# Clinical Policy: Atezolizumab (Tecentriq)

Reference Number: CP.PHAR.235
Effective Date: 06.01.16
Last Review Date: 02.22
Line of Business: Commercial, Medicaid, HIM

Coding Implications
Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

Atezolizumab (Tecentriq®) is a programmed death-ligand 1 (PD-L1) blocking antibody.

## FDA Approved Indication(s)

Tecentriq is indicated:

- **Urothelial carcinoma (UC)**
  - For the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who:
    - are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 5% of the tumor area), as determined by an FDA-approved test.
    - are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.

    *This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).*
- **Non-small cell lung cancer (NSCLC)**
  - As a single agent and 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.
  - As a single agent 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.
  - 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.
  - 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.
  - As a single agent 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.
- **Small cell lung cancer (SCLC)**

- In combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

- **Heptatocellular carcinoma (HCC)**
  - In combination with bevacizumab for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy.
- **Melanoma**
  - In combination with cobimetinib and vemurafenib for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Tecentriq is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Urothelial Carcinoma** (must meet all)**:**

1. Diagnosis of UC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. One of the following (a or b):
   a. Member is ineligible for cisplatin-containing chemotherapy, and the tumor expresses PD-L1;
   b. Member is ineligible for any platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) regardless of PD-L1 status;
5. Prescribed as a single agent;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 1,680 mg every 4 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 6 months**

**B. Non-Small Cell Lung Cancer** (must meet all)**:**

1. Diagnosis of NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a, b, or c):
   a. For stage II to IIIA NSCLC, prescribed as a single agent and meets one of the following (i or ii):
      i. Member has had previous resection;
      ii. Member has all the following (1, 2 and 3):
         1) High-risk stage IIA NSCLC (*see Appendix D*);
         2) PD-L1 expression ≥ 1%;
         3) Previously received platinum-containing chemotherapy *(see Appendix B)*;

b. For member with both a negative or unknown EGFR or ALK mutation status AND recurrent, advanced, or metastatic NSCLC: Member meets one of the following (i, ii, iii, or iv):
   i. Request is for use as a single agent as first-line therapy for tumors that have high PD-L1 expression (PD-L1 ≥ 50% [TC ≥ 50%] or tumor-infiltrating IC covering ≥ 10% of the tumor area [IC ≥ 10%]);
   ii. Disease is non-squamous, and Tecentriq is prescribed in combination with one of the following (1 or 2):
      1) Bevacizumab, paclitaxel, and carboplatin;
      2) Paclitaxel protein-bound (Abraxane®) and carboplatin;
   iii. Member has previously received platinum-containing chemotherapy *(see Appendix B)*;
   iv. If no prior progression on a PD-1/PD-L1 inhibitor (i.e., Tecentriq as well as nivolumab, pembrolizumab, durvalumab), request is for single agent as subsequent therapy;

c. For member with a positive EGFR or ALK mutation status AND recurrent, advanced, or metastatic NSCLC: Member has a history of disease progression during or following an NCCN-recommended therapy for the specific mutation *(see Appendix B)*;

5. Request meets one of the following (a or b):*
   a. Dose does not exceed 1,680 mg every 4 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 6 months**

**C. Small Cell Lung Cancer** (must meet all)**:**
1. Diagnosis of extensive-stage SCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with carboplatin and etoposide;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 1,680 mg every 4 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 6 months**

**D. Hepatocellular Carcinoma** (must meet all):
1. Diagnosis of HCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with bevacizumab as first-line systemic therapy;
5. Confirmation of Child-Pugh class A status;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 1,680 mg every 4 weeks;

b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 6 months**

**E. Melanoma** (must meet all):

1. Diagnosis of melanoma with BRAF V600 mutation;
2. Disease is unresectable or metastatic;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Prescribed in combination with cobimetinib and vemurafenib;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 840 mg every 2 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 6 months**

**F. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid.

## II. Continued Therapy

**A. All Indications in Section I** (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Tecentriq for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b, or c):*
   a. For HCC, NSCLC, extensive-stage SCLC, UC: New dose does not exceed 1,680 mg every 4 weeks;
   b. For TNBC, melanoma: New dose does not exceed 840 mg every 2 weeks;
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 6 months (whichever is less)**; or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid.

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid, or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

ALK: anaplastic lymphoma kinase
EGFR: epidermal growth factor receptor
FDA: Food and Drug Administration
HCC: hepatocellular carcinoma
NSCLC: non-small cell lung cancer
PD-L1: programmed death-ligand 1
SCLC: small cell lung cancer
UC: urothelial carcinoma

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| cisplatin-, oxaliplatin- (Eloxatin®) or carboplatin-containing chemotherapy | UC: Varies | Varies |
| cisplatin-, or carboplatin-containing chemotherapy | NSCLC: Varies | Varies |
| Xalkori® (crizotinib)<br>Alecensa® (alectinib)<br>Zykadia® (ceritinib) | NSCLC with ALK tumor aberration: Varies | Varies |
| Tarceva® (erlotinib)<br>Gilotrif® (afatinib)<br>Iressa® (gefitinib) | NSCLC with EGFR tumor aberration: Varies | Varies |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

None reported

*Appendix D: General Information*

- NSCLC examples of high-risk factors: may include poorly differentiated tumors (including lung neuroendocrine tumors [excluding well-differentiated neuroendocrine tumors]), vascular invasion, wedge resection, tumors > 4 cm, visceral pleural involvement, and unknown lymph node status. These factors independently may or may not be an indication and may be considered when determining treatment with adjuvant chemotherapy.
- SCLC consists of two stages: limited-stage and extensive-stage. Extensive-stage is defined as stage IV (T any, N any M 1a/b) or T3-4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a

tolerable radiation plan.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| UC | 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks | 1,680 mg/4 weeks |
| NSCLC | As a single agent: 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks<br><br>When administering with chemotherapy with or without bevacizumab: 1,200 mg IV every 3 weeks prior to chemotherapy and bevacizumab<br><br>Following completion of 4-6 cycles of chemotherapy, and if bevacizumab is discontinued, administer Tecentriq 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks | 1,680 mg/4 weeks |
| SCLC | When administering with carboplatin and etoposide: 1,200 mg IV every 3 weeks prior to chemotherapy<br><br>Following completion of 4 cycles of carboplatin and etoposide: administer Tecentriq 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks | 1,680 mg/4 weeks |
| HCC | 1,200 mg IV every 3 weeks plus bevacizumab 15 mg/kg IV on the same day<br><br>If bevacizumab is discontinued for toxicity, the recommended dosage of Tecentriq is 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks | 1,680 mg/4 weeks |
| Melanoma | Following completion of a 28 day cycle of cobimetinib and vemurafenib, administer Tecentriq 840 mg IV every 2 weeks with cobimetinib 60 mg PO QD (21 days on/7 days off) and vemurafenib 720 mg PO BID | 840 mg/2 weeks |

## VI. Product Availability

Single-dose vial: 840 mg/14 mL, 1,200 mg/20 mL

## VII. References

1. Tecentriq Prescribing Information. South San Francisco, CA: Genentech, Inc.; October 2021. Available at: https://www.tecentriq.com. Accessed November 4, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: nccn.org. Accessed November 13, 2021.

3. National Comprehensive Cancer Network Guidelines. Non-Small Cell Lung Cancer Version 7.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed October 15, 2020.
4. National Comprehensive Cancer Network Guidelines. Hepatobiliary Cancers Version 5.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed November 14, 2021.

**Coding Implications**
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|---|---|
| J9022 | Injection, atezolizumab, 10 mg |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 1Q18 annual review:<br>Converted to new template<br>No significant changes<br>Added continuation of therapy for all covered indications<br>References reviewed and updated | 11.10.17 | 02.18 |
| 1Q 2019 annual review; HIM-Medical Benefit line of business added; new indication added under UC for patients ineligible for any platinum-containing chemotherapy regardless of PD-L1 status; for UC cisplatin ineligibility, expression of PD-L1 is added per PI and NCCN; for NSCLC, prior therapy requirement is removed given the number of variations in which Tecentriq may be used as both first- and second-line therapy per NCCN; references reviewed and updated. | 11.13.18 | 02.19 |
| Criteria added for new FDA indication: first-line treatment of metastatic non-squamous NSCLC; added specialist involvement in care for all indications; added off-label criteria for SCLC; references reviewed and updated. | 01.08.19 | 02.19 |
| Criteria added for new FDA indication: triple-negative breast cancer in combination with paclitaxel protein-bound; off-label designation removed for SCLC as it is now FDA-approved; references reviewed and updated. | 04.16.19 | 05.19 |
| 1Q 2020 annual review: criteria added for new FDA indication: metastatic non-squamous NSCLC in combination with paclitaxel protein-bound and carboplatin; for NSCLC, added indication as subsequent therapy if no progression on other PD-1/PD-L1 inhibitors; references reviewed and updated. | 01.14.20 | 02.20 |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| RT4 policy update to add criteria for newly FDA-approved indications: 1) first-line therapy for metastatic NSCLC with high PD-L1 expression, and 2) first-line therapy for HCC in combination with bevacizumab; references reviewed and updated. | 06.08.20 | |
| Added Commercial line of business; RT4 policy update to add criteria for newly FDA-approved indication for melanoma in combination with cobimetinib and vemurafenib; references reviewed and updated. | 08.15.20 | |
| 1Q 2021 annual review: for HCC, unresectable or metastatic removed to accommodate local disease per NCCN; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated. | 10.15.20 | 02.21 |
| RT4 policy update to remove the indication, previously approved under accelerated approval, for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy. | 05.12.21 | |
| 1Q 2022 annual review: RT4: removed breast cancer indication and added NSCLC stage II to IIIA treatment indication per updated label; added criterion for use as single-agent therapy for urothelial carcinoma per NCCN; added criterion for Child-Pugh class A status in HCC per NCCN; references reviewed and updated. | 01.18.22 | 02.22 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note:**
**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.