Reference number(s)
6667-A

Standard Medicare Part B Management Tecentriq Hybreza

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tecentriq Hybreza	atezolizumab and hyaluronidase-tqjs

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 Indications[1]

- 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.

© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

    - 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.
- Small Cell Lung Cancer (SCLC)
    - 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 lurbinectedin, is indicated for maintenance treatment of adult patients with ES-SCLC whose disease has not progressed after first-line induction therapy with Tecentriq Hybreza or intravenous atezolizumab, and carboplatin plus etoposide.
- 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 and pediatric patients (12 years of age or older who weigh 40 kg or greater) with unresectable or metastatic alveolar soft part sarcoma (ASPS).

Compendial Uses[2]

- Non-small cell lung cancer (NSCLC)
- Small cell lung cancer (SCLC)
- Hepatocellular carcinoma (HCC)
- Mesothelioma
- Cervical cancer
- Urothelial carcinoma
- Colon cancer
- Thymic carcinoma
- Chronic lymphocytic leukemia (CLL)
- Small bowel adenocarcinoma

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Documentation

The following documentation must be available, upon request, for all submissions:

- 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, RET, or ROS1 gene fusions (where applicable)
- Documentation of laboratory report confirming microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) with ultra-hypermutated tumor mutational burden [TMB] (greater than 50 mutations/megabase [mut/Mb]) (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)[1,2]

- Authorization of 12 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, RET, or ROS1 gene fusions (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 or subsequent therapy as a single agent.
- Authorization of 12 months may be granted for adjuvant treatment of stage IB to IIIB non-small cell lung cancer that is PD-L1 positive as a single agent when there are no EGFR exon 19 deletions or L858R mutations or ALK, RET, or ROS1 gene fusions (unless testing is not feasible due to insufficient tissue).

Small Cell Lung Cancer (SCLC)[1,2]

Authorization of 12 months may be granted for treatment of SCLC when the requested medication will be used in combination with etoposide and carboplatin, followed by maintenance therapy as a single agent or with lurbinectedin, for extensive-stage disease.

© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Hepatocellular Carcinoma (HCC)[1,2]

Authorization of 12 months may be granted in combination with bevacizumab for the treatment of progressive, unresectable, or metastatic hepatocellular carcinoma (HCC).

Melanoma[1,2]

Authorization of 12 months may be granted for subsequent 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)[1,2]

Authorization of 12 months may be granted for the treatment of unresectable or metastatic ASPS when used as a single agent.

Mesothelioma[2]

Authorization of 12 months may be granted for subsequent treatment of peritoneal mesothelioma, pericardial mesothelioma, or tunica vaginalis testis mesothelioma when used in combination with bevacizumab.

Cervical Cancer[2]

Authorization of 12 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 (may be used as a single agent for maintenance).
- The member has recurrent or metastatic adenocarcinoma, adenosquamous, or squamous cell carcinoma and the requested medication will be used in combination with bevacizumab, paclitaxel, and either cisplatin or carboplatin (may be used in combination with bevacizumab for maintenance).

Urothelial Carcinoma[2]

Authorization of 12 months may be granted for treatment of urothelial carcinoma when the member is not eligible for any platinum containing chemotherapy and the requested medication will be used as a single agent as first line therapy.

© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Colon Cancer[2]

Authorization of 12 months may be granted for adjuvant treatment of stage IIC to III colon cancer when all of the following criteria are met:

- The requested medication will be used in combination with FOLFOX or CAPEOX regimens (followed by single agent maintenance).
- The member's disease is confirmed to be deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (TMB >50 mut/Mb).

Thymic Carcinoma[2]

Authorization of 12 months may be granted for first-line or postoperative systemic therapy for thymic carcinoma in combination with carboplatin and paclitaxel followed by single agent maintenance.

Chronic Lymphocytic Leukemia (CLL)[2]

Authorization of 12 months may be granted for the treatment of chronic lymphocytic leukemia (CLL) with Richter's transformation when the requested medication will be used in combination with venetoclax and obinutuzumab.

Small Bowel Adenocarcinoma

Authorization of 12 months may be granted for the treatment of small bowel adenocarcinoma when the disease is confirmed to be deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (TMB >50 mut/Mb) in any of the following settings:

- As adjuvant therapy when used combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CAPEOX (capecitabine and oxaliplatin) regimens, followed by single agent maintenance.
- As neoadjuvant therapy for resectable disease, when used as a single agent.
- As treatment for locally unresectable, medically inoperable, advanced, or metastatic disease, when used as a single agent.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent. Authorization for 12 months (12 months total for adjuvant HCC, NSCLC, colon cancer, and small bowel adenocarcinoma, or 24 months total for the treatment of thymic carcinoma) may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.

© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

- The requested medication is being used to treat an indication listed in the coverage criteria section.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen and
    - No evidence of disease progression while on the current regimen

Summary of Evidence

The contents listed in these criteria were created after examining the following resources:

- The prescribing information for Tecentriq Hybreza.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Non-small cell lung cancer
- NCCN Guideline: Cutaneous melanoma
- NCCN Guideline: Small cell lung cancer
- NCCN Guideline: Soft tissue sarcoma
- NCCN Guideline: Mesothelioma: peritoneal
- NCCN Guideline: Hepatocellular carcinoma
- NCCN Guideline: Cervical cancer
- NCCN Guideline: Bladder cancer
- NCCN Guideline: Colon cancer
- NCCN Guideline: Chronic lymphocytic leukemia/small lymphocytic lymphoma
- NCCN Guideline: Thymomas and thymic carcinomas
- NCCN Guideline: Small bowel adenocarcinoma

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Tecentriq are covered in addition to the following:

- Non-small cell lung cancer
- Small cell lung cancer
- Mesothelioma
- Cervical cancer
- Hepatocellular carcinoma
- Urothelial carcinoma
- Colon cancer
- Thymic carcinoma
- Chronic lymphocytic leukemia
- Small bowel adenocarcinoma

© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Tecentriq to treat non-small cell lung cancer, hepatocellular carcinoma, cervical cancer, melanoma, alveolar soft part carcinoma, small cell lung cancer, urothelial carcinoma, thymic carcinoma, chronic lymphocytic leukemia, colon cancer, peritoneal mesothelioma, and small bowel adenocarcinoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Tecentriq Hybreza [package insert]. South San Francisco, CA: Genentech, Inc.; November 2025.
2. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed March 9, 2026.

© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.