Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Atezolizumab (Tecentriq®)	MP-RX-FP-88-23	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B DRUG

Service Description

This document addresses the use of Tecentriq (atezolizumab), an anti-programmed death ligand 1 (PD- L1) monoclonal antibody approved by the Food and Drug Administration (FDA) for the treatment of non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), hepatocellular carcinoma (HCC), melanoma and alveolar soft part sarcoma (ASPS).

Background Information

The FDA approved indications for Tecentriq (atezolizumab) includes:

- Individuals requiring first-line or maintenance therapy for metastatic nonsquamous NSCLC.
- Individuals requiring subsequent therapy of metastatic nonsquamous and squamous NSCLC.
- Individuals requiring first-line therapy as single agent for metastatic NSCLC.
- Individuals with extensive-stage small cell lung cancer (SCLC).
- Individuals requiring first-line treatment of unresectable or metastatic hepatocellular carcinoma (HCC)
- Individuals with unresectable or metastatic melanoma in combination with cobimetinib and vemurafenib with BRAF V600 mutation positive disease.
- Individuals using as adjuvant treatment following resection and platinum-based chemotherapy for Stage II to IIIA NSCLC whose tumors have PD-L1 expression on ≥ 1% of tumor cells.
- Individuals with alveolar soft part sarcoma (ASPS).

The National Comprehensive Cancer Network (NCCN) provides additional recommendations with a category 1 or 2A level of evidence for the use of:

- Individuals requiring first-line or maintenance therapy for recurrent or advanced nonsquamous NSCLC
- Individuals requiring subsequent therapy for recurrent or advanced nonsquamous and squamous NSCLC
- Individuals requiring first-line treatment for metastatic or unresectable hepatocellular carcinoma (HCC)
- Individuals with extensive stage small cell lung cancer (SCLC).

Definitions and Measures

- Actionable molecular markers include EGFR, ALK, ROS1, BRAF, NTRK, MET and RET mutations. The NCCN panel recommends testing prior to initiating therapy to help guide appropriate treatment. If there is insufficient tissue to allow testing for all these markers, repeat biopsy and/or plasma testing should be done. If these are

not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes (NCCN 1, 2A).

- Adjuvant treatment: Additional cancer treatment given after the primary treatment to lower the risk that the cancer will come back. Adjuvant therapy may include chemotherapy, radiation therapy, hormone therapy, targeted therapy, or biological therapy.
- ECOG Performance Status: A scale used to determine the individual's level of functioning. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:
    - 0= Fully active, able to carry on all pre-disease performance without restriction
    - 1= Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
    - 2= Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
    - 3= Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
    - 4= Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
    - 5= Dead
- Extensive-stage small cell lung cancer: Cancer has spread to other parts of the body and could include the fluid around the lungs.
- Immune checkpoint inhibitor: A type of drug that blocks certain proteins made by some types of immune system cells, such as T cells, and some cancer cells. When these proteins are blocked, the “brakes” on the immune system are released and T cells are able to kill cancer cells better. Examples of checkpoint proteins found on T cells or cancer cells include programmed death (PD)-1, PD-ligand 1 (PD-L1), and cytotoxic T-lymphocyte–associated antigen (CTLA)-4/B7-1/B7-2 (NCI, 2018).
- Kinase inhibitor: Type of drug which works by blocking several enzymes that promote cell growth, which has been found to be an effective approach to treat a variety of cancers.
- Line of therapy:
    - First-line therapy: The first or primary treatment for the diagnosis. This may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
    - Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
    - Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (second- line therapy) are not effective or there is disease progression.
- Locally advanced cancer: Cancer that has spread from where it started to nearby tissue or lymph nodes.
- Metastatic: The spread of cancer from one part of the body to another. A metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.
- Neoadjuvant treatment: Treatment given as a first step to shrink a tumor before the main treatment, which is usually surgery, is given. Examples of neoadjuvant therapy include chemotherapy, radiation therapy, and hormone therapy. It is a type of induction therapy.
- Programmed death (PD)-1 proteins: PD-1 proteins are found on T-cells and attach to PD ligands (PD-L1) found on normal (and cancer) cells (see immune checkpoint inhibitor above). Normally, this process keeps T-cells

from attacking other cells in the body. However, this can also prevent T-cells from attacking cancer cells in the body. Examples of FDA approved anti-PD-1 agents include Keytruda (pembrolizumab), Opdivo (nivolumab), and Libtayo (cemiplimab).

- Programmed death ligand (PD-L)-1: The ligands found on normal (and cancer) cells to which the PD-1 proteins attach (see immune checkpoint inhibitor above). Cancer cells can have large amounts of PD-L1 on their surface, which helps them to avoid immune attacks. Examples of FDA approved anti-PD-L1 agents include Bavencio (avelumab), Tecentriq (atezolizumab), and Imfinzi (durvalumab.

Approved Indications

See Background section above.

Other Uses

See Background section above.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J9022	Injection, atezolizumab, 10 mg [Tecentriq]

ICD-10	Description
C22.0-C22.9	Malignant neoplasm of liver and intrahepatic bile ducts
C34.00-C34.92	Malignant neoplasm of bronchus and lung
C43.0-C43.9	Malignant melanoma of skin
C45.0-C45.9	Mesothelioma
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C50.011-C50.929	Malignant neoplasm of breast
C53.0-C53.9	Malignant neoplasm of cervix uteri
C61	Malignant neoplasm of prostate
C65.1-C65.9	Malignant neoplasm of renal pelvis
C66.1-C66.9	Malignant neoplasm of ureter
C67.0-C67.9	Malignant neoplasm of bladder
C68.0-C68.9	Malignant neoplasm of the urinary system

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Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.3	Personal history of malignant neoplasm of breast
Z85.51	Personal history of malignant neoplasm of bladder
Z85.53-Z85.54	Personal history of malignant neoplasm of renal pelvis, ureter

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Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Atezolizumab (Tecentriq®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual has a diagnosis of one of the following:

A. 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 or B; **AND**
   3. Individual has an ECOG performance status of 0-2;

OR

B. First-line treatment of recurrent, advanced, or metastatic nonsquamous Non-Small Cell Lung Cancer (NSCLC) (Label, NCCN 2A); **AND**
   1. Individual is using in a combination regimen with nab-paclitaxel (paclitaxel, protein-bound) and carboplatin; **AND**
   2. Individual does not have presence of actionable molecular markers*; **AND**
   3. Individual has a ECOG performance status of 0-2;

OR

C. First-line, subsequent line, or maintenance therapy 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); **OR**
   2. Individual is using as monotherapy;

OR

D. 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 ECOG performance status of 0-2;

OR

E. Subsequent treatment of recurrent, advanced, or metastatic NSCLC (nonsquamous or squamous) (Label); **AND**
   1. Disease has progressed during or following platinum-containing chemotherapy (e.g. cisplatin); **AND**
   2. Individual has a ECOG performance status of 0-2;

OR

F. 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, NTRK, or MET 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;

OR

G. Treatment of stage II to IIIB NSCLC (Label, NCCN 2A); **AND**
   1. Individual is using as adjuvant therapy following resection and platinum-based chemotherapy; **AND**
   2. Individual has PD-L1 expression on tumor cells [TC] that is greater than or equal to 1% [TC ≥ 1%], as confirmed through an FDA-approved test;

OR

H. First-line treatment of metastatic NSCLC (Label); **AND**
   1. Tecentriq will be used as monotherapy; **AND**
   2. The tumor has high PD-L1 expression (≥50% of tumor cells or ≥10% of tumor-infiltrating immune cells), as determined by an FDA-approved test; **AND**
   3. The patient has no **EGFR or ALK** genomic tumor aberrations.

OR

I. Treatment of unresectable or metastatic Melanoma (Label); **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;

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);

OR

K. Treatment of unresectable or metastatic alveolar soft part sarcoma (ASPS) (Label, NCCN 2A); **AND**
   1. Individual is 2 years of age or older; **AND**
   2. Individual is using as monotherapy;

OR

L. Treatment of persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervical cancer (NECC); **AND**
   1. Individual is using in combination with etoposide and platinum-therapy (NCCN 2A).

OR

M. Treatment of mesothelioma including pericardial, tunica vaginalis, and testis (NCCN 2A); AND
   1. Individual is using in combination with bevacizumab (or bevacizumab biosimilar); AND
   2. Individual is using as subsequent therapy.

***Note:** Actionable molecular markers include EGFR, ALK, ROS1, BRAF, NTRK, MET and RET mutations. The NCCN panel recommends testing prior to initiating therapy to help guide appropriate treatment. If there is insufficient tissue to allow testing for all of these markers, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes (NCCN 1, 2A).

B. Criteria For Continuation of Therapy

i. MMM considers continuation of atezolizumab (Tecentriq®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen, and the recommended duration of therapy has not been exceeded. The following information should be submitted for reauthorization:
   A. A current oncology notes documenting the patient's response to treatment showing no progression of disease or unacceptable toxicity.

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B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

ii. Total Duration of Therapy

A. When atezolizumab (Tecentriq) is used as adjuvant therapy of NSCLC, approval will be granted for a maximum of 12 months.
For all other indications atezolizumab (Tecentriq®) will be approved until unacceptable toxicity or disease progression**.**

C. Authorization Duration

i. Initial Approval Duration: Up to 6 months
ii. Reauthorization Approval Duration: Up to 6 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Individual has received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **OR**
ii. Individual is receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant; **OR**
iii. When the above criteria are not met and for all other indications

Limits or Restrictions

A. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Use	Combination Therapy or Single Therapy	Dosing Regimen
NSCLC		
Metastatic NSCLC (as first-line treatment or in patients who have disease progression)	Single agent	• 840 mg every 2 weeks or • 1200 mg every 3 weeks or • 1680 mg every 4 weeks
Adjuvant Treatment of NSCLC (following resection and platinum-based chemotherapy for adult patients with stage II to IIIA)	Single agent	• 840 mg every 2 weeks or • 1200 mg every 3 weeks or • 1680 mg every 4 weeks

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Use	Combination Therapy or Single Therapy	Dosing Regimen
Metastatic NSCLC (as first line in patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.)	In combination with bevacizumab, paclitaxel, and carboplatin	• 840 mg every 2 weeks or • 1200 mg every 3 weeks or • 1680 mg every 4 weeks **Should be administered prior to chemotherapy and bevacizumab when given on the same day.
	In combination with paclitaxel protein-bound and carboplatin	
Small Cell Lung Cancer		
Extensive-Stage Small Cell Lung Cancer (ES-SCLC)	In combination with carboplatin and etoposide	• 840 mg every 2 weeks or • 1200 mg every 3 weeks or • 1680 mg every 4 weeks **Should be administered prior to chemotherapy and bevacizumab when given on the same day.
Hepatocellular Carcinoma		
Unresectable or metastatic hepatocellular carcinoma (HCC)	In combination with bevacizumab	• 840 mg every 2 weeks or • 1200 mg every 3 weeks or • 1680 mg every 4 weeks **Should be administered prior to bevacizumab when given on the same day. Bevacizumab is administered at 15 mg/kg every 3 weeks
Melanoma		
BRAF V600 mutation-positive unresectable or metastatic melanoma	In combination with cobimetinib and vemurafenib	• 840 mg every 2 weeks or • 1200 mg every 3 weeks or • 1680 mg every 4 weeks **Should be administered with cobimetinib 60 mg orally once daily (21 days on and 7 days off) and vemurafenib 720 mg orally twice daily. **Prior to initiating Tecentriq, patients should complete a 28-day treatment cycle of cobimetinib 60 mg orally once daily (21 days on and 7 days off) and vemurafenib 960 mg orally

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Use	Combination Therapy or Single Therapy	Dosing Regimen
		twice daily from Days 1-21 and vemurafenib 720 mg orally twice daily from Days 22-28.
Alveolar Soft Part Sarcoma		
Alveolar Soft Part Sarcoma, ASPS (adult)	Single agent	• 840 mg every 2 weeks or • 1200 mg every 3 weeks or • 1680 mg every 4 weeks
ASPS (pediatric, 2 years of age and older)	Single agent	• 15 mg/kg (up to a maximum 1200 mg) every 3 weeks

Reference Information

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12. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
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    a. Bladder Cancer. V1.2023. Revised February 9, 2023.
    b. Cervical Cancer. V1.2023. Revised January 6, 2023.
    c. Melanoma: Cutaneous. V2.2023. Revised March 10, 2023.
    d. Mesothelioma: Peritoneal. V1.2023. Revised December 15, 2022.
    e. Hepatocellular Carcinoma. V1.2023. Revised March 10, 2023.
    f. Malignant Peritoneal Mesothelioma V1.2022. Revised December 22, 2021.
    g. Non-Small Cell Lung Cancer. V2.2023. Revised February 17, 2023.
    h. .Small Cell Lung Cancer. V3.2023. Revised December 21, 2022.
    i. Soft Tissue Sarcoma. V1.2023. Revised March 13, 2023.
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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.

Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	• Update Child-Pugh score for HCC, wording, and formatting. • Modify non-squamous Non-Small Cell Cancer Lung Cancer (NSCLC) to allow use in actionable molecular markers and PDL-1 expression, Update NSCLC to allow for subsequent line or maintenance therapy, update alveolar soft part sarcoma for all stages, add mesothelioma criteria, update do not approve criteria. Coding Reviewed: Added ICD-10-CM C45.0-C45.9.	11/18/2024	12/17/2024
Annual Review	Update statement for criteria for initial approval: Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met all approval criteria.	3/25/2024	5/9/2024
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023

Revised: 10/23/2024