Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Atezolizumab (Tecentriq®), Atezolizumab and hyaluronidase-tqjs (Tecentriq Hybreza®)	MP-RX-FP-88-23	☒ MMM MA ☒ MMM MultiHealth	11/30/2023	2/22/2026
			Last Review Date: 2/22/2026	Frequently Revision: 2/22/2027

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) and Tecentriq Hybreza® (atezolizumab and hyaluronidase-tqjs), 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:

Tecentriq® (atezolizumab) and Tecentriq Hybreza™ (atezolizumab and hyaluronidase-tqjs) are programmed death-ligand 1 (PD-L1) inhibitors used in the management of multiple malignancies. Tecentriq is approved by the U.S. Food and Drug Administration (FDA) for use as monotherapy and in combination regimens for non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), hepatocellular carcinoma (HCC), melanoma, and alveolar soft part sarcoma (ASPS). Tecentriq Hybreza is a subcutaneous formulation of atezolizumab that provides an alternative route of administration and has demonstrated comparable efficacy and safety to intravenous atezolizumab, with different dosing and administration requirements.

The National Comprehensive Cancer Network (NCCN) Guidelines and NCCN Drugs & Biologics Compendium support the use of atezolizumab with Category 1 and Category 2A recommendations across these disease states. In addition, NCCN Guidelines and Compendia includes several clinical settings beyond FDA labeling, such as thymic carcinoma, cervical cancer, mesothelioma, chronic lymphocytic leukemia/small lymphocytic lymphoma with histologic transformation (Richter's syndrome), and colon cancer. NCCN also provides Category 2A recommendations for Tecentriq Hybreza as a substitute for Tecentriq in most FDA-approved and NCCN-supported indications, recognizing clinical equivalence between formulations when used according to approved instructions.

Non-Small Cell Lung Cancer

Non–small cell lung cancer (NSCLC) remains a major global health burden and is the leading cause of cancer-related mortality worldwide. In 2020, lung cancer accounted for an estimated 1.8 million deaths globally, and in the United States alone, approximately 240,000 new cases and 130,000 deaths occur each year. Despite this high mortality, survival outcomes for patients with NSCLC have improved over time, largely due to earlier detection through screening and significant advances in systemic therapies, including targeted agents and immunotherapy.

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Molecular characterization has transformed the management of NSCLC. Identification of oncogenic driver mutations—such as epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), ROS1, and other actionable alterations—has enabled personalized treatment strategies that often result in superior response rates and improved outcomes compared with traditional cytotoxic chemotherapy. Prognosis in NSCLC is most strongly influenced by disease stage at diagnosis, as defined by the tumor–node–metastasis (TNM) staging system, with survival declining progressively as stage advances. Additional factors independently associated with poorer outcomes include diminished performance status, weight loss, and reduced appetite at diagnosis, whereas ethnicity alone does not appear to independently predict survival once clinical factors are considered.

Recurrence remains a significant challenge even among patients who undergo complete surgical resection. In large retrospective analyses, approximately 40 percent of patients develop recurrent disease, typically within the first year after surgery, and survival following recurrence is generally poor. Factors associated with shorter survival after recurrence include poor performance status, short disease-free interval, prior neoadjuvant or adjuvant therapy, and the presence of distant metastases. However, patients whose tumors harbor actionable molecular alterations may experience more favorable outcomes with targeted therapies in the recurrent or metastatic setting.

Management strategies for NSCLC vary based on resectability, operability, and stage. Tecentriq (atezolizumab) is FDA-approved as adjuvant therapy following resection and platinum-based chemotherapy in patients with stage II to IIIA NSCLC whose tumors express PD-L1 on at least 1 percent of tumor cells. In advanced disease, atezolizumab-based regimens offer effective immunotherapy options, including combinations with chemotherapy and antiangiogenic agents. Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs), a subcutaneous formulation, has demonstrated comparable efficacy to the intravenous formulation; however, it has different dosing and administration instructions compared with atezolizumab administered by intravenous infusion.

Small Cell Lung Cancer

Small cell lung cancer (SCLC) is an aggressive neuroendocrine malignancy that accounts for approximately 15 percent of all lung cancers and occurs predominantly in individuals with a history of cigarette smoking. Compared with non–small cell lung cancer (NSCLC), SCLC is characterized by a rapid doubling time, high proliferative rate, and a strong propensity for early metastatic spread. While SCLC is initially highly sensitive to chemotherapy and radiotherapy, responses are typically short-lived, and relapse commonly occurs within months of completing treatment, contributing to its poor overall prognosis.

Clinically, SCLC is classified into limited-stage and extensive-stage disease, which guides treatment planning. Limited-stage SCLC (LS-SCLC) is confined to the ipsilateral hemithorax and regional lymph nodes and can be encompassed within a tolerable radiation field. In contrast, extensive-stage SCLC (ES-SCLC) is defined by disease that extends beyond the ipsilateral thorax, including distant metastases, malignant pleural or pericardial effusions, or involvement of contralateral supraclavicular or hilar lymph nodes.

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For patients with ES-SCLC, the preferred initial treatment approach is immunotherapy combined with a platinum agent and etoposide, followed by maintenance immunotherapy. Atezolizumab, when added to a platinum–etoposide backbone during induction and continued as maintenance therapy, has demonstrated a significant survival benefit and represents a major therapeutic advance in this disease setting. In a pivotal randomized trial involving patients with previously untreated ES-SCLC, the addition of atezolizumab to carboplatin and etoposide improved both overall survival and progression-free survival compared with chemotherapy alone, without increasing the incidence of severe toxicity. The optimal duration of first-line chemotherapy is not well established; however, treatment typically consists of four to six cycles, with atezolizumab continued as maintenance therapy until disease progression or unacceptable toxicity.

Hepatocellular Carcinoma (HCC)

Hepatocellular carcinoma (HCC) is the most common primary malignancy of the liver and represents a major cause of cancer-related mortality. In the United States, tens of thousands of new cases are diagnosed annually, and most patients present with advanced disease that is not amenable to curative surgical resection or liver-directed therapies. Systemic therapy is therefore a key treatment option for patients with unresectable or metastatic HCC who have preserved performance status and adequate underlying liver function, most commonly Child-Pugh class A cirrhosis.

Atezolizumab-based immunotherapy has become a cornerstone of first-line systemic treatment for advanced HCC. For patients with no prior liver transplantation, an Eastern Cooperative Oncology Group (ECOG) performance status of 0–1, and Child-Pugh class A cirrhosis, the combination of atezolizumab plus bevacizumab is a preferred initial regimen. This combination demonstrated significant improvements in overall survival and progression-free survival compared with antiangiogenic therapy in phase III clinical trials and is particularly favored in patients with symptomatic disease or rapidly progressive tumors due to its relatively high objective response rates.

Selection of systemic therapy in HCC is individualized and depends on tumor burden, rate of disease progression, comorbid conditions, bleeding risk, and patient preference. Atezolizumab plus bevacizumab is generally preferred when there are no contraindications to anti–vascular endothelial growth factor therapy, including active bleeding or high-risk vascular conditions. In appropriately selected patients, this regimen offers an effective immunotherapy-based option that has redefined the standard of care for first-line treatment of advanced hepatocellular carcinoma.

Melanoma

Metastatic melanoma is a biologically heterogeneous disease in which molecular profiling has become essential to guide systemic therapy selection. Activating mutations in the BRAF gene (codon V600) are among the most common and clinically actionable alterations, present in approximately 40% to 60% of patients with metastatic melanoma. Additional actionable alterations may include NRAS, KIT, and rare NTRK (TRK) gene fusions, and

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broader next-generation sequencing (NGS) is increasingly used to identify these variants and inform therapeutic options.

For patients with BRAF V600–mutant metastatic melanoma, systemic treatment decisions are individualized based on mutation status, disease tempo, comorbidities, performance status, and prior therapy. In general, checkpoint inhibitor immunotherapy is preferred as initial treatment for most eligible patients because it offers the potential for durable responses and long-term survival benefit, whereas targeted therapy can produce rapid tumor responses but is often limited by eventual resistance and shorter durability.

Atezolizumab is relevant in melanoma as part of an FDA-approved triplet regimen that combines PD-L1 inhibition with targeted therapy. Specifically, Tecentriq (atezolizumab) in combination with vemurafenib and cobimetinib is an option for patients with BRAF V600 mutation–positive unresectable or metastatic melanoma, providing a strategy that integrates immunotherapy with BRAF/MEK inhibition. While multiple systemic options exist (including BRAF/MEK inhibitor combinations and PD-1–based immunotherapy regimens), the atezolizumab-containing combination represents a targeted-therapy backbone augmented by immunotherapy for select patients with BRAF V600–mutant disease.

Alveolar Soft Sarcoma

Alveolar soft part sarcoma (ASPS) is a rare subtype of soft tissue sarcoma, accounting for approximately 0.5% of all soft tissue sarcomas, and most commonly affects adolescents and young adults, with a median age at diagnosis of about 25 years. The disease is characterized by an indolent but progressive course, often presenting as a slow-growing soft tissue mass with a high propensity for late metastatic spread, particularly to the lungs, bone, and brain. Prognosis for unresectable or metastatic disease has historically been poor; however, outcomes have improved with the introduction of immunotherapy.

Atezolizumab is a key systemic treatment option for patients with unresectable or metastatic ASPS, particularly in those with limited but progressive disease. Clinical trial data have demonstrated meaningful and durable responses with atezolizumab, leading to its FDA approval for ASPS.

Importantly, the approved indications differ between atezolizumab formulations. Tecentriq (atezolizumab IV) is approved for use in adult and pediatric patients aged 2 years and older with unresectable or metastatic ASPS. In contrast, Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs, subcutaneous) is approved for adult patients and pediatric patients aged 12 years and older who weigh at least 40 kg with unresectable or metastatic ASPS.

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

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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.
- Contraindications for treatment with PD-1/PD-L1 inhibitors: may include active or previously documented autoimmune disease and/or current use of immunosuppressive agents, and some oncogenic drivers (ie, EGFR exon 19 deletion or L858R mutation; ALK, RET, or ROS1 gene fusions) have been shown to be associated with less benefit from PD-1/PD-L1 inhibitors.
- 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.

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  - 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

Non-Small Cell Lung Cancer (NSCLC)

- Adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage II to IIIA non-small cell lung cancer (NSCLC) whose tumors have PD-L1 expression on ≥1% of tumor cells, as determined by an FDA-approved test.
- First-line treatment of adult patients with metastatic NSCLC whose tumors have high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]), as determined by an FDA approved test, with no EGFR or ALK genomic tumor aberrations.
- In combination with bevacizumab, paclitaxel, and carboplatin, for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.
- In combination with paclitaxel protein-bound and carboplatin for the first line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.
- For the treatment of adult patients with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for NSCLC harboring these aberrations prior to receiving TECENTRIQ.

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Small Cell Lung Cancer (SCLC)

- In combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).
- In combination with lurbinectedin, for the maintenance treatment of adult patients with extensive stage-SCLC whose disease has not progressed after first-line induction therapy with TECENTRIQ or atezolizumab and hyaluronidaset-qjs, carboplatin and etoposide.

Hepatocellular Carcinoma (HCC)

- In combination with bevacizumab for the treatment of adult patients with unresectable or metastatic HCC who have not received prior systemic therapy.

Melanoma

- In combination with cobimetinib and vemurafenib for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.

Alveolar Soft Part Sarcoma (ASPS)

- For the treatment of adult and pediatric patients 2 years of age and older with unresectable or metastatic ASPS. (Tecentriq)
- For the treatment of adult patients and pediatric patients (12 years of age and older who weigh 40 kg or greater) with unresectable or metastatic ASPS. (Tecentriq Hybreza)

Other Uses for Tecentriq and Tecentriq Hybreza (unless otherwise specified)

<u>NCCN Categories of Evidence 1 or 2A only</u>

Non-Small Cell Lung Cancer (NSCLC)

- For use as single-agent systemic therapy after completion of adjuvant chemoradiation for margin-positive (R1 or R2) residual disease that is PD-L1 ≥1% with no known EGFR mutations or ALK gene fusions with no contraindications to immune checkpoint inhibitors for ≥ 4 cm or node positive NSCLC stages IB-IIIA, IIIB [T2-3, N2b; T4, N2]. (Tecentriq) (NCCN 1)
- For use as continuation maintenance therapy as a single agent for recurrent, advanced, or metastatic disease for PD-L1 expression positive (≥50%) tumors that are negative for actionable biomarkers (may be KRAS G12C mutation positive) and no contraindications to PD-1 or PD-L1 inhibitors in patients with performance status 0-2 who achieve a response or stable disease following first-line therapy with single agent atezolizumab. (NCCN 1)

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- For use as single-agent treatment for recurrent, advanced, or metastatic disease for those with performance status 3 and no contraindications to PD-1 or PD-L1 inhibitors as monotherapy. (NCCCN 2A)
- For use as continuation maintenance therapy as a single agent for recurrent, advanced, or metastatic disease for those with performance status 3 and no contraindications to PD-1 or PD-L1 inhibitors regardless of PD-L1 status and negative for actionable biomarkers (may be KRAS G12C mutation positive) who achieve a response or stable disease following first-line therapy with single agent atezolizumab.(NCCN 2A)
- For recurrent, advanced, or metastatic disease as first-line therapy for PD-L1 expression positive (≥1%) tumors that are negative for actionable biomarkers (may be KRAS G12C mutation positive) and no contraindications to PD-1 or PD-L1 inhibitors and performance status 0-2 for nonsquamous cell histology in combination with bevacizumab, carboplatin and paclitaxel (if no history of recent hemoptysis). (NCCN 1)
- For recurrent, advanced, or metastatic disease as first-line therapy for PD-L1 expression positive (≥1%) tumors that are negative for actionable biomarkers (may be KRAS G12C mutation positive) and no contraindications to PD-1 or PD-L1 inhibitors and performance status 0-2 for nonsquamous cell histology in combination with carboplatin and albumin-bound paclitaxel. (NCCN 2A)
- For use as continuation maintenance therapy in combination with bevacizumab for recurrent, advanced, or metastatic disease for PD-L1 expression positive (≥1%) tumors that are negative for actionable biomarkers (may be KRAS G12C mutation positive) and no contraindications to PD-1 or PD-L1 inhibitors in those with performance status 0-2 who achieve a response or stable disease following first-line therapy with atezolizumab/carboplatin/paclitaxel/bevacizumab for nonsquamous cell histology with no history of recent hemoptysis. (NCCN 1)
- For use as continuation maintenance therapy as a single agent for recurrent, advanced, or metastatic disease for PD-L1 expression positive (≥1%) tumors that are negative for actionable biomarkers (may be KRAS G12C mutation positive) and no contraindications to PD-1 or PD-L1 inhibitors in those with performance status 0-2 who achieve a response or stable disease following first-line therapy with atezolizumab/carboplatin/albumin-bound paclitaxel for nonsquamous cell histology. (NCCN 2A)
- For use as subsequent systemic therapy as a single agent for recurrent, advanced, or metastatic disease in those with performance status 0-2 if no contraindications to PD-1 or PD-L1 inhibitors and no prior progression on a PD-1/PD-L1 inhibitor (preferred for first progression subsequent therapy) (NCCN 1) (other recommended option for subsequent progression) (NCCN 2A)

Small Cell Lung Cancer (SCLC) – Subsequent Therapy

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- For use as preferred primary treatment as single agent maintenance following carboplatin/etoposide + atezolizumab for extensive stage disease with or without brain metastases. (NCCN 1, 2A)
- For use as subsequent systemic therapy for relapse or progression in patients with extensive-stage small cell lung cancer, in combination with carboplatin and etoposide, followed by maintenance atezolizumab. (NCCN 2A)

Thymic Carcinoma

- Post-operative therapy for thymic carcinoma in combination with carboplatin and paclitaxel, after an R1 or R2 resection. (NCCN 2A)
- First line treatment of recurrent, advanced, or metastatic thymic carcinoma in combination with carboplatin and paclitaxel. (NCCN 2A)

Cervical Cancer

- Preferred first-line, second-line, or subsequent therapy (if not previously used as first line) in combination with bevacizumab, paclitaxel, and cisplatin or carboplatin, with atezolizumab and bevacizumab continued as maintenance, for locoregional recurrence or stage IVB/distant metastatic cervical cancer. (NCCN 1)
- First-line, second-line or subsequent therapy (if not used previously as first-line) for persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervix (NECC) in combination with cisplatin or carbaoplatin and etoposide and continued as a single agent for maintenance therapy. (NCCN 2A)
- For the treatment of cervical cancer (including squamous cell carcinoma, adenocarcinoma, adenosquamous carcinoma, and small cell neuroendocrine carcinoma of the cervix), when used as a substitute for intravenous atezolizumab. (TECENTRIQ HYBREZA) *(NCCN 2A)*

Mesothelioma (peritoneal)

- Subsequent systemic therapy in combination with bevacizumab in patients not previously treated with immune checkpoint inhibitors. (NCCN 2A)

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma - Histologic Transformation (Richter)

- Part of a non-chemotherapy immunotherapy regimen (with venetoclax and obinutuzumab) for Richter's transformation, including use as additional therapy in patients with untreated CLL or clonally unrelated disease who have an inadequate response or progression on initial chemoimmunotherapy, and as first-line or continuation therapy in previously treated CLL with clonally related (or unknown) disease. (NCCN 2A).

Colon Cancer

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- Adjuvant treatment, in combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CAPEOX (capecitabine and oxaliplatin) chemotherapy, for resected colon cancer with deficient DNA mismatch repair or MSI-high status (or POLE/POLD1 ultra-mutated phenotype). This applies to stage III disease (preferred in low-risk Stage III T1-3 N1 and high-risk Stage III T4 or N2). (NCCN 2A)

Alveolar Soft Part Sarcoma

- Preferred single-agent therapy for the treatment of alveolar soft part sarcoma (ASPS).

Codes Information:

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]
J9024	Injection, atezolizumab and hyaluronidase-tqjs, 5 mg [Tecentriq Hybreza]

ICD-10	Description
C18.0; C18.2–C18.9; Z85.038	Malignant neoplasm of colon (colon cancer)
C22.0-C22.9	Malignant neoplasm of liver and intrahepatic bile ducts (hepatocellular carcinoma)
C33	Malignant neoplasm of trachea
C34.00-C34.92	Malignant neoplasm of bronchus and lung
C37; D15.0; D38.4; Z85.238	Thymic carcinoma (neoplasm of thymus)
C43.0-C43.9	Malignant melanoma of skin (cutaneous melanoma)
C45.0-C45.9	Malignant mesothelioma
C49.0–C49.9; Z85.831	Alveolar soft part sarcoma (soft-tissue sarcoma)
C50.011-C50.929	Malignant neoplasm of breast
C53.0-C53.9	Malignant neoplasm of cervix uteri (cervical cancer)
C65.1-C65.9	Malignant neoplasm of renal pelvis
C66.1-C66.9	Malignant neoplasm of ureter
C68.0-C68.9	Malignant neoplasm of the urinary system

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C83.00-C83.09	Non-Hodgkin lymphoma, unspecified / small B-cell lymphoma (range used for Richter transformation capture)
C83.30-C83.39	Diffuse large B-cell lymphoma (DLBCL)
C91.10, C91.12	Chronic lymphocytic leukemia (CLL) (includes variants used to support Richter transformation coding)
Z85.12	Personal history of malignant neoplasm of trachea
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.3	Personal history of malignant neoplasm of breast
Z85.53-Z85.54	Personal history of malignant neoplasm of renal pelvis, ureter
Z85.59	Personal history of malignant neoplasm of other urinary tract organ

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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®) and Atezolizumab and hyaluronidase-tqjs (Tecentriq Hybreza®)

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 unresectable, or metastatic *hepatocellular carcinoma (HCC)* (Label, NCCN 1); **AND**
   1. Individual is using atezolizumab in combination with bevacizumab (or bevacizumab biosimilar); **AND**
   2. Individual has unresectable liver-confined disease or metastatic disease; **AND**
   3. Individual is not a candidate for curative resection, liver transplantation, or locoregional therapy;

OR

B. Subsequent-line treatment of *hepatocellular carcinoma (HCC)* (NCCN 2A); **AND**
   1. Individual has not been previously treated with a checkpoint inhibitor; **AND**
   2. Individual is using atezolizumab in combination with bevacizumab; **AND**
   3. Disease has progressed on or after prior systemic therapy.

OR

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

OR

D. First-line, subsequent line, or maintenance therapy for recurrent, advanced, or metastatic *nonsquamous NSCLC* (Label, NCCN 1, 2A); **AND**
   1. Individual is using atezolizumab:

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a. in combination with carboplatin, paclitaxel, and bevacizumab (or bevacizumab biosimilar);

OR

b. in combination with carboplatin and albumin-bound paclitaxel;

OR

c. as monotherapy; **AND;**

2. Individual has a ECOG performance status of 0-2;

OR

E. Continuation maintenance therapy for recurrent, advanced, or metastatic *nonsquamous NSCLC* (Label, NCCN 1, 2A); **AND**

1. Individual is using atezolizumab as monotherapy or in combination with bevacizumab (or biosimilar); **AND**
2. Individual has achieved tumor response or stable disease following first-line systemic therapy that included atezolizumab; **AND**
3. Individual has a ECOG performance status of 0-2;

OR

F. 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);

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, NTRK, or MET mutations); **AND**
2. Individual is using atezolizumab 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

H. Treatment of stage II to IIIB *NSCLC (*Label, NCCN 2A); **AND**

1. Individual is using atezolizumab as adjuvant therapy following resection and platinum-based chemotherapy; **AND**

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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

I. First-line treatment of metastatic *NSCLC* (Label); **AND**
   1. Tecentriq is 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

J. Treatment of unresectable or metastatic *Melanoma* (Label, NCCN 2A); **AND**
   1. Individual is using in combination with cobimetinib and vemurafenib; **AND**
   2. Individual has BRAF V600 mutation positive disease, confirmed by an FDA-approved test;

OR

K. Treatment of unresectable or metastatic *Melanoma* (NCCN 2A)
   1. Individual is using atezolizumab in combination with cobimetinib and vemurafenib; **AND**
   2. Individual has BRAF V600 mutation–positive disease, confirmed by an FDA-approved test; **AND**
   3. Individual has an ECOG performance status of 0–2; **AND**
   4. ONE of the following applies:
      a. Disease has progressed on, or the individual was intolerant to, prior BRAF-targeted therapy;

      OR

      b. Therapy is being used as re-induction, provided:
         i. Prior treatment with BRAF/MEK inhibitor plus PD-1/PD-L1 checkpoint inhibitor resulted in disease control (CR, PR, or SD); **AND**
         ii. There is no residual immune-related toxicity; **AND**
         iii. Disease progression or relapse occurred >3 months after discontinuation of prior therapy;

OR

L. Treatment of extensive-stage *Small Cell Lung Cancer (SCLC)* (Label, NCCN 1, 2A); **AND**
   1. Individual is using as first-line treatment; **AND**
   2. Individual is using atezolizumab in combination with etoposide and carboplatin;

   OR

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3. Individual is using as a single agent maintenance therapy; **AND**
4. Individual previously received carboplatin/etoposide in combination with atezolizumab;

OR

5. Individual is using atezolizumab in combination with lurbinectedin as maintenance treatment; **AND**
6. Disease has not progressed after first-line induction therapy with
    a. Tecentriq (atezolizumab) or Tecentriq Hybreza (atezolizumab and hyaluronidaset-qjs); **AND**
    b. Carboplatin plus etoposide;

OR

7. Individual has achieved at least stable disease following four cycles of carboplatin/etoposide plus atezolizumab; **AND**
8. ECOG performance status 0–1; **AND**
9. Individual has no history of brain metastases; **AND**
10. Lurbinectedin has not been used previously.

OR

11. Individual is using as subsequent systemic therapy for disease progression or relapse; **AND**
    a. Individual has relapsed or progressive ES-SCLC after a prolonged disease-free interval; **AND**
    b. ECOG performance status 0–2; **AND**
    c. Individual is using ONE of the following regimens:
        i. Carboplatin and etoposide, followed by single-agent maintenance atezolizumab;

        OR

        ii. Carboplatin and etoposide, followed by maintenance atezolizumab plus lurbinectedin, if lurbinectedin has not been used previously.

OR

M. Treatment of unresectable or metastatic *alveolar soft part sarcoma (ASPS)* (Label, NCCN 2A); **AND**
    1. Individual is using Tecentriq intravenous formulation; **AND**
        a. Individual is receiving Tecentriq as monotherapy; **AND**
        b. Individual is 2 years of age or older;

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OR

2. Individual is using Tecentriq Hybreza; **AND**
    a. Individual is receiving Tecentriq Hybreza as monotherapy; **AND**
    b. Individual is 12 years of age or older; **AND**
    c. Indivual weigh 40 kg or greater;

OR

N. First line, second line, or subsequent therapy for the treatment of persistent, recurrent, or metastatic *small cell neuroendocrine carcinoma of the cervical cancer (NECC)* (NCCN 2A); **AND**
    1. Atezolizumab has not been previously used as first line treatment; **AND**
    2. Individual is receiving atezolizumab in combination with *one* of the following:
        a. Cisplatin and etoposide;
        OR
        b. Carboplatin and etoposide; **AND**
    3. Atezolizumab is continued as single-agent maintenance therapy, as clinically appropriate;

OR

O. First line, second line, or subsequent therapy for the treatment of *cervical cancer* adenocarcinoma, adenosquamous carcinoma, or squamous cell carcinoma (NCCN 1); **AND**
    1. Atezolizumab has not been previously used as first line treatment; **AND**
    2. Individual is receiving atezolizumab in combination with bevacizumab, paclitaxel, and *one* of the following:
        a. Cisplatin;
        OR
        b. Carboplatin; **AND**
    3. Atezolizumab and bevacizumab may be continued as maintenance therapy, as clinically appropriate..

OR

P. Treatment of *peritoneal mesothelioma (*including pericardial mesothelioma, mesothelioma of the tunica vaginalis testis) (NCCN 2A); **AND**
    1. Individual is using atezolizumab in combination with bevacizumab (or bevacizumab biosimilar); **AND**
    2. Atezolizumab is requested for subsequent systemic therapy; **AND**

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3. Individual has not been previously treated with an immune checkpoint inhibitor.

***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.
   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) and atezolizumab and hyaluronidase-tqjs (Tecentriq Hybreza) is used as adjuvant therapy of NSCLC, approval will be granted for a maximum of 12 months.
   B. For all other indications atezolizumab (Tecentriq®) and hyaluronidase-tqjs (Tecentriq Hybreza) 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 disease progression with another anti-PD-1 or anti-PD-L1 inhibitor (NCCN); **OR**
ii. Individual is receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant (NCCN); **OR**
iii. When the above criteria are not met and for all other indications.

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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		**Tecentriq inj. (IV)** 840 mg/14 mL (60 mg/mL) vial 1200 mg/20 mL (60 mg/mL) vial	**Tecentriq Hybreza (SC)** 1,875 mg atezolizumab and 30,000 units hyaluronidase per 15 mL per vial (125 mg/2,000 units per mL)
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	• 1,875 mg of atezolizumab and 30,000 units of hyaluronidase every 3 weeks. (one 15mL injection SubQ)
Adjuvant Treatment of NSCLC (following resection and up to 4 cycles of platinum-based chemotherapy	Single agent	• 840 mg every 2 weeks or • 1200 mg every 3 weeks or • 1680 mg every 4 weeks **Up to one year, unless there is disease recurrence or unacceptable toxicity.	• 1,875 mg of atezolizumab and 30,000 units of hyaluronidase every 3 weeks for up to 1 year. (one 15mL injection SubQ)
Metastatic NSCLC (as first line in patients	In combination with bevacizumab,	• 840 mg every 2 weeks or	• 1,875 mg of atezolizumab and 30,000

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Use	Combination Therapy or Single Therapy	Dosing Regimen	
with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.)	paclitaxel, and carboplatin	• 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.	units of hyaluronidase every 3 weeks. (one 15mL injection SubQ) **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) (first line treatment)	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.	• 1,875 mg of atezolizumab and 30,000 units of hyaluronidase every 3 weeks. (one 15mL injection SubQ) **Should be administered prior to chemotherapy and bevacizumab when given on the same day.
Extensive-Stage Small Cell Lung Cancer (ES-SCLC) (maintenance following carboplatin/etoposide + atezolizumab)	Single agent	• 1,680 mg every 28 days	• 1,875 mg of atezolizumab and 30,000 units of hyaluronidase every 3 weeks. (one 15mL injection SubQ)
Extensive-Stage Small Cell Lung Cancer (ES-SCLC) (maintenance treatment of patients whose disease has not progressed)	In combination with lurbinectedin	• 1,200 mg every 21 days	• 1,875 mg of atezolizumab and 30,000 units of hyaluronidase every 3 weeks. (one 15mL injection SubQ)

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Use	Combination Therapy or Single Therapy	Dosing Regimen	
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	• 1,875 mg of atezolizumab and 30,000 units of hyaluronidase every 3 weeks. (one 15mL injection SubQ) **Should be administered prior to chemotherapy and bevacizumab when given on the same day.
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	• 1,875 mg of atezolizumab and 30,000 units of hyaluronidase every 3 weeks. (one 15mL injection SubQ) **Prior to initiating TECENTRIQ HYBREZA, patients should receive the following 28-day treatment cycle of cobimetinib and vemurafenib: *Days 1 to 21: cobimetinib 60 mg orally once daily in combination with 960 mg of oral vemurafenib twice daily.

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Use	Combination Therapy or Single Therapy	Dosing Regimen	
		vemurafenib 960 mg orally twice daily from Days 1-21 and vemurafenib 720 mg orally twice daily from Days 22-28.	*Days 22 to 28: withhold cobimetinib and administer vemurafenib 720 mg orally twice daily.
Alveolar Soft Part Sarcoma			
Alveolar Soft Part Sarcoma, ASPS (adult) (Preferred treatment)	Single agent	• 840 mg every 2 weeks or • 1200 mg every 3 weeks or • 1680 mg every 4 weeks	• 1,875 mg of atezolizumab and 30,000 units of hyaluronidase every 3 weeks. (one 15mL injection SubQ)
ASPS (Preferred treatment)	Single agent	• 15 mg/kg (up to a maximum 1200 mg) every 3 weeks ** For use in patients 2 years of age and older	• 1,875 mg of atezolizumab and 30,000 units of hyaluronidase every 3 weeks. (one 15mL injection SubQ) **For use in patients 12 years of age and older who weigh 40 kg or greater
Thymic Carcinoma			
Postoperative systemic therapy First line combination therapy	In combination with carboplatin/paclitaxel	• 840 mg every 2 weeks or • 1200 mg every 3 weeks or • 1680 mg every 4 weeks	• 1,875 mg of atezolizumab and 30,000 units of hyaluronidase every 3 weeks. (one 15mL injection SubQ)
Cervical Cancer			

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Use	Combination Therapy or Single Therapy	Dosing Regimen	
Preferred first line, second-line, or subsequent therapy	In combination with bevacizumab, paclitaxel, and cisplatin or carboplatin	• 840 mg every 2 weeks or • 1200 mg every 3 weeks or • 1680 mg every 4 weeks	• 1,875 mg of atezolizumab and 30,000 units of hyaluronidase every 3 weeks. (one 15mL injection SubQ)
First-line, second-line or subsequent therapy (if not used previously as first-line) for persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervix (NECC)	In combination with cisplatin or carbaoplatin and etoposide	• 840 mg every 2 weeks or • 1200 mg every 3 weeks or • 1680 mg every 4 weeks	• 1,875 mg of atezolizumab and 30,000 units of hyaluronidase every 3 weeks. (one 15mL injection SubQ)
Mesothelioma			
Subsequent therapy (For peritoneal, pericardial, and tunica vaginalis testis mesothelioma)	In combination with bevacizumab	• 840 mg every 2 weeks or • 1200 mg every 3 weeks or • 1680 mg every 4 weeks	• 1,875 mg of atezolizumab and 30,000 units of hyaluronidase every 3 weeks. (one 15mL injection SubQ)
Chronic Lymphocytic Leukemia(CLL)/Small Lymphocytic Lymphoma (SLL)-Histologic Transformation (Richter)			
Richter Transformation	In combination with venetoclax and obinutuzumab	• 840 mg every 2 weeks or • 1200 mg every 3 weeks or • 1680 mg every 4 weeks	• 1,875 mg of atezolizumab and 30,000 units of hyaluronidase every 3 weeks. (one 15mL injection SubQ)
Colon Cancer			
Resected colon cancer with deficient DNA mismatch repair	In combination with FOLFOX (fluorouracil, leucovorin, and	• 840 mg every 2 weeks or	• 1,875 mg of atezolizumab and 30,000 units of hyaluronidase

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Use	Combination Therapy or Single Therapy	Dosing Regimen	
or MSI-high status (stage III disease	oxaliplatin) or CAPEOX (capecitabine and oxaliplatin)	• 1200 mg every 3 weeks or • 1680 mg every 4 weeks	every 3 weeks. (one 15mL injection SubQ)

Duration of Therapy: Until disease progression or unacceptable toxicity.

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    e. Non-Small Cell Lung Cancer. V3.2026. Revised December 24, 2025.
    f. Small Cell Lung Cancer. V2.2026. Revised September 16, 2025.
    g. Soft Tissue Sarcoma. V1.2026. Revised January 16, 2026.
    h. Chronic Lymphocytic Leukemia/Small Lymphocycitic Lymphoma (Richter Transformation). V2.2026. Revised December 22,2025.
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Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Atezolizumab (Tecentriq®), Atezolizumab and hyaluronidase-tqjs (Tecentriq Hybreza®)	MP-RX-FP-88-23	☒ MMM MA ☒ MMM MultiHealth	11/30/2023	2/22/2026
			Last Review Date:	Frequently Revision:
			2/22/2026	2/22/2027

subtypes?search=alveolar%20soft%20part%20sarcomqa%20AND%20atezolizumab&source=search_result&selectedTitle=1~78&usage_type=default&display_rank=1.

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:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Updated the Background Information section to include a concise summary of disease states covered under FDA-approved indications and NCCN Category 1 and 2A guideline recommendations. Added contraindications to the Definitions and Measures section to align with FDA labeling and NCCN guidance. Expanded FDA Indications to include combination use with Zepzelca® (lurbinectedin) for maintenance treatment of extensive-stage small cell lung cancer (ES-SCLC), and incorporated NCCN Category 1 and 2A "Other Uses." Added and updated Criteria for Initial Approval and dosing across multiple disease states to reflect FDA labeling and NCCN Category 1 and 2A recommendations. Coding reviewed: Add ICD codes: C18.0; C18.2–C18.9; Z85.038; C37;	2/13/2026	2/22/2026

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	D15.0; D38.4; Z85.238; C49.0–C49.9; Z85.831; C83.00-C83.09; C83.30-C83.39; C91.10, C91.12; D09.0; Z85.12. Removed ICD code C61: (malignant neoplasm of prostate), as it is not applicable to urothelial carcinoma indications. Updated the References section to reflect current FDA labeling and NCCN Guidelines.		
Annual Review	• Addition of Tecentriq Hybreza as a new dosage form for atezolizumab. • Addition of Tecentriq Hybreza dose for QL.	3/17/2025	4/2/2025
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