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| **Section:** | Prescription Drugs | **Effective Date:** | January 1, 2025 |
| **Subsection:** | Antineoplastic Agents | **Original Policy Date:** | June 3, 2016 |
| **Subject:** | Tecentriq | **Page:** | 1 of 8 |

***Last Review Date:*** December 13, 2024

# Tecentriq

## Description

### Tecentriq (atezolizumab)

### Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs)

**Background**
Tecentriq (atezolizumab) is a programmed death-ligand 1 (PD-L1) blocking antibody indicated for the treatment of patients with non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), hepatocellular carcinoma (HCC), melanoma, and alveolar soft part sarcoma (ASPS). PD-L1 is an immune check point protein expressed on tumor cells and tumor infiltrating cells that down regulates anti-tumor t-cell function. Tecentriq works by blocking the PD-L1 pathway which may help the body's own immune system fight off the cancer cells. Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs) is a coformulation of atezolizumab and hyaluronidase. Hyaluronidase increases permeability of the subcutaneous tissue by depolarizing hyaluronan (1-2).

**Regulatory Status**
FDA-approved indications: Tecentriq and Tecentriq Hybreza are indicated for the treatment of patients with: (1-2)

1. Non-small cell lung cancer (NSCLC):
    a. As 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
    b. For the 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

c. 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
d. 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
e. 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 or Tecentriq Hybreza

2. Small cell lung cancer (SCLC):
    a. In combination with carboplatin and etoposide for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)
3. Hepatocellular carcinoma (HCC)
    a. In combination with bevacizumab for the treatment of adult patients with unresectable or metastatic HCC who have not received prior systemic therapy
4. Melanoma
    a. In combination with cobimetinib and vemurafenib for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma
5. Alveolar soft part sarcoma (ASPS)
    a. For the treatment of adult and pediatric patients 2 years of age and older (adult patients only for Tecentriq Hybreza) with unresectable or metastatic ASPS

Patients should be monitored for multiple immune-related conditions including the following: immune-related pneumonitis, immune-related hepatitis, immune-related colitis, immune-related endocrinopathies, immune-related pancreatitis, and immune-related myasthenic syndrome/myasthenia gravis, or meningoencephalitis. Additionally, patients should be monitored for the development of other conditions including ocular inflammatory toxicity, severe or life-threatening infections, infusion reactions, and severe intestinal obstructions. Immune-mediated hepatitis occurred in patients receiving Tecentriq and Tecentric Hybreza treatment. Liver test abnormalities also occurred in patients who received Tecentriq and Tecentric Hybreza. Monitor patients for signs and symptoms of hepatitis. Liver function tests should be performed periodically during treatment with Tecentriq and Tecentric Hybreza including bilirubin, ALT, and

AST. Therapy with this agent should be withheld for the development of moderate conditions associated with treatment and permanently discontinued for severe conditions (1-2).

The safety and effectiveness of Tecentriq for ASPS has not been established in pediatric patients younger than 2 years of age. The safety and effectiveness of Tecentriq Hybreza for ASPS has not been established in pediatric patients less than 18 years of age. The safety and effectiveness of Tecentriq and Tecentriq Hybreza in pediatric patients less than 18 years of age for all other indications have not been established (1-2).

**Related policies.**
Imfinzi, Keytruda, Opdivo

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Tecentriq and Tecentriq Hybreza may be considered **medically necessary** if the conditions indicated below are met.

Tecentriq and Tecentriq Hybreza may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age or older

**Diagnoses**

Patient must have **ONE** of the following:

1. Stage II to IIIA non-small cell lung cancer (NSCLC)
    a. Used as adjuvant treatment following resection and platinum-based chemotherapy
    b. PD-L1 expression on ≥1% of tumor cells as determined by an FDA-approved test

2. Metastatic non-small cell lung cancer (NSCLC) with **ONE** of the following:
    a. Negative for EGFR or ALK tumor expression **AND ONE** of the following:

i. Disease progression on or after platinum-containing chemotherapy
ii. Used as first-line treatment in patients with tumors that have high PD-L1 expression as determined by an FDA-approved test

b. Positive EGFR or ALK tumor expression
i. Disease progression on or after platinum-containing chemotherapy
ii. Disease progression after targeted FDA-approved therapy

3. Metastatic non-squamous non-small cell lung cancer (NSCLC)
a. First-line treatment
b. Used in combination with **ONE** of the following:
i. Bevacizumab, paclitaxel, and carboplatin
ii. Paclitaxel protein-bound and carboplatin
c. Negative for EGFR or ALK tumor expression

4. Extensive-stage small cell lung cancer (ES-SCLC)
a. First-line treatment
b. Used in combination with carboplatin and etoposide

5. Unresectable or metastatic hepatocellular carcinoma (HCC)
a. Used as monotherapy or in combination with bevacizumab
b. Patient has not received prior systemic therapy

6. Unresectable or metastatic melanoma
a. Used in combination with cobimetinib and vemurafenib
b. Positive for BRAF V600 mutation as determined by an FDA-approved test

**AND ALL** of the following:
a. Prescriber agrees to monitor liver enzymes including ALT, AST, and bilirubin
b. Prescriber agrees to monitor for immune-related toxicities

**Diagnosis**

Patient must have the following:
1. Unresectable or metastatic alveolar soft part sarcoma (ASPS)

a. **Tecentriq only**: 2 years of age or older
b. **Tecentriq Hybreza only**: 18 years of age or older

**AND ALL** of the following:
a. Prescriber agrees to monitor liver enzymes including ALT, AST, and bilirubin
b. Prescriber agrees to monitor for immune-related toxicities

## Prior – Approval *Renewal* Requirements

**Age** 18 years of age or older

**Diagnoses**

Patient must have **ONE** of the following:
1. Metastatic non-small cell lung cancer (NSCLC)
2. Metastatic non-squamous non-small cell lung cancer (NSCLC)
3. Extensive-stage small cell lung cancer (ES-SCLC)
4. Unresectable or metastatic hepatocellular carcinoma (HCC)
5. Unresectable or metastatic melanoma

**AND** the following:
a. **NO** disease progression or unacceptable toxicities

**Diagnosis**

Patient must have the following:
1. Unresectable or metastatic alveolar soft part sarcoma (ASPS)
   a. **Tecentriq only**: 2 years of age or older
   b. **Tecentriq Hybreza only**: 18 years of age or older

**AND** the following:
a. **NO** disease progression or unacceptable toxicities

## Policy Guidelines

### Pre - PA Allowance

None

## Prior - Approval Limits

**Duration** 12 months

## Prior – Approval *Renewal* Limits

**Duration** 12 months

**NO** renewal for Stage II to IIIA NSCLC

## Rationale

**Summary**
Tecentriq (atezolizumab) and Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs) are indicated for the treatment of patients with non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), hepatocellular carcinoma (HCC), melanoma, and alveolar soft part sarcoma (ASPS). Tecentriq and Tecentriq Hybreza have been associated with many toxicities and patients should be monitored accordingly. The safety and effectiveness of Tecentriq for ASPS has not been established in pediatric patients younger than 2 years of age. The safety and effectiveness of Tecentriq Hybreza for ASPS has not been established in pediatric patients younger than 18 years of age. The safety and effectiveness of Tecentriq and Tecentriq Hybreza in pediatric patients less than 18 years of age for all other indications have not been established (1-2).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Tecentriq and Tecentriq Hybreza while maintaining optimal therapeutic outcomes.

**References**

1. Tecentriq [package insert]. South San Francisco, CA: Genentech Inc.; April 2024.
2. Tecentriq Hybreza [package insert]. South San Francisco, CA: Genentech Inc.; September 2024.
3. NCCN Drugs & Biologics Compendium® Atezolizumab 2024. National Comprehensive Cancer Network, Inc. Accessed on October 24, 2024.

## Policy History

| Date | Action |
|---|---|
| June 2016 | Addition to PA |

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| November 2016 | Additional of metastatic non-small cell lung cancer diagnosis to criteria |
| March 2017 | Annual review |
| June 2017 | Annual editorial review and reference update<br>Addition to locally advanced or metastatic urothelial carcinoma the option of patients not eligible for cisplatin-containing chemotherapy |
| September 2017 | Annual Review |
| June 2018 | Annual editorial review |
| July 2018 | Addition of use of medication in patients with locally advanced or metastatic urothelial carcinoma in patients who are not eligible for any platinum-containing chemotherapy<br>Removal of requirement: Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy |
| September 2018 | Annual review |
| November 2018 | Annual review |
| December 2018 | Addition of new indication: Metastatic non-squamous NSCLC |
| March 2019 | Addition of new indications: Triple-negative breast cancer (TNBC) and Extensive-stage small cell lung cancer |
| June 2019 | Annual review |
| December 2019 | Addition of indication: Metastatic non-squamous NSCLC in combination with paclitaxel protein-bound and carboplatin |
| March 2020 | Annual review |
| June 2020 | Addition of indication: Metastatic NSCLC whose tumors have high PD-L1 expression as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations. Revised NSCLC indication with EGFR or ALK tumor expression. Addition of indication: hepatocellular carcinoma |
| August 2020 | Addition of indication: Unresectable or metastatic melanoma |
| September 2020 | Annual review |
| April 2021 | Removed locally advanced or metastatic urothelial carcinoma post-platinum therapy. Added limitations of use for TNBC based on product label update. Added “unresectable” to TNBC indication |
| June 2021 | Annual review |
| September 2021 | Annual review and reference update. Removed TNBC indication per manufacturer announcement |
| November 2021 | Addition of indication: Stage II to IIIA NSCLC. Changed initial approval duration to 12 months |
| December 2021 | Annual review |
| September 2022 | Annual review and reference update |
| December 2022 | Removal of indication per PI update: locally advanced or metastatic urothelial carcinoma. Per PI update, added indication of alveolar soft part sarcoma (ASPS) |
| March 2023 | Annual review and reference update |
| September 2023 | Annual review and reference update |
| March 2024 | Annual review and reference update |

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| September 2024 | Annual review and reference update |
| December 2024 | Annual review and reference update. Addition of Tecentric Hybreza to PA |

Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.**