgkin lymphoma, intrathoracic lymph nodes
C81.03	Nodular lymphocyte predominate Hodgkin lymphoma, intra-abdominal lymph nodes
C81.04	Nodular lymphocyte predominate Hodgkin lymphoma, lymph nodes of axilla and upper limb

C81.05	Nodular lymphocyte predominate Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.06	Nodular lymphocyte predominate Hodgkin lymphoma, intrapelvic lymph nodes
C81.07	Nodular lymphocyte predominate Hodgkin lymphoma, spleen
C81.08	Nodular lymphocyte predominate Hodgkin lymphoma, lymph nodes of multiple sites
C81.09	Nodular lymphocyte predominate Hodgkin lymphoma, extranodal and solid organ sites
C81.10	Nodular sclerosis classical Hodgkin lymphoma, unspecified site
C81.11	Nodular sclerosis classical Hodgkin lymphoma, lymph nodes of head, face and neck
C81.12	Nodular sclerosis classical Hodgkin lymphoma, intrathoracic lymph nodes
C81.13	Nodular sclerosis classical Hodgkin lymphoma, intra-abdominal lymph nodes
C81.14	Nodular sclerosis classical Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.15	Nodular sclerosis classical Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.16	Nodular sclerosis classical Hodgkin lymphoma, intrapelvic lymph nodes
C81.17	Nodular sclerosis classical Hodgkin lymphoma, spleen
C81.18	Nodular sclerosis classical Hodgkin lymphoma, lymph nodes of multiple sites
C81.19	Nodular sclerosis classical Hodgkin lymphoma, extranodal and solid organ sites
C81.20	Mixed cellularity classical Hodgkin lymphoma, unspecified site
C81.21	Mixed cellularity classical Hodgkin lymphoma, lymph nodes of head, face and neck
C81.22	Mixed cellularity classical Hodgkin lymphoma, intrathoracic lymph nodes
C81.23	Mixed cellularity classical Hodgkin lymphoma, intra-abdominal lymph nodes
C81.24	Mixed cellularity classical Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.25	Mixed cellularity classical Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.26	Mixed cellularity classical Hodgkin lymphoma, intrapelvic lymph nodes
C81.27	Mixed cellularity classical Hodgkin lymphoma, spleen
C81.28	Mixed cellularity classical Hodgkin lymphoma, lymph nodes of multiple sites
C81.29	Mixed cellularity classical Hodgkin lymphoma, extranodal and solid organs
C81.30	Lymphocyte depleted classical Hodgkin lymphoma, unspecified site
C81.31	Lymphocyte depleted classical Hodgkin lymphoma, lymph nodes of head, face and neck
C81.32	Lymphocyte depleted classical Hodgkin lymphoma, intrathoracic lymph nodes
C81.33	Lymphocyte depleted classical Hodgkin lymphoma, intra-abdominal lymph nodes
C81.34	Lymphocyte depleted classical Hodgkin lymphoma, lymph nodes of axilla and upper limb

C81.35	Lymphocyte depleted classical Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.36	Lymphocyte depleted classical Hodgkin lymphoma, intrapelvic lymph nodes
C81.37	Lymphocyte depleted classical Hodgkin lymphoma, spleen
C81.38	Lymphocyte depleted classical Hodgkin lymphoma, lymph nodes of multiple sites
C81.39	Lymphocyte depleted classical Hodgkin lymphoma, extranodal and solid organ sites
C81.40	Lymphocyte-rich classical Hodgkin lymphoma, unspecified site
C81.41	Lymphocyte-rich classical Hodgkin lymphoma, lymph nodes of head, face and neck
C81.42	Lymphocyte-rich classical Hodgkin lymphoma, intrathoracic lymph nodes
C81.43	Lymphocyte-rich classical Hodgkin lymphoma, intra-abdominal lymph nodes
C81.44	Lymphocyte-rich classical Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.45	Lymphocyte-rich classical Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.46	Lymphocyte-rich classical Hodgkin lymphoma, intrapelvic lymph nodes
C81.47	Lymphocyte-rich classical Hodgkin lymphoma, spleen
C81.48	Lymphocyte-rich classical Hodgkin lymphoma, lymph nodes of multiple sites
C81.49	Lymphocyte-rich classical Hodgkin lymphoma, extranodal and solid organ sites
C81.70	Other classical Hodgkin lymphoma, unspecified site
C81.71	Other classical Hodgkin lymphoma, lymph nodes of head, face and neck
C81.72	Other classical Hodgkin lymphoma, intrathoracic lymph nodes
C81.73	Other classical Hodgkin lymphoma, intra-abdominal lymph nodes
C81.74	Other classical Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.75	Other classical Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.76	Other classical Hodgkin lymphoma, intrapelvic lymph nodes
C81.77	Other classical Hodgkin lymphoma, spleen
C81.78	Other classical Hodgkin lymphoma, lymph nodes of multiple sites
C81.79	Other classical Hodgkin lymphoma, extranodal and solid organ sites
C81.90	Hodgkin lymphoma, unspecified, 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

D03.0	Melanoma in situ of lip
D03.10	Melanoma in situ of unspecified eyelid, including canthus
D03.11	Melanoma in situ of right eyelid, including canthus
D03.12	Melanoma in situ of left eyelid, including canthus
D03.2	Melanoma in situ of ear and external auricular canal
D03.20	Melanoma in situ of unspecified ear and external auricular canal
D03.21	Melanoma in situ of right ear and external auricular canal
D03.22	Melanoma in situ of left ear and external auricular canal
D03.3	Melanoma in situ of other and unspecified parts of face
D03.30	Melanoma in situ of unspecified part of face
D03.39	Melanoma in situ of other parts pf face
D03.4	Melanoma in situ of scalp and neck
D03.5	Melanoma in situ of trunk
D03.51	Melanoma in situ of anal skin
D03.52	Melanoma in situ of breast (skin) (soft tissue)
D03.59	Melanoma in situ of other parts of trunk
D03.6	Melanoma in situ of upper limb, including shoulder
D03.60	Melanoma in situ of unspecified upper limb, including shoulder
D03.61	Melanoma in situ of right upper limb, including shoulder
D03.62	Melanoma in situ of left upper limb, including shoulder
D03.7	Melanoma in situ of lower limb, including hip
D03.70	Melanoma in situ of unspecified lower limb, including hip
D03.71	Melanoma in situ of right lower limb, including hip
D03.72	Melanoma in situ of left lower limb, including hip
D03.8	Melanoma in situ of other sites
D03.9	Melanoma in situ, unspecified
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.528	Personal history of other malignant neoplasm of kidney
Z85.53	Personal history of malignant neoplasm of renal pelvis
Z85.820	Personal history of malignant melanoma of skin

REIMBURSEMENT

Participating facilities will be reimbursed per their Gateway Health℠ contract.

SUMMARY OF LITERATURE

Immune-mediated pneumonitis or interstitial lung disease, defined as requiring use of corticosteroids and no clear alternate etiology, including fatal cases, occurred with Opdivo treatment. Across clinical trial experience with solid tumors receiving Opdivo as a single agent, fatal immune-mediated pneumonitis occurred in 0.4% (5/1384) of patients. All five fatal cases occurred in a dose-finding study with Opdivo doses of 1 mg/kg (two patients), 3 mg/kg (two patients), and 10 mg/kg (one patient).

Per the drug package insert:

Withhold Opdivo for any of the following:

1. Grade 2 pneumonitis *[see Warnings and Precautions (5.1)]*
2. Grade 2 or 3 colitis *[see Warnings and Precautions (5.2)]*
3. Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) greater than 3 and up to 5 times upper limit of normal (ULN) or total bilirubin greater than 1.5 and up to 3 times ULN *[see Warnings and Precautions (5.3)]*
4. Creatinine greater than 1.5 and up to 6 times ULN or greater than 1.5 times baseline *[see Warnings and Precautions (5.4)]*
5. Any other severe or Grade 3 treatment or Grade 4 rash treatment-related adverse reactions *[see Warnings and Precautions (5.6)]*

Resume Opdivo in patients whose adverse reactions recover to Grade 0-1.

Permanently discontinue Opdivo for any of the following:

1. Any life-threatening or Grade 4 adverse reaction
2. Grade 3 or 4 pneumonitis *[see Warnings and Precautions (5.1)]*
3. Grade 4 colitis *[see Warnings and Precautions (5.2)]*
4. AST or ALT greater than 5 times ULN or total bilirubin greater than 3 times ULN *[see Warnings and Precautions (5.3)]*
5. Creatinine greater than 6 times ULN *[see Warnings and Precautions (5.4)]*
6. Any severe or Grade 3 treatment-related adverse reaction that recurs
7. Inability to reduce corticosteroid dose to 10 mg or less of prednisone or equivalent per day within 12 weeks
8. Persistent Grade 2 or 3 treatment-related adverse reactions that do not recover to Grade 0-1 within 12 weeks after last dose of Opdivo

POLICY SOURCE(S)

National Comprehensive Cancer Network®. NCCN clinical practice guidelines in oncology (NCCN Guidelines®). Kidney Cancer, v.2.2016 [cited 2015 Nov 25]. Accessed on March 14, 2016 and available from: http://www.nccn.org/professionals/physician_gls/f_guidelines.asp.

National Comprehensive Cancer Network®. NCCN clinical practice guidelines in oncology (NCCN Guidelines®). Melanoma, v.1.2016 [cited 2015 Nov 10]. Accessed on March 14, 2016 and available from: http://www.nccn.org/professionals/physician_gls/f_guidelines.asp.

NCCN Drugs & Biologics Compendium [Internet]. Fort Washington (PA): National Comprehensive Cancer Network; 2015 [cited 2015-Nov 25]. Accessed on March 14, 2016 and available from: http://www.nccn.org/professionals/drug_compendium/content/contents.asp/.

OPDIVO® (Nivolumab) injection [package insert]. Bristol-Myers Squibb Company. Princeton, NJ. September 2015. Accessed on March 14, 2016 and available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125554s012lbl.pdf.

OPDIVO® (Nivolumab) injection [package insert]. Bristol-Myers Squibb Company. Princeton, NJ. May 2016. Accessed on July 27, 2016 and available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125554s019lbl.pdf.

Orphan Drug Designations and Approval [Internet]. Silver Spring (MD): U.S. Food and Drug Administration. Accessed on March 14, 2016 and available from: http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm/.

Postow MA, Chesney J, Pavlick AC, et al. Nivolumab and ipilimumab versus ipilimumab in untreated melanoma. New Engl J Med. 2015; 372: 2006-17. Accessed on March 14, 2016 and available at: http://www.nejm.org/doi/full/10.1056/NEJMoa1414428.

Motzer RJ, Escudier B, McDermott DF, et al. CheckMate 025 Investigators. Nivolumab versus everolimus in advanced renal-cell carcinoma. N Engl J Med. 2015 Sep 25. [Epub ahead of print]. Accessed on March 14, 2016 and available at: http://www.nejm.org/doi/full/10.1056/NEJMoa1510665.

Larkin J, Chiarion-Sileni V, Gonzalez R, et al. Combined nivolumab and ipilimumab or monotherapy in untreated melanoma. N Engl J Med. 2015; 373(1):23-34. Accessed on March 16, 2016 and available at: http://www.ncbi.nlm.nih.gov/pubmed/26027431.

Hodi FS, O'Day SJ, McDermott DF, et al. Improved survival with ipilimumab in patients with metastatic melanoma. N Engl J Med. 2010; 363:711-23. Accessed on March 14, 2016. And available at: http://www.nejm.org/doi/full/10.1056/NEJMoa1003466.

Borghaei H, Paz-Ares L, Horn L, et al. Nivolumab versus docetaxel in advanced nonsquamous non-small cell lung cancer. *N Engl J Med.* 2015; 373:1627-1639. Accessed on March 14, 2016 and abstract available at: http://www.nejm.org/doi/full/10.1056/NEJMoa1507643.

Policy History

Date	Activity
03/28/2016	Initial policy developed
12/01/2016	Provider effective date
12/13/2016	Revisions update **Criteria Changes:** • Treatment criteria for **unresectable/metastatic melanoma** was updated to include single agent; • Drug interaction deletion for **unresectable/ metastatic melanoma** - *The patient has not been treated previously with a PD-1 inhibitor (e.g., Keytruda®);* • Treatment type criteria deletion for **unresectable/ metastatic melanoma** occurred for Yervoy combination, as first-line therapy/subsequent therapy and ECOG performance status was eliminated per Pharmacy requirement - *as first-line therapy or as subsequent therapy for disease progression or following maximum clinical benefit from BRAF targeted therapy for patients with a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2*; • Treatment type description of monotherapy for subsequent therapy and the ECOG status was removed for **non-squamous non-small cell lung cancer** indication- *The drug is being used as monotherapy for subsequent therapy with disease progression after platinum-based chemotherapy in patients with a current ECOG performance status of 0-2*; • **non-squamous non-small cell lung cancer** The Genomic tumor aberration note was added into revised policy under the platinum-based chemotherapy criteria - *Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Opdivo*; • The disease criteria was revised for **Renal cell carcinoma** -- OLD CRITERIA: *The patient has experienced a relapse or Stage IV disease that is surgically unresectable* NEW CRITERIA*: The Treatment will be used for advanced disease;* • The treatment type was removed from the **renal cell carcinoma** indication - *The drug is being used as monotherapy for subsequent therapy in disease that has progressed after treatment with a tyrosine kinase inhibitor*; • Age criteria deletion for **Hodgkin lymphoma** - *The patient is not aged 55 years or older; Complete addition of head and neck squamous cell disease indication* • Dosing was updated to match the FDA dosing requirements for **all disease indications**
05/17/2017	QI/UM approval
07/01/2017	Provider effective date