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

Tecentriq (atezolizumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Tecentriq (atezolizumab)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Tecentriq (atezolizumab) may be approved if following criteria are met:

I. Individual has a diagnosis of one of the following:
   A. First-line treatment of metastatic or unresectable, locally advanced, histologically confirmed triple-negative Breast Cancer (lack of estrogen- and progesterone-receptor expression and no overexpression of HER2) (NCCN 2A); **AND**
      1. Individual is using in combination with nab-paclitaxel (paclitaxel, protein-bound); **AND**
      2. Individual has PD-L1 expression on tumor-infiltrating immune cells [IC] covering greater than or equal to 1% [IC ≥ 1%] of the tumor area; **AND**
      3. Individual has a current ECOG performance status of 0-2; **AND**
      4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
      5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

   OR

   B. First-line treatment of advanced, unresectable, or metastatic hepatocellular carcinoma (HCC) (Label, NCCN 2A); **AND**
      1. Individual is using in combination with bevacizumab (or bevacizumab biosimilar); **AND**
      2. Individual has Child-Pugh Class A; **AND**
      3. Individual has an ECOG performance status of 0-2; **AND**
      4. Individual has not had previous treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
      5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

   OR

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C. First-line treatment of recurrent, advanced or metastatic nonsquamous Non-Small Cell Lung Cancer (NSCLC); **AND**
   1. Individual is using in a combination regimen with nab-paclitaxel (paclitaxel, protein-bound) and carboplatin; **AND**
   2. Individual has confirmation of EGFR, ALK, ROS1, and BRAF mutations that are negative or unknown; **AND**
   3. Individual has a ECOG performance status of 0-2; **AND**
   4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
   5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

D. First-line treatment of recurrent, advanced or metastatic nonsquamous NSCLC (Label, NCCN 1, 2A); **AND**
   1. Individual is using in a combination regimen with carboplatin, paclitaxel, and bevacizumab (or bevacizumab biosimilar); **AND**
   2. Individual has confirmation of EGFR, ALK, ROS1, and BRAF mutations that are negative or unknown; **AND**
   3. Individual has a current ECOG performance status of 0-2; **AND**
   4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
   5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

E. Continuation maintenance therapy for recurrent, advanced or metastatic nonsquamous NSCLC (Label, NCCN 1, 2A); **AND**
   1. Individual is using in combination with or without bevacizumab (or bevacizumab biosimilar); **AND**
   2. Individual has confirmation of achievement of tumor response or stable disease following initial cytotoxic therapy (first-line atezolizumab/carboplatin; paclitaxel/bevacizumab regimen **or** atezolizumab/carboplatin/nab-paclitaxel regimen); **AND**
   3. Individual has a current ECOG performance status of 0-2; **AND**
   4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
   5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

F. Subsequent treatment of recurrent, advanced or metastatic NSCLC (nonsquamous or squamous) (Label, NCCN); **AND**
   1. Disease has progressed during or following platinum-containing chemotherapy (for example, cisplatin); **AND**

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Applicable	X	X	X	X	X	X

2. When anaplastic lymphoma kinase (ALK) or epidermal growth factor receptor (EGFR) genomic tumor aberrations are present, must have demonstrated disease progression; **AND**
3. Individual has a current ECOG performance status of 0-2; **AND**
4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

G. Subsequent treatment of recurrent, advanced or metastatic nonsquamous NSCLC (NCCN 1, 2A); **AND**
   1. Disease has progressed during or following treatment with a targeted agent for the expressed oncogene (for example, kinase inhibitors that target EGFR, ALK, ROS1, BRAF, or NTRK mutations); **AND**
   2. Individual is using in a combination regimen with *one* of the following:
      a. Carboplatin, paclitaxel, and bevacizumab (or bevacizumab biosimilar); **OR**
      b. Carboplatin and nab-paclitaxel (albumin-bound paclitaxel); **AND**
   3. Individual has a ECOG performance status of 0-2; **AND**
   4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
   5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

H. First-line treatment of metastatic NSCLC; **AND**
   1. Individual is using as monotherapy; **AND**
   2. Individual has *one* of the following:
      a. Individual has PD-L1 expression on tumor cells [TC] that is greater than or equal to 50% [TC ≥ 50%], as confirmed through an FDA-approved test; **OR**
      b. Individual has PD-L1 expression on tumor-infiltrating immune cells [IC] covering greater than or equal to 10% [IC ≥ 10%] of the tumor area, as confirmed by an FDA-approved test; **AND**
   3. Individual has confirmation of EGFR or ALK mutations that are negative or unknown; **AND**
   4. Individual has a ECOG performance status of 0-2; **AND**
   5. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
   6. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

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I. Treatment of unresectable or metastatic Melanoma; AND
   1. Individual is using in combination with cobimetinib and vemurafenib; **AND**
   2. Individual has BRAF V600 mutation positive disease with test result confirmed; **AND**
   3. Individual has ECOG performance status of 0-2; **AND**
   4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
   5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

J. First-line treatment of extensive-stage Small Cell Lung Cancer (SCLC) (Label, NCCN 1); **AND**
   1. Individual is using in combination with etoposide and carboplatin (followed by maintenance atezolizumab monotherapy); **AND**
   2. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
   3. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

OR

K. First-line treatment of locally advanced or metastatic Urothelial Carcinoma; **AND**
   1. Individual is ineligible for any platinum-containing chemotherapy;
      OR
   2. Individual is not eligible for cisplatin-containing chemotherapy, and tumor testing indicates that PD-L1 stained tumor-infiltrating immune cells [IC] covers greater than or equal to 5% [IC ≥ 5%] of the tumor area through FDA-approved test;

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

OR

L. Subsequent treatment of locally advanced or metastatic Urothelial Carcinoma ; **AND**
   1. Individual has disease progression during or following platinum-containing chemotherapy (for example, cisplatin);
      OR
   2. Individual has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; **AND**
   3. Individual has a current ECOG performance status of 0-2; **AND**

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4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant**.**

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

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    a. Bladder Cancer. V3.2020. Revised January 17, 2020.
    b. Breast Cancer. V3.2020. Revised March 6, 2020.
    c. Cutaneous Melanoma. V4.2020. Revised September 1, 2020.
    d. Hepatobiliary Cancers. V1.2020. Revised March 23, 2020.
    e. Non-Small Cell Lung Cancer. V5.2020. Revised May 27, 2020.
    f. Small Cell Lung Cancer. V3.2020. Revised February 5, 2020.

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.

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Applicable	X	X	X	X	X	X

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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