Reference number(s)
2132-A

STANDARD MEDICARE PART B MANAGEMENT

TECENTRIQ (atezolizumab)

POLICY

I. 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.

A. FDA-Approved Indications

1. Non-small cell lung cancer (NSCLC)

i. Tecentriq, as a single-agent, is indicated as adjuvant treatment following resection and platinum-based chemotherapy for adult 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

ii. Tecentriq, as a single-agent, 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.

iii. Tecentriq, 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.

iv. Tecentriq, 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.

v. Tecentriq, as a single agent 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 the requested medication.

2. Small cell lung cancer (SCLC)

Tecentriq, 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).

3. Hepatocellular Carcinoma (HCC)

Tecentriq, in combination with bevacizumab, is indicated for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy.

4. Melanoma

Tecentriq, in combination with cobimetinib and vemurafenib, is indicated for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.

5. Alveolar Soft Part Sarcoma (ASPS)

Tecentriq, as a single agent, is indicated for the treatment of adult and pediatric patients age 2 years and older with unresectable or metastatic ASPS.

B. Compendial Uses
   1. Urothelial carcinoma
   2. Non-small cell lung cancer (NSCLC)
   3. Mesothelioma
   4. Renal cell cancer

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

II. CRITERIA FOR INITIAL APPROVAL

A. Urothelial carcinoma

Authorization of 12 months may be granted for treatment of urothelial carcinoma when any of the following criteria is met:

1. Member is not eligible for cisplatin-containing chemotherapy, and the member's tumor expresses PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥5% of the tumor area).
2. Member is not eligible for any platinum containing chemotherapy.
3. The requested medication will be used for the for the first-line treatment of locally advanced or metastatic urothelial carcinoma in combination with gemcitabine and cisplatin or gemcitabine and carboplatin.

B. Non-small cell lung cancer (NSCLC)

1. 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 rearrangements (unless testing is not feasible due to insufficient tissue) and any of the following criteria are met:
   i. The requested medication will be used as continued maintenance therapy as a single agent or in combination with bevacizumab.
   ii. The requested medication will be used as first line or subsequent therapy in combination with chemotherapy.
   iii. The requested medication will be used as first line therapy for PD-L1 expression positive (≥50%) tumors as a single agent.
2. Authorization of 12 months may be granted for treatment of recurrent, advanced or metastatic non-small cell lung cancer as single agent subsequent therapy.
3. Authorization of 12 months may be granted for treatment of stage II to IIIB non-small cell lung cancer that is PD-L1 positive as single agent adjuvant therapy.

C. Small cell lung cancer (SCLC)

Authorization of 12 months may be granted for treatment of small cell lung cancer 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.

D. Hepatocellular carcinoma (HCC)

Authorization of 12 months may be granted for treatment of unresectable or metastatic hepatocellular carcinoma when the requested medication will be used as initial treatment in combination with bevacizumab.

E. Melanoma
Authorization of 12 months may be granted for treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma when the requested medication is used in combination with cobimetinib and vemurafenib.

F. Mesothelioma
Authorization of 12 months may be granted for subsequent treatment of malignant peritoneal mesothelioma when used in combination with bevacizumab.

G. Renal cell cancer
Authorization of 12 months may be granted for first-line treatment of advanced or metastatic renal cell cancer, in combination with bevacizumab.

H. Alveolar Soft Part Sarcoma (ASPS)
Authorization of 12 months may be granted for the treatment of patients with unresectable or metastatic alveolar soft part sarcoma when used as a single agent.

III. 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 NSCLC) may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with the requested medication.
B. The requested medication is being used to treat an indication enumerated in Section II.
C. The member is receiving benefit from therapy. Benefit is defined as:
    1. No evidence of unacceptable toxicity while on the current regimen AND
    2. No evidence of disease progression while on the current regimen.

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Tecentriq.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. NCCN Guideline: Small cell lung cancer
4. NCCN Guideline: Peritoneal mesothelioma
5. NCCN Guideline: Cutaneous melanoma
6. NCCN Guideline: Non-small cell lung cancer
7. NCCN Guideline: Hepatocellular carcinoma
8. NCCN Guideline: Soft tissue sarcoma
9. NCCN Guideline: Bladder cancer

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:

A. Urothelial carcinoma
B. Non-small cell lung cancer
C. Mesothelioma
D. Renal cell cancer

V. EXPLANATION OF RATIONALE

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

Support for using Tecentriq to treat urothelial carcinoma, non-small cell lung cancer and peritoneal mesothelioma 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).

Support for using Tecentriq to treat renal cell cancer can be found in the Clinical Pharmacology database. Use of information in the Clinical Pharmacology database 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). The Clinical Pharmacology database supports the use of Tecentriq as first-line treatment of advanced or metastatic renal cell cancer in combination with bevacizumab.

VI. REFERENCES

1. Tecentriq [package insert]. South San Francisco, CA: Genentech, Inc.; December 2022.
2. The NCCN Drugs & Biologics Compendium®© 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 4, 2023.
3. Clinical Pharmacology powered by ClinicalKey. Tampa (FL): Elsevier. 2022- [cited July 6, 2022]. Available from: http://www.clinicalkey.com.