Draft Revised Policy: Do Not Implement

Atezolizumab and Hyaluronidase-tqjs (Tecentriq Hybreza™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication(s)

- Non-Small Cell Lung Cancer (NSCLC)
  - Tecentriq Hybreza, as monotherapy, is indicated 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.
  - Tecentriq Hybreza, as monotherapy, is indicated 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.
  - Tecentriq Hybreza, in combination with bevacizumab, paclitaxel, and carboplatin, is indicated for the first-line treatment, of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.
  - Tecentriq Hybreza, in combination with paclitaxel protein-bound and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.
  - Tecentriq Hybreza as monotherapy, is indicated 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 Hybreza.
- Tecentriq Hybreza, in combination with carboplatin and etoposide, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).
- Tecentriq Hybreza, in combination with bevacizumab, is indicated for the treatment of adult patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy.
- Tecentriq Hybreza, in combination with cobimetinib and vemurafenib, is indicated for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma as determined by an FDA-approved test.
- Tecentriq Hybreza, as monotherapy, is indicated for the treatment of adult patients with unresectable or metastatic alveolar soft part sarcoma (ASPS).

Compendial Uses

- Non-small cell lung cancer
- Mesothelioma
- Hepatocellular carcinoma
- Cervical cancer
- ~~Melanoma~~
- ~~Alveolar soft part sarcoma~~

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- Test results confirming PD-L1 tumor expression (where applicable)
- Test results confirming tumor is positive for BRAF V600 mutation (where applicable)
- Test results confirming the absence of EGFR exon 19 deletion, L858R mutations, and ALK rearrangements (where applicable)

EXCLUSIONS

Coverage will not be provided for members who have experienced disease progression while on PD-1 or PD-L1 inhibitor therapy.

COVERAGE CRITERIA

NON SMALL CELL LUNG CANCER (NSCLC)

- Authorization of 6 months may be granted for treatment of recurrent, advanced or metastatic non-small cell lung cancer when there are no EGFR exon 19 deletions or L858R mutations or ALK rearrangements (unless testing is not feasible due to insufficient tissue) and any of the following criteria are met:
  - The requested medication will be used as continued maintenance therapy as a single agent or in combination with bevacizumab.
  - The requested medication will be used as first line or subsequent therapy in combination with chemotherapy with or without bevacizumab.
  - The requested medication will be used as first line therapy ~~for PD-L1 expression positive (≥50%) tumors~~ as a single agent.
- Authorization of 6 months may be granted for treatment of stage II to III non-small cell lung cancer that is PD-L1 positive as single agent adjuvant therapy when there are no EGFR exon 19 deletions or L858R mutations or ALK rearrangements (unless testing is not feasible due to insufficient tissue).
- Authorization of 6 months may be granted for treatment of recurrent, advanced or metastatic non-small cell lung cancer as single agent subsequent therapy.

SMALL CELL LUNG CANCER (SCLC)

Authorization of 6 months may be granted for treatment of SCLC when the requested medication will be used as initial treatment in combination with etoposide and carboplatin (followed by single agent maintenance) for extensive-stage disease.

HEPATOCELLULAR CARCINOMA (HCC)

- Authorization of 6 months may be granted in combination with bevacizumab for first-line treatment of unresectable or metastatic HCC.
- Authorization of 6 months may be granted in combination with bevacizumab for adjuvant treatment following resection or ablation.

MELANOMA

Authorization of 6 months may be granted for the treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma when the requested medication will be used in combination with cobimetinib (Cotellic) and vemurafenib (Zelboraf).

ALVEOLAR SOFT PART SARCOMA (ASPS)

Authorization of 6 months may be granted for the treatment of unresectable or metastatic ASPS when used as a single agent.

MESOTHELIOMA

Authorization of 6 months may be granted for the subsequent treatment of peritoneal mesothelioma, pericardial mesothelioma, or tunica vaginalis testis mesothelioma when used in combination with bevacizumab.

CERVICAL CANCER

Authorization of 6 months may be granted for the treatment of cervical cancer when either of the following criteria is met:

- The member has persistent, recurrent or metastatic small cell neuroendocrine carcinoma of the cervix (NECC) when used in combination with etoposide and either cisplatin or carboplatin (followed by single agent maintenance).
- The member has recurrent or metastatic adenocarcinoma, adenosquamous, or squamous cell carcinoma and the requested medicaion will be used in combination with bevacizumab, paclitaxel, and either cisplatin or carboplatin (may be used in combination with bevacizumab for maintenance).

CONTINUATION OF THERAPY

ADJUVANT TREATMENT OF HEPATOCELLULAR CARCINOMA (HCC) OR NON-SMALL CELL LUNG CANCER (NSCLC)

Authorization of 6 months may be granted (up to 12 months total) for continued treatment in members requesting reauthorization of adjuvant therapy of hepatocellular carcinoma or non-small cell lung cancer who have not experienced disease recurrence or an unacceptable toxicity.

All other indications

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Tecentriq Hybreza (Atezolizumab-Hyaluronidase-tqjs)	Alveolar Soft Part Sarcoma (ASPS)	Route of Administration: Subcutaneous 1875/30,000mg-units every 3 weeks
Tecentriq Hybreza (Atezolizumab-Hyaluronidase-tqjs)	Cervical Cancer	Route of Administration: Subcutaneous 1875/30,000mg-units every 3 weeks
Tecentriq Hybreza (Atezolizumab-Hyaluronidase-tqjs)	Hepatocellular Carcinoma	Route of Administration: Subcutaneous 1875/30,000mg-units every 3 weeks
Tecentriq Hybreza (Atezolizumab-Hyaluronidase-tqjs)	Malignant Peritoneal Mesothelioma, Pericardial Mesothelioma, or Tunica Vaginalis Testis Mesothelioma	Route of Administration: Subcutaneous 1875/30,000mg-units every 3 weeks
Tecentriq Hybreza (Atezolizumab-Hyaluronidase-tqjs)	Melanoma	Route of Administration: Subcutaneous 1875/30,000mg-units every 3 weeks
Tecentriq Hybreza (Atezolizumab-Hyaluronidase-tqjs)	Non-Small Cell Lung Cancer or Small Cell Lung Cancer	Route of Administration: Subcutaneous 1875/30,000mg-units every 3 weeks

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Tecentriq Hybreza [package insert]. South San Francisco, CA: Genentech, Inc.; September 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed May 5, 2025.

EFFECTIVE DATE

ID_CHS

BlueCross BlueShield of Tennessee

Policy

Medical Policy Manual

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