# Medical Policy:

## Tecentriq® (atezolizumab) Intravenous and Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs) Subcutaneous

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---|---|---|
| MG.MM.PH.169 | October 17, 2024 | |



The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## Definitions

Tecentriq (atezolizumab) is a monoclonal antibody which binds to PD-L1 expressed on tumor cells or tumor infiltrating immune cells and blocks its interaction with PD-1 and B7.1 receptors present on T cells and antigen presenting cells, which releases the inhibition of the immune response and activates the antitumor response.

## Length of Authorization

Coverage will be provided for 12 months and may be renewed.

## Dosing Limits [Medical Benefit]

**Max Units (per dose and over time):**

**Tecentriq:**

1. 168 billable units per 28 days
2. 120 billable units per 21 days

3. 84 billable units per 14 days

**Tecentriq Hybreza**

• 1,875 mg/30,000 units every 21 days

## Guideline

I. **Initial Approval Criteria**

***Tecentriq/Tecentriq Hybreza*** *may be considered medically necessary when any of the following selection criteria is met:*

1. **Non-Small Cell Lung Cancer (NSCLC)**
    A. Member is 18 years or older; **AND**
    A. As a single-agent, is indicated as adjuvant treatment following resection and platinum-based chemotherapy for 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
    B. As a single agent, is indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (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
    C. In combination with bevacizumab, paclitaxel, and carboplatin, is indicated for the first-line treatment of patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.
    D. In combination with paclitaxel protein-bound and carboplatin, is indicated for the first-line treatment of patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.
    E. As a single-agent, is indicated for the treatment of 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.

2. **Small Cell Lung Cancer (SCLC)**
    A. Member is taking in combination with carboplatin and etoposide, for the first-line treatment of adult members with extensive-stage small cell lung cancer (ES-SCLC); **AND**
    B. Member is 18 years of age or older

3. **Hepatocellular Carcinoma (HCC)**
    A. In combination with bevacizumab for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy; **AND**
    B. Member is 18 years of age or older

4. **Melanoma**
    A. Member has a documented diagnosis of BRAF V600 mutation-positive unresectable or metastatic melanoma; **AND**
    B. Tecentriq (atezolizumab) will be used in combination with cobimetinib and vemurafenib; **AND**
    C. Member is 18 years of age or older

5. **Alveolar Soft Part Sarcoma.** Approve if the patient meets the following criteria (A, B, C, and D):
    A. Patient is ≥ 2 years of age (**Tecentriq**) or Patient is ≥ 18 years of age (**Tecentriq Hybreza**); **AND**
    B. Patient has unresectable or metastatic disease; **AND**
    C. The medication is used as a single agent; **AND**
    D. The medication is prescribed by or in consultation with an oncologist.

### Limitations/Exclusions

Tecentriq (atezolizumab) is not considered medically necessary when any of the following selection criteria is met:

1. Tecentriq (atezolizumab) is being used after disease progression with the same regimen.
2. Therapy will not be used concomitantly with intravenous atezolizumab
3. Prior use of immune checkpoint blockade therapies, including anti-PD-1, and anti-PD-L1 therapeutic antibodies. (e.g., nivolumab, pembrolizumab, durvalumab, avelumab, cemiplimab, dostarlimab, nivolumab/relatlimab, retifanlimab, toripalimab, tislelizumab, etc.) unless otherwise specified *(Note: Not applicable when used as switch-therapy with intravenous atezolizumab)*
4. Patients <62 kg should use the IV formulation of Tecentriq
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. **Renewal Criteria**

Coverage can be renewed based upon the following criteria:

1. Member continues to meet the criteria in INITIAL APPROVAL CRITERIA; **AND**
2. Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
3. Absence of unacceptable toxicity from the drug including severe infusion reactions, immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction, skin, etc.), severe infection, ocular inflammatory toxicity, myasthenic syndrome, Guillain-Barre syndrome, meningoencephalitis, pancreatitis, etc.
4. **NSCLC (Adjuvant Treatment)-** Patient has not exceeded 12 months of therapy

### Dosage/Administration

**Tecentriq:**

| Indication | Dose |
|---|---|
| Hepatocellular Cancer | Administer TECENTRIQ as 840 mg every 2 weeks, 1200 mg every 3 weeks, or 1680 mg every 4 weeks. Administer TECENTRIQ prior to bevacizumab when given on the same day. Bevacizumab is administered at 15 mg/kg every 3 weeks. |
| SCLC | Administer TECENTRIQ as 840 mg every 2 weeks, 1200 mg every 3 weeks, or 1680 mg every 4 weeks. When administering with carboplatin and etoposide, administer TECENTRIQ prior to chemotherapy when given on the same day |
| Melanoma | Following completion of a 28 day cycle of cobimetinib and vemurafenib, administer TECENTRIQ 840 mg every 2 weeks, 1200 mg every 3 weeks, or 1680 mg every 4 weeks with cobimetinib 60 mg orally once daily (21 days on /7 days off) and vemurafenib 720 mg orally twice daily. |

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| NSCLC | In the adjuvant setting, administer TECENTRIQ following resection and up to 4 cycles of platinum-based chemotherapy as 840 mg every 2 weeks, 1200 mg every 3 weeks or 1680 mg every 4 weeks for up to 1 year.<br>In the metastatic setting, administer TECENTRIQ as 840 mg every 2 weeks, 1200 mg every 3 weeks, or 1680 mg every 4 weeks.<br>When administering with chemotherapy with or without bevacizumab, administer TECENTRIQ prior to chemotherapy and bevacizumab when given on the same day. |
| Alveolar Soft Part Sarcoma | The recommended dosage is administered intravenously until disease progression or unacceptable toxicity: Adult patients: – 840 mg every 2 weeks or – 1200 mg every 3 weeks or – 1680 mg every 4 weeks<br>Pediatric patients at least 2 years of age: – 15 mg/kg (up to a maximum 1200 mg) every 3 weeks |

**Tecentriq Hybreza:**

| Indication | Dose |
|---|---|
| All Indications | The recommended dosage of Tecentriq Hybreza is one 15 mL injection (containing 1,875 mg of atezolizumab and 30,000 units of hyaluronidase administered subcutaneously every 3 weeks, until disease progression or unacceptable toxicity.<br>− When used as combination therapy, administer prior to chemotherapy when given on the same day.<br>− For adjuvant treatment of NSCLC, duration of therapy is up to one year, unless there is disease recurrence or unacceptable toxicity<br>− For treatment of Melanoma, prior to initiating Tecentriq Hybreza, patients should receive the following 28-day treatment cycle of cobimetinib and vemurafenib:<br>o Days 1 to 21: cobimetinib 60 mg orally once daily in combination with 960 mg of oral vemurafenib twice daily.<br>o Days 22 to 28: withhold cobimetinib and administer vemurafenib 720 mg orally twice daily. |
| *Tecentriq Hybreza must be administered by a healthcare provider* | |
| ***Note:*** *− Tecentriq Hybreza has different recommended dosage and administration than intravenous atezolizumab products. − Patients who are treated with IV atezolizumab can switch to SQ Tecentriq Hybreza at their next scheduled dose; or patients who are treated with Tecentriq Hybreza can switch to IV atezolizumab at their next scheduled dose. − Tecentriq Hybreza is for subcutaneous use in the thigh only administered over approximately 7 minutes.* | |

## Applicable Procedure Codes

| Code | Description |
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| J9022 | Injection, atezolizumab, 10 mg, 1 billable unit = 10 mg |
| J9999 | Not otherwise classified, antineoplastic drugs (Tecentriq Hybreza) |
| C9399 | Unclassified drugs or biologicals (hospital outpatient use only) (Tecentriq Hybreza) |

## Applicable NDCs

| Code | Description |
|---|---|
| 50242-0917-xx | Tecentriq 1200mg/20mL single use vial |
| 50242-0918-xx | Tecentriq 840mg/14mL single use vial |
| 50242-0933-xx | Tecentriq 1,875 mg and 30,000 units/15 mL in a single-dose vial |

## ICD-10 Diagnoses

| Code | Description |
|---|---|
| C22.0 | Liver cell carcinoma, hepatocellular carcinoma |

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| C22.8 | Malignant neoplasm of liver, primary, unspecified as to type |
| C33 | Malignant neoplasm of trachea |
| C34.00 | Malignant neoplasm of unspecified main bronchus |
| C34.01 | Malignant neoplasm of right main bronchus |
| C34.02 | Malignant neoplasm of left main bronchus |
| C34.10 | Malignant neoplasm of upper lobe, unspecified bronchus or lung |
| C34.11 | Malignant neoplasm of upper lobe, right bronchus or lung |
| C34.12 | Malignant neoplasm of upper lobe, left bronchus or lung |
| C34.2 | Malignant neoplasm of middle lobe, bronchus or lung |
| C34.30 | Malignant neoplasm of lower lobe, unspecified bronchus or lung |
| C34.31 | Malignant neoplasm of lower lobe, right bronchus or lung |
| C34.32 | Malignant neoplasm of lower lobe, left bronchus or lung |
| C34.80 | Malignant neoplasm of overlapping sites of unspecified bronchus and lung |
| C34.81 | Malignant neoplasm of overlapping sites of right bronchus and lung |
| C34.82 | Malignant neoplasm of overlapping sites of left bronchus and lung |
| C34.90 | Malignant neoplasm of unspecified part of unspecified bronchus or lung |
| C34.91 | Malignant neoplasm of unspecified part of right bronchus or lung |
| C34.92 | Malignant neoplasm of unspecified part of left bronchus or lung |
| C43.0 | Malignant melanoma of lip |
| C43.111 | Malignant melanoma of right upper eyelid, including canthus |
| C43.112 | Malignant melanoma of right lower eyelid, including canthus |
| C43.121 | Malignant melanoma of left upper eyelid, including canthus |
| C43.122 | Malignant melanoma of left lower eyelid, including canthus |
| C43.20 | Malignant melanoma of unspecified ear and external auricular canal |
| C43.21 | Malignant melanoma of right ear and external auricular canal |
| C43.22 | Malignant melanoma of left ear and external auricular canal |
| C43.30 | Malignant melanoma of unspecified part of face |
| C43.31 | Malignant melanoma of nose |
| C43.39 | Malignant melanoma of other parts of face |
| C43.4 | Malignant melanoma of scalp and neck |
| C43.51 | Malignant melanoma of anal skin |
| C43.52 | Malignant melanoma of skin of breast |
| C43.59 | Malignant melanoma of other part of trunk |
| C43.60 | Malignant melanoma of unspecified upper limb, including shoulder |
| C43.61 | Malignant melanoma of right upper limb, including shoulder |
| C43.62 | Malignant melanoma of left upper limb, including shoulder |
| C43.70 | Malignant melanoma of unspecified lower limb, including hip |
| C43.71 | Malignant melanoma of right lower limb, including hip |
| C43.72 | Malignant melanoma of left lower limb, including hip |
| C43.8 | Malignant melanoma of overlapping sites of skin |
| C43.9 | Malignant melanoma of skin, unspecified |
| C45.1 | Mesothelioma of peritoneum |
| C45.2 | Mesothelioma of pericardium |
| C45.7 | Mesothelioma of other sites |
| C45.9 | Mesothelioma, unspecified |
| C53.0 | Malignant neoplasm of endocervix |

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| C53.1 | Malignant neoplasm of exocervix |
| C53.8 | Malignant neoplasm of overlapping sites of cervix uteri |
| C53.9 | Malignant neoplasm of cervix uteri, unspecified |
| C7A.1 | Malignant poorly differentiated neuroendocrine tumors |
| C78.00 | Secondary malignant neoplasm of unspecified lung |
| C78.01 | Secondary malignant neoplasm of right lung |
| C78.02 | Secondary malignant neoplasm of left lung |
| C79.31 | Secondary malignant neoplasm of brain |
| C79.51 | Secondary malignant neoplasm of bone |
| C79.52 | Secondary malignant neoplasm of bone marrow |
| D09.0 | Carcinoma in situ of bladder |
| D19.1 | Benign neoplasm of mesothelial tissue of peritoneum |
| Z85.118 | Personal history of other malignant neoplasm of bronchus and lung |
| Z85.820 | Personal history of malignant melanoma of skin |

## Revision History

| Company(ies) | DATE | REVISION |
|---|---|---|
| EmblemHealth & ConnectiCare | 10/17/2024 | Revision: added Tecentriq Hybreza, updated dosing limits, Jcodes, NDCs, dosing.<br>Initial Criteria: updated the age limit on Alveolar Soft Part Sarcoma. To read "Patient is ≥ 2 years of age (Tecentriq) or Patient is > 18 years of age (Tecentriq Hybreza); AND"<br>Added the following to Limitations and Exclusions:" Therapy will not be used concomitantly with intravenous atezolizumab" and "Patients <62 kg should use the IV formulation of Tecentriq"<br>Added the examples to the following: "Prior use of immune checkpoint blockade therapies, including anti-PD-1, and anti-PD-L1 therapeutic antibodies. (e.g., nivolumab, pembrolizumab, durvalumab, avelumab, cemiplimab, dostarlimab, nivolumab/relatlimab, retifanlimab, toripalimab, tislelizumab, etc.) unless otherwise specified (Note: Not applicable when used as switch-therapy with intravenous atezolizumab)"<br>Added the following to renewal criteria: "NSCLC (Adjuvant Treatment)- Patient has not exceeded 12 months of therapy" |
| EmblemHealth & ConnectiCare | 1/2/2024 | Annual Review:<br>Removed Bladder Cancer Indication and Criteria<br><u>Initial Criteria: Non-Small Cell Lung Cancer (NSCLC)</u><br>Removed: The member has NSCLC and Tecentriq (atezolizumab) is being used (if pembrolizumab/nivolumab not previously given) as subsequent therapy for metastatic disease in ONE of the following:<br>For the first-line treatment of adult members 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; OR In combination with bevacizumab, paclitaxel, and carboplatin, for the first-line treatment of adult members with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations; OR In combination with paclitaxel protein-bound and carboplatin for the first-line treatment of adult members with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations; OR For the treatment |

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| | | of adult members with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy. Members with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for NSCLC harboring these aberrations prior to receiving Tecentriq (atezolizumab).OR For the adjuvant treatment following resection and platinum-based chemotherapy for adult patients with Stage II to IIIA NSCLC whose tumors have PD-L1 expression on ≥ 1% of tumor cells, as determined by an FDA-approved test."<br>Added" Member is 18 years or older; AND As a single-agent, is indicated as adjuvant treatment following resection and platinum-based chemotherapy for 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. As a single agent, is indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (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, is indicated for the first-line treatment of patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.<br>In combination with paclitaxel protein-bound and carboplatin, is indicated for the first-line treatment of patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.<br>As a single-agent, is indicated for the treatment of 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.<br>Removed 18 and up for exclusion criteria and added to appropriate indications individually, also removed: anti-CTLA-4,and Concurrent active infections, autoimmune diseases, or central nervous system metastases requiring therapy. |
| EmblemHealth & ConnectiCare | 4/21/2023 | Annual Review:<br>Added: Alveolar Soft Part Sarcoma indication and criteria<br>Added codes C43-C53.9, D19.1, Z85.820 Deleted Z85.51, Z85.59, C61 |
| EmblemHealth & ConnectiCare | 8/22/2022 | Removal of "Tecentriq (atezolizumab) is being used (if pembrolizumab/nivolumab not previously given) as subsequent therapy for metastatic disease" for NSCLC |
| EmblemHealth & ConnectiCare | 07/19/2022 | Bladder Cancer: Removal of - As subsequent therapy post platinum chemotherapy , or within 12 months of neoadjuvant or adjuvant chemotherapy<br><br>Removal of Triple Negative Breast Cancer Indication due to voluntary withdrawal by the manufacturer.<br><br>NSCLC: addition of- For the adjuvant treatment following resection and platinum-based chemotherapy for adult patients with Stage II to IIIA NSCLC whose tumors have PD-L1 expression on ≥ 1% of tumor cells, as determined by an FDA-approved test.<br><br>Updated Billable Units/Dosing for all indications per FDA label<br><br>Removal of Breast Cancer Diagnosis/procedure codes |

<table>
<tr><td>EmblemHealth & ConnectiCare</td><td>8/5/2020</td><td>Updated the following Indications/criteria and dosing per FDA Label:<br>1. BRAF V600 mutation-positive unresectable or metastatic melanoma.<br>2. Added the following ICD-10 codes:<br><table><tr><th>ICD-10</th><th>ICD-10 Description</th></tr><tr><td>C43.0-C43.9</td><td>Malignant melanoma of skin, by site</td></tr></table></td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>06/05/2020</td><td>Updated the following Indications/criteria per FDA Label:<br>1. Under Initial Criteria: Bladder Cancer – added bolded text to the criteria: As subsequent therapy post platinum chemotherapy , or within 12 months of neoadjuvant or adjuvant chemotherapy.<br><br>2. Non-Small Cell Lung Cancer - For the first-line treatment of adult members 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.<br><br>3. Hepatocellular Carcinoma (HCC) newly approved indication - In combination with bevacizumab for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy.<br><br>Under Limitations and Exclusions (added): Member must be 18 years of age or older<br><br>Added the following ICD-10 codes:<br><table><tr><th>ICD-10</th><th>ICD-10 Description</th></tr><tr><td>C22.0</td><td>Liver cell carcinoma, hepatocellular carcinoma</td></tr><tr><td>C22.8</td><td>Malignant neoplasm of liver, primary, unspecified as to type</td></tr></table></td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>12/16/2019</td><td>Updated indications to match FDA label: added Small Cell Lung Cancer (SCLC) and criteria: Member is taking in combination with carboplatin and etoposide, for the first-line treatment of adult members with extensive-stage small cell lung cancer (ES-SCLC).</td></tr>
</table>

## References


1. Tecentriq (atezolizumab) [prescribing information]. South San Francisco, CA: Genentech Inc; January 2022.
2. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2022