Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Keytruda (pembrolizumab)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Keytruda (pembrolizumab)

APPROVAL CRITERIA

Requests of Keytruda (pembrolizumab) may be approved if the following criteria are met:

I. Individual has a diagnosis of recurrent or metastatic Cervical Cancer; **AND**
   A. Individual is using as monotherapy; **AND**
   B. Individual has a tumor with PD-L1 gene expression with Combined Positive Score (CPS) of greater than or equal to 1; **AND**
   C. Individual has not received treatment with another anti-PD-1 or anti-PD-L1agent ; **AND**
   D. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2; **AND**
   E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

II. Individual has a diagnosis of Colorectal Cancer; **AND**
   A. Individual is using as monotherapy; **AND**
   B. Individual meets **one** of the following criteria:
      1. Primary treatment as a single agent for unresectable metachronous metastases (defective mismatch repair/high microsatellite instability [dMMR/MSIH] only) and previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months; **OR**
      2. Subsequent therapy as a single agent (if nivolumab or pembrolizumab not previously given) for unresectable advanced or metastatic disease (dMMR/MSIH only) following previous treatment with one of the following:
         a. Oxaliplatin-irinotecan and fluoropyrimidine-based therapy; **OR**
         b. Oxaliplatin-irinotecan;

   AND
   C. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   D. Individual has a current ECOG performance status of 0-2; **AND**
   E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

OR

III. Individual has a diagnosis of advanced Endometrial Cancer (not dMMR/MSIH); **AND**
   A. Individual is using in combination with lenvatinib; **AND**
   B. Individual has confirmed disease progression after one or more prior lines of systemic therapy; **AND**
   C. Individual is not a candidate for curative surgery or radiation; **AND**
   D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   E. Individual has a current ECOG performance status of 0-2; **AND**
   F. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

IV. Individual has a diagnosis for recurrent locally advanced or metastatic squamous cell Esophageal Cancer; **AND**
   A. Individual is using as monotherapy; **AND**
   B. Individual has a tumor with PD-L1 gene expression with CPS of greater than or equal to 10; **AND**
   C. Individual has demonstrated disease progression after one or more prior lines of systemic therapy; **AND**
   D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   E. Individual has a current ECOG performance status of 0-2; **AND**
   F. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

V. Individual has a diagnosis for the recurrent locally advanced or metastatic Gastric or Gastroesophageal Junction Adenocarcinoma; **AND**
   A. Individual is using as monotherapy; **AND**
   B. Individual has a tumor with PD-L1 gene expression with CPS of greater than or equal to 1; **AND**
   C. Individual has demonstrated disease progression on or after two or more prior lines of therapy including fluoropyrimidine and platinum-containing chemotherapy, if appropriate HER2/neu-targeted therapy; **AND**
   D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent ; **AND**
   E. Individual has a current ECOG performance status of 0-2; **AND**
   F. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

VI. Individual has a diagnosis of recurrent, unresectable, or metastatic Head and Neck

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Squamous Cell Carcinoma (HNSCC); **AND**

A. Individual is using as monotherapy; **AND**
    1. Individual meets one of the following:
        a. Individual is using as first-line treatment for tumor with PD-L1 gene expression with CPS of greater than or equal to 1; **OR**
        b. Individual has demonstrated disease progression on or after platinum-containing chemotherapy;

OR

B. Individual is using as first-line treatment in combination with platinum-containing chemotherapy and fluorouracil regardless of PD-L1 expression; **AND**
C. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
D. Individual has a current ECOG performance status of 0-2; **AND**
E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

VII. Individual has a diagnosis of Hepatocellular Carcinoma (HCC); **AND**
    A. Individual has Child-Pugh Class A advanced HCC; **AND**
    B. Individual is using as monotherapy; **AND**
    C. Individual has demonstrated disease progression or intolerance on or after treatment with an approved first-line agent; **AND**
    D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
    E. Individual has a current ECOG performance status of 0-2; **AND**
    F. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

VIII. Individual has a diagnosis of relapsed or refractory Hodgkin lymphoma, except for those with lymphocyte-predominant Hodgkin lymphoma (Label, NCCN 2A);

OR

IX. Individual has a diagnosis of Malignant Pleural Mesothelioma; **AND**
    A. Individual is using as subsequent therapy; **OR**
    B. Individual is ineligible for platinum-based chemotherapy, defined as having one or more of the following risk factors for platinum-based chemotherapy toxicity:
        1. ECOG performance status equal to 2;
        2. Glomerular filtration rate less than 60 mL/min;
        3. Hearing loss (measured at audiometry) of 25 dB at two contiguous frequencies;
        4. Grade 2 or greater peripheral neuropathy; **AND**
    C. Individual is using as monotherapy; **AND**
    D. Individual has a current ECOG performance status of 0-2; **AND**
    E. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent ; **AND**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

F. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

X. Individual has a diagnosis of Melanoma (cutaneous and uveal); **AND**
   A. Individual has confirmed presence of unresectable or metastatic melanoma; **AND**
   B. Individual is using as monotherapy; **AND**
   C. Individual meets one of the following:
      1. Individual is using as first-line therapy in untreated disease; **OR**
      2. Individual is using as second-line or subsequent therapy for confirmed disease progression while receiving or since completed most recent therapy;

   AND
   D. Individual has a current ECOG performance status of 0-2; **AND**
   E. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   F. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

XI. Individual has a diagnosis of Melanoma (cutaneous and uveal); **AND**
   A. Individual has resected, high-risk stage III disease; **AND**
   B. Individual is using as monotherapy; **AND**
   C. Individual is using adjuvant therapy for up to 12 months; **AND**
   D. Individual has current ECOG performance status of 0-2; **AND**
   E. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   F. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

XII. Individual has a diagnosis of Merkel Cell Carcinoma (MCC); **AND**
   A. Individual is using as monotherapy; **AND**
   B. Individual has presence of metastatic or advanced locoregional MCC determined to be not amenable to definitive surgery or radiation therapy; **AND**
   C. Individual has a current ECOG performance status of 0-2; **AND**
   D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

XIII. Individual has a diagnosis of Non-Hodgkin Lymphoma, Primary Mediastinal Large B-Cell Lymphoma; **AND**
   A. Individual is using as monotherapy; **AND**
   B. Individual is using to treat refractory disease or subsequent therapy for disease relapse after receiving two or more prior lines of therapy; **AND**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

C. Individual has a current ECOG performance status 0-2; **AND**
D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

XIV. Individual has a diagnosis of locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) (Label, NCCN 2A); **AND**
A. Individual is using for the first-line treatment; **AND**
B. Individual's disease is confirmed cytologically as stage III or IV NSCLC; **AND**
C. Individual is using as monotherapy; **AND**
D. Confirmation tumor expresses PD-L1 gene on at least 1% or greater of tumor cells; **AND**
E. Individual has confirmation of EGFR, ALK, ROS1, and BRAF mutations that are negative or unknown; **AND**
F. Individual has not received another anti-PD-1 or anti-PD-L1 agent and has not undergone previous systemic therapy for metastatic disease; **AND**
G. Individual has a current ECOG performance status of 0-2; **AND**
H. Individual is not receiving therapy for an autoimmune disease, chronic condition or interstitial lung disease with a systemic immunosuppressant;

OR

XV. Individual has a diagnosis of advanced or metastatic nonsquamous NSCLC (Label, NCCN 2A); **AND**
A. Individual is using for first-line treatment; **AND**
B. Disease is confirmed cytologically as stage IIIb or IV NSCLC; **AND**
C. Individual is using in combination with pemetrexed and a platinum agent; **AND**
D. Individual has confirmation of EGFR, ALK, ROS1, and BRAF mutations that are negative or unknown
; **AND**
E. Individual has not received another anti-PD-1 or anti-PD-L1 agent and has not undergone previous systemic therapy for metastatic disease; **AND**
F. Individual has a current ECOG performance status of 0-2; **AND**
G. Individual is not receiving therapy for an autoimmune disease, chronic condition or interstitial lung disease with a systemic immunosuppressant;

OR

XVI. Individual has a diagnosis of metastatic squamous NSCLC (Label, NCCN 2A); **AND**
A. Individual is using for first line treatment; **AND**
B. Disease is confirmed cytologically as stage IV NSCLC; **AND**
C. Individual is using combination with carboplatin plus paclitaxel or nab-paclitaxel; **AND**
D. Individual has confirmation of EGFR, ALK, ROS1, and BRAF mutations that are negative or unknown; **AND**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

E. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent and has not undergone previous systemic therapy for metastatic disease; **AND**
F. Individual has a current ECOG performance status of 0-2; **AND**
G. Individual is not receiving therapy for an autoimmune disease, chronic condition or interstitial lung disease with a systemic immunosuppressant;

OR

XVII. Individual has a diagnosis of recurrent or metastatic nonsquamous NSCLC; **AND**
A. Individual is using in combination with pemetrexed as **continuation maintenance therapy**, if given first-line as part of pembrolizumab/pemetrexed and platinum-based regimen; **AND**
B. Individual has confirmed achievement tumor response or stable disease following initial cytotoxic therapy; **AND**
C. Individual has not received another anti-PD-1 or anti-PD-L1 agent ; **AND**
D. Individual has a current ECOG performance status of 0-2; **AND**
E. Individual is not receiving therapy for an autoimmune disease, chronic condition or interstitial lung disease with a systemic immunosuppressant;

OR

XVIII. Individual has a diagnosis of recurrent or metastatic squamous cell NSCLC; **AND**
A. Individual is using as monotherapy as **continuation maintenance therapy**, if given first-line as part of pembrolizumab/carboplatin/paclitaxel (or nab-paclitaxel) regimen; **AND**
B. Individual has confirmed achievement of tumor response or stable disease following initial cytotoxic therapy; **AND**
C. Individual has not received another anti-PD-1 or anti-PD-L1 agent; **AND**
D. Individual has a current ECOG performance status of 0-2; **AND**
E. Individual is not receiving therapy for an autoimmune disease, chronic condition or interstitial lung disease with a systemic immunosuppressant;

OR

XIX. Individual has a diagnosis of metastatic NSCLC; **AND**
A. Individual is using as monotherapy in second or subsequent line of therapy; **AND**
B. Individual has confirmed tumor with PD-L1 gene expression level greater than or equal to 1% with disease progression on or after platinum-containing chemotherapy; **AND**
C. If individual has anaplastic lymphoma kinase (ALK) or epidermal growth factor receptor (EGFR) genomic tumor aberrations are present, must have demonstrated disease progression on U.S. Food and Drug Administration (FDA) approved therapy for the aberrations prior to receiving pembrolizumab (Keytruda); **AND**
D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
E. Individual has a current ECOG performance status of 0-2; **AND**
F. Individual is not receiving therapy for an autoimmune disease, chronic condition or

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

interstitial lung disease with a- systemic immunosuppressant;

OR

XX. Individual has diagnosis of advanced Renal Cell Carcinoma (RCC) (Label, NCCN 2A); **AND**
- A. Individual has histological confirmation of RCC with clear cell component; **AND**
- B. Individual is using as first-line therapy; **AND**
- C. Individual is using in combination with axitinib; **AND**
- D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
- E. Individual has a current Karnofsky performance status of ≥ 70%; **AND**
- F. Individual is not receiving therapy for an autoimmune disease, chronic condition, or interstitial lung disease with a systemic immunosuppressant;

OR

XXI. Individual has a diagnosis of Small Cell Lung Cancer (NCCN 2A); **AND**
- A. Individual is using as monotherapy as subsequent therapy; **AND**
- B. Individual meets one of the following:
  1. Individual has confirmed disease relapse within 6 months following complete or partial response or stable disease with initial treatment; **OR**
  2. Individual has confirmed primary progressive disease; **OR**
  3. Individual has no response with initial treatment;

AND
- D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
- E. Individual has a current ECOG performance status of 0-2; **AND**
- F. Individual is not receiving therapy for an autoimmune disease, chronic condition or interstitial lung disease with a systemic immunosuppressant;

OR

XXII. Individual has a diagnosis of unresectable or metastatic Thymic Carcinoma (NCCN 2A); **AND**
- A. Individual is using as monotherapy; **AND**
- B. Individual has confirmed disease progression following chemotherapy; **AND**
- C. Individual does not have thymomas; **AND**
- D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
- E. Individual has a current ECOG performance status of 0-2; **AND**
- F. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

XXIII. Individual has a diagnosis of unresectable or metastatic solid tumors (dMMR/MSIH only); **AND**
- A. Individual is using as monotherapy; **AND**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

B. Individual has confirmed disease progression following prior treatment with no other satisfactory alternative treatment options; **AND**
C. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
D. Individual's has a current ECOG performance status of 0-2; **AND**
E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

XXIV. Individual has a diagnosis of locally advanced or metastatic Urothelial Carcinoma; **AND**
A. Individual is using as monotherapy; **AND**
B. Individual meets one of the following:
1. Individual is not eligible for any platinum-containing chemotherapy; **OR**
2. Individual is not eligible for cisplatin- containing chemotherapy, and tumor expresses PD-L1 with CPS of greater than or equal to 10; **OR**
3. Individual has confirmed disease progression on or after platinum-containing chemotherapy; **OR**
4. Individual has confirmed disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy;

AND

C. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
D. Individual has a current ECOG performance status of 0-2; **AND**
E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

XXV. Individual has a diagnosis of high risk non-muscle invasive (T1, high grade Ta, and/or carcinoma in situ [CIS]) Urothelial Carcinoma of the Bladder with or without papillary tumors (Label, NCT02625961); **AND**
A. Individual has Bacillus Calmette-Guerin (BCG)- unresponsive disease defined as one of the following:
1. Persistent disease despite adequate BCG therapy (adequate defined as administration of at least 5 doses of an initial induction course *plus either* at least 2 doses of maintenance therapy or at least 2 doses of a second induction course); **OR**
2. Disease recurrence after an initial tumor-free state following adequate BCG therapy (adequate defined as administration of at least 5 doses of an initial induction course *plus either* at least 2 doses of maintenance therapy or at least 2 doses of a second induction course); **OR**
3. T1 disease (i.e., tumor has spread to the connective tissue, but not the muscle) following a single induction course of BCG; **AND**
B. Individual is ineligible for cystectomy; **AND**
C. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
D. Individual has a current ECOG performance status of 0-2; **AND**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

Requests for Keytruda (pembrolizumab) may not be approved when the above criteria are not met and for all other indications.

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    a. Anal Carcinoma V1.2020. Revised November 19, 2019.
    b. B-Cell Lymphomas V1.2020. Revised January 22, 2020.
    c. Bladder Cancer V3.2020. Revised January 17, 2020.
    d. Bone Cancer V1.2020. Revised August 12, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

e. Breast Cancer V3.2020. Revised March 6, 2020.
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j. Esophageal and Esophagogastric Junction Cancers. V1.2020. Revised March 18, 2020.
k. Gastric Cancer V1.2020. Revised March 19, 2020.
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m. Head and Neck Cancer V1.2020. Revised February 12, 2020.
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o. Hodgkin Lymphoma V2.2020. Revised April 17, 2020.
p. Kidney Cancer V2.2020. Revised August 5, 2019.
q. Malignant Pleural Mesothelioma V1.2020. Revised November 27, 2019.
r. Merkel Cell Carcinoma V1.2020. Revised October 2, 2019.
s. Neuroendocrine and Adrenal Tumors V1.2019. Revised March 5, 2019.
t. Non-Small Cell Lung Cancer. V3.2020. Revised February 11, 2020.
u. Occult Primary. V2.2020. Revised January 31, 2020.
v. Ovarian Cancer V1.2020. Revised March 11, 2020.
w. Pancreatic Adenocarcinoma V1.2020. November 26, 2019.
x. Penile Cancer V1.2020. Revised January 14, 2020.
y. Primary Cutaneous Lymphomas. V2.2020. Revised April 10, 2020.
z. Rectal Cancer V2.2020. Revised March 3, 2020.
aa. Small Bowel Adenocarcinoma V1.2020. Revised July 30, 2019.
bb. Small Cell Lung Cancer. V3.2020. Revised February 5, 2020.
cc. T-Cell Lymphomas V1.2020. Revised January 6, 2020.
dd. Testicular cancer V2.2020. Revised November 20, 2019.
ee. Thymomas and Thymic Carcinomas V1.2020. Revised November 27, 2019.
ff. Uterine Neoplasms V1.2020. Revised March 6, 2020.
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hh. Vulvar Cancer (Squamous Cell Carcinoma) V1.2020. Revised January 29, 2020.

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