CLINICAL GUIDELINES FOR MEDICAL NECESSITY

MEDICAL POLICY

Atezolizumab (Tecentriq®)

Version: 1.0

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Atezolizumab (Tecentriq®)

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Please refer to the CMS website at http://www.cms.gov for additional information.

Note: For Medicaid members/enrollees, circumstances when state Medicaid coverage provisions conflict with the coverage provisions within this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Atezolizumab (Tecentriq): Discussion

Atezolizumab is a programmed death-ligand blocking antibody that binds to PD-L1 and blocks its interactions with both PD-1 and B7.1 receptors. This releases the PD-L1/PD-1 mediated inhibition of the immune response, including activation of the anti-tumor immune response without inducing antibody-dependent cellular cytotoxicity. [1]

PD-L1 may be expressed on tumor cells and/or tumor-infiltrating immune cells and can contribute to the inhibition of the anti-tumor immune response in the tumor microenvironment. The binding of PD-L1 to the PD-1 and B7.1 receptors found on T cells and antigen-presenting cells suppresses cytotoxic T-cell activity, T-cell proliferation, and cytokine production. [1]

Atezolizumab can cause immune-mediated adverse reactions, which may be severe or fatal; and can occur in any organ system or tissue. Immune-mediated adverse reactions can occur at any time after starting a PD1/PD-L1 blocking antibody. While immune-mediated adverse reactions usually manifest during treatment with PD-1/PD-L1 blocking antibodies, immune-mediated adverse reactions can also manifest after discontinuation of PD-1/PD-L1 blocking antibodies. [1]

Non-Small Cell Lung Cancer (NSCLC)

1. As adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage II-IIIA NSCLC whose tumors have PD-L1 expression $\geq$ 1% of tumor cells; OR
2. For the first-line treatment of adult patients with metastatic NSCLC whose tumors have high PD-L1 expression (PD-L1 stained $\geq$ 50% of tumor cells [TC $\geq$ 50%] or PD-L1stained tumor-infiltrating immune cells [IC] covering $\geq$ 10% of the tumor area [IC $\geq$0%]), with no EGFR or ALK genomic tumor aberrations; OR 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; OR
3. 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; OR

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4. 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.

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).

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 or older with unresectable or metastatic ASPS. [1]

The National Comprehensive Cancer Network (NCCN) endorses atezolizumab in the following cancer types: urothelial cancer of the bladder, urothelial cancer of the urethra, urothelial cancer of the upper genitourinary tract, urothelial cancer of the prostate, cervical (small cell neuroendocrine carcinoma of the cervix), hepatocellular, melanoma (cutaneous), mesothelioma (peritoneal), non-small cell and small cell lung cancer, and alveolar soft part sarcoma. [2,3,4,5,6,7,8,9]

Atezolizumab: Definitions

- **Anaplastic lymphoma kinase (ALK) rearrangement –** About 5% of patients with NSCLC have ALK gene rearrangements and are associated with adenocarcinoma histology and either a never smoking or light smoking history.[7] ALK is a tyrosine kinase that can be aberrantly expressed in several tumor types. ALK-positive tumors (tumors harboring a rearranged ALK gene/fusion protein) are highly sensitive to therapy with ALK-targeted inhibitors.
- **BRAF V600E mutation –** BRAF is a serine/threonine kinase that is part of the MAP/ERK signaling pathway.[7] Mutations in the gene lead to unrestrained cell growth and proliferation. BRAF mutations are most commonly found in the 600th codon (V600), most frequently V600E (80%) but also including V600K (15%) and a few others. BRAF V600 mutations are associated with sensitivity to BRAF inhibitors and MEK inhibitors in

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melanoma.[2] BRAF mutations are most commonly associated with melanoma and NSCLC. The BRAF V600E mutation occurs in 1-2% of patients with lung adenocarcinoma; it is the most common of the BRAF point mutations when considered against all tumor types. Mutations in BRAF typically do not overlap with EGFR and MET exon 14 skipping mutations, RET rearrangements, ALK rearrangements and ROS1 rearrangements. [7]

- **Child-Pugh Class A or Class B–** Child-Pugh is a scoring system that has been traditionally used for the assessment or hepatic reserve in patients with cirrhosis. The C-P score incorporates laboratory measurements (i.e., serum albumin, bilirubin, and PT) as well as more subjective clinical assessments of encephalopathy and ascites. The scores go from A-C. It provides a general estimate of liver function by classifying patients as having compensated (class A) or decompensated (classes B and C) cirrhosis. The advantages of the C-P score include ease of performance (i.e., can be done at the bedside) and the inclusion of clinical parameters. Class A is the least severe liver disease (good operative risk) and Class C is the worst (poor operative risk). [4]
- **Epidermal growth factor receptor (EGFR) exon 19 deletion and epidermal growth factor receptor 21 L858R mutations** – The two most commonly found EGFR gene mutations are deletions in exon 19 in 45% of patients and a point mutation in exon 21 (L858R in 40%). These mutations are predictive of treatment benefits from EGFR tyrosine kinase inhibitor (EGFR TKI) therapy. Most patients harboring them have adenocarcinoma histology and have either never smoked or had a light smoking history.[7]
- **Food and Drug Administration (FDA)** – The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
- **Immune checkpoint inhibitors (ICIs) -** Immunotherapy drugs called immune checkpoint inhibitors work by blocking checkpoint proteins from binding with their partner proteins. This prevents the "off" signal from being sent, allowing the T cells to kill cancer cells. One such drug acts against a checkpoint protein called CTLA-4. Other immune checkpoint inhibitors act against a checkpoint protein called PD-1 or its partner protein PD-L1. [10]
- **Immune-mediated adverse reactions (IMARs) -** Immune checkpoint proteins, such as cytotoxic T-lymphocyte antigen-4 and programmed death-1, are part of the normal immune system and regulate immune activation. Treatment with inhibitors for these checkpoint proteins can result in adverse reactions that present similarly to other conditions. These immune-mediated adverse reactions (IMARs) are most commonly gastrointestinal, respiratory, endocrine, or dermatologic. More rarely, neurologic, ocular, cardiovascular, hematologic, and renal IMARs can occur. The median time to onset of IMARs with anti-PD-1/PD-L1 antibodies is typically between 1 and 6 months; however, IMARs again may present as late as 41 months after treatment initiation. For ipilimumab (anti-CTLA-4), dermatologic IMARs typically present after 2–3 weeks of treatment, while GI and hepatic IMARs appear after 6–7 weeks and some endocrinopathies can appear 9 weeks or later after immunotherapy. [11]

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- **National Comprehensive Cancer Network (NCCN) -** An alliance of 32 leading cancer centers devoted to patient care, research, and education. The NCCN guidelines are utilized for Radiation Therapy and Medical Oncology standards. NCCN consensus clinical standards are periodically updated and NantHealth, Inc. reviews these and updates its policies within a timely manner.
- **Oncogenic drivers –** Genes whose mutation facilitates tumor growth are called driver genes. Cancer develops because of the accumulation of a somatic (after conception) mutation and other genetic alterations that impair cell division, checkpoints, etc., which result in abnormal cell proliferation and eventually cancer – such mutations are called "driver mutations".[13] The discovery of oncogenic drivers led to the design of therapies targeting tumors harboring specific gene alterations that cause aberrant signaling and growth. [14]
- **Programmed cell death protein 1 (PD-1)/Programmed cell death-ligand 1 (PD-L1) –** Checkpoint proteins, such as PD-L1 on tumor cells and PD-1 on T-cells, help keep immune responses in check. The binding of PD-L1 to PD-1 keeps T cells from killing tumor cells in the body. Blocking the binding of PD-L1 to PD-1 with an immune checkpoint inhibitor (anti-PD-L1 or anti-PD-1) allows the T cells to kill tumor cells. [10]
- **ROS1 rearrangement –** A distinct receptor tyrosine kinase that is very similar to ALK and members of the insulin receptor family. It is estimated that ROS1 gene rearrangements occur in about 1-2% of patients with NSCLC. These mutations most frequently occur in nonsquamous histology but can also occur in squamous cell histology, although at a lower rate. [7]

Atezolizumab: Policy

Atezolizumab will be considered for coverage when the following criteria are met:

Note:

1. Individuals receiving PD-1 or PD-L1 blocking antibodies should NOT be receiving therapy for an autoimmune disease or chronic condition with a systemic immunosuppressant.
2. Coverage of atezolizumab will be provided for an FDA-approved indication or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1, 2A, or 2B recommendation OR when all criteria are met.

Urothelial Cancer of the Bladder

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Used as first-line systemic therapy as a single agent in cisplatin-ineligible patients whose tumors express PD-L1 for one of the following:
    a) Stage II (cT2, N0) disease or stage IIIA (cT3, N0; cT4a, N0; cT1-T4a, N1) disease if the tumor is present following reassessment of tumor status 2-3 months after primary treatment with bladder preserving concurrent

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chemoradiotherapy and maximal transurethral resection of bladder tumor (TURBT)

b) Stage II (cT2, N0) disease or stage IIIA (cT3, N0; cT4a, N0; cT1-T4a, N1) disease if the tumor is present following reassessment of tumor status 2-3 months after primary treatment with radiotherapy alone or TURBT
c) Stage IIIB (cT1-T4a, N2,3) disease as downstaging systemic therapy
d) Stage IIIB (cT1-T4a, N2,3) disease following partial response or progression after primary treatment with concurrent chemoradiotherapy
e) Stage IVA (cT4b, any N, M0; any T, any N, M1a) disease
f) Stage IVA (cT4b, any N, M0) disease as consolidation systemic therapy if no tumor present following the reassessment of tumor status 2-3 months after primary treatment with concurrent chemoradiotherapy
g) Stage IVA (cT4b, any N, M0) disease if tumor present following a reassessment of the tumor status 2-3 months after primary treatment with concurrent radiotherapy
h) Metastatic stage IVB (any T, any N, M1b) disease
i) Muscle invasive local recurrence or persistent disease in a preserved bladder treated with curative intent
j) Metastatic or local recurrence post cystectomy treated with curative intent.

Urothelial Cancer of the Urethra

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Primary treatment as a single agent for clinical stage T3-4, cN1-2 disease, or cN1-2 palpable inguinal lymph nodes as first-line systemic therapy in cisplatin-ineligible patients whose tumors express PD-L1; OR
4. Used as a single agent for recurrent or metastatic disease as first-line systemic therapy in cisplatin-ineligible patients whose tumors express PD-L1.

Urothelial Cancer of the Renal Pelvis and Ureter

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Therapy for metastatic disease as a single agent for first-line systemic therapy in cisplatin-ineligible patients whose tumors express PD-L1.

Urothelial Cancer of the Prostate

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Therapy for metastatic disease as a single agent for first-line systemic therapy in cisplatin-ineligible patients whose tumors express PD-L1**.** [2]

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Cervical Cancer

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. First-line, second-line, or subsequent therapy as clinically appropriate (if not used previously as first-line) for persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervix (NECC) for one of the following:
   a) In combination with cisplatin and etoposide
   b) In combination with carboplatin and etoposide. [3]

Hepatocellular Carcinoma

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. First-line treatment in combination with bevacizumab (Child-Pugh Class A; useful in certain circumstances for Child-Pugh Class B) for those who have one of the following:
   a) Unresectable disease and are not a transplant candidate
   b) Liver-confined disease, inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease
   c) Metastatic disease or extensive liver tumor burden. [4]

Melanoma: Cutaneous

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Useful in certain circumstances in combination with vemurafenib and cobimetinib as one of the following:
   a) Second-line or subsequent therapy option for metastatic or unresectable disease with a BRAF V600 activating mutation following progression or intolerance if BRAF/MEK and/or PD(L)-1 checkpoint inhibition has not previously been used
   b) May be considered as re-induction therapy if prior combination BRAF/MEK + PD(L)-1 checkpoint inhibition resulted in disease control (complete response, partial response, or stable disease), no residual toxicity, and disease progression/relapse >3 months after treatment discontinuation. [5]

Mesothelioma: Peritoneal

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Subsequent systemic therapy for ECOG performance status (PS) 0-2 in combination with bevacizumab if not previously treated with immune checkpoint inhibitors.

Note:
Atezolizumab may also be used for pericardial mesothelioma and tunica vaginalis testis mesothelioma. [6]

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Non-Small Cell Lung Cancer

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Single-agent therapy for those with completely resected stage IIB-IIIA, high-risk stage IIA, or stage IIIB (T3, N2) disease that is PD-L1 ≥1% and negative for EGFR exon 19 deletion or exon 21 L858R mutations, or ALK rearrangements who received previous adjuvant chemotherapy and with no contraindications to immune checkpoint inhibitors; OR
4. Treatment for recurrent, advanced, or metastatic disease as first-line therapy as a single agent for PD-L1 expression positive (≥50%) tumors that are negative for actionable molecular biomarkers and no contraindications to PD-1 or PD-L1 inhibitors and performance status 0-2; OR
5. Treatment for recurrent, advanced, or metastatic disease as first-line therapy for PD-L1 expression positive (≥1%) tumors that are negative for actionable molecular biomarkers and no contraindications to PD-1 or PD-L1 inhibitors and performance status 0-2 for nonsquamous cell histology in combination with one of the following:
    a) Bevacizumab, carboplatin, and paclitaxel (if no history of recent hemoptysis)
    b) Carboplatin and albumin-bound paclitaxel; OR
6. Treatment for recurrent, advanced, or metastatic disease for patients with performance status (PS) 0-1, no contraindications to PD-1 or PD-L1 inhibitors, and tumors of nonsquamous cell histology in combination with one of the following:
    a) Carboplatin, paclitaxel, and bevacizumab (if no history of recent hemoptysis)
    b) Carboplatin and albumin-bound paclitaxel

Note:
The above regimens are used for one of the following:

a) Initial systemic therapy for PD-L1 <1% and negative for actionable molecular biomarkers
b) First-line therapy for EGFR exon 20 mutation-positive tumors
c) First-line therapy for KRAS G12C mutation-positive tumors
d) First-line or subsequent therapy for BRAF V600E mutation-positive tumors
e) First-line or subsequent therapy for NTRK1/2/3 gene fusion-positive tumors
f) First-line or subsequent therapy for MET exon 14 skipping mutation-positive tumors
g) First-line or subsequent therapy for RET rearrangement-positive tumors
h) First-line therapy for ERBB2 (HER2) mutation-positive tumors
i) Subsequent therapy for EGFR exon 19 deletion or exon 21 L858R tumors and prior erlotinib +/- (ramucirumab or bevacizumab), afatinib, gefitinib, osimertinib, or dacomitinib therapy
j) Subsequent therapy for EGFR S768I, L861Q, and/or G719X mutation-positive tumors and prior afatinib, osimertinib, erlotinib, gefitinib, or dacomitinib therapy
k) Subsequent therapy for ALK rearrangement positive tumors and prior crizotinib, ceritinib, alectinib, brigatinib, or lorlatinib therapy
l) Subsequent therapy for ROS1 rearrangement positive tumors and prior crizotinib, entrectinib, or ceritinib therapy; OR

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7. 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 molecular biomarkers 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; OR
8. 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 molecular biomarkers 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 atezolizumab, carboplatin, and albumin-bound paclitaxel for nonsquamous cell histology; OR
9. Continuation maintenance therapy as a single agent (if previously received first-line atezolizumab, carboplatin, and albumin-bound paclitaxel) for recurrent, advanced, or metastatic disease with PD-L1 expression <1% tumors that are negative for actionable molecular biomarkers and no contraindications to PD-1 or PD-L1 inhibitors, performance status 0-2, and tumors of nonsquamous cell histology in patients who achieve tumor response or stable disease following initial systemic therapy; OR
10. 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 molecular biomarkers 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 atezolizumab, carboplatin, paclitaxel, and bevacizumab for nonsquamous cell histology with no history of recent hemoptysis; OR
11. Continuation maintenance therapy in combination with bevacizumab (if previously received first-line atezolizumab, carboplatin, paclitaxel, and bevacizumab regimen) for recurrent, advanced, or metastatic disease with PD-L1 expression <1% tumors that are negative for actionable molecular biomarkers and no contraindications to PD-1 or PD-L1 inhibitors, performance status 0-2, and tumors of nonsquamous cell histology with no history of recent hemoptysis in patients who achieve tumor response or stable disease following initial systemic therapy; OR
12. Preferred single agent as subsequent therapy for recurrent, advanced, or metastatic disease in those with performance status 0-2 and no prior progression on a PD-1/PD-L1 inhibitor. [7]

Note:

1. If there is insufficient tissue to allow testing for all EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2), 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.
2. 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 (i.e., EGFR exon 19 deletion or exon 21 L858R, ALK rearrangements) have been shown to be associated with less benefit from PD-1/PD-L1 inhibitors.

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Small Cell Lung Cancer

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Preferred primary treatment in combination with etoposide and carboplatin followed by single-agent maintenance for extensive-stage disease in patients one of the following:
   a) Without localized symptomatic sites or brain metastases and good performance status (PS) 0-2
   b) Without localized symptomatic sites or brain metastases and poor PS (3-4) due to small cell lung cancer
   c) With localized symptomatic sites
   d) With brain metastases [8]

Alveolar Soft Part Sarcoma (ASPS)

1. At least 2 years of age; AND [1]
2. Prescribed by or in consultation with an oncologist; AND
3. Preferred single-agent therapy for the treatment of alveolar soft part sarcoma (ASPS). [9]

Authorization Period and Renewal Criteria

1. Initial Authorization Period: 12 months
2. Renewal Criteria: No evidence of disease progression or unacceptable toxicity
3. Renewal Authorization Period: 12 months

Atezolizumab: References

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Atezolizumab: Coding (CPT®, ICD 10 and HCPCS) *

*Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all-inclusive and is subject to updates. In addition, the codes listed are not a guarantee of payment. CPT codes are available through the AMA.

CODE	DESCRIPTION
C22.0	Liver cell carcinoma
C34.90 -C34.92	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C43.9	Malignant melanoma of skin, unspecified

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C45.1	Mesothelioma of peritoneum
C49.0	Malignant neoplasm of connective and soft tissue of head, face, and neck
C53.9	Malignant neoplasm: Cervix uteri, unspecified
C65.1 – C65.2	Malignant neoplasm of right renal pelvis
C67.9	Malignant neoplasm of bladder, unspecified
C68.0	Malignant neoplasm of urethra
C68.8	Malignant neoplasm of overlapping sites of urinary organs
J9022	Atezolizumab (Tecentriq®)

Atezolizumab: Revision and Review History

No.	Description	Date(s)
1	Original Effective Date:	1/1/2024
2	Policy Review Dates:	6/13/2023
3	Policy Revision Dates:	
4	Department Owner:	Medical Affairs
5	NH Advisory Committee Approval Dates:	7/7/2023
6	Revision Changes:	

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