

Clinical Policy: Atezolizumab (Tecentriq)

Reference Number: CP.PHAR.235

Effective Date: 06.01.16

Last Review Date: 02.20

Line of Business: 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 for the treatment of patients with:

- Locally advanced or metastatic urothelial carcinoma (UC)[†] who
 - are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] covering $\geq 5\%$ of the tumor area), as determined by an FDA-approved test, or
 - are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status, or
 - have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy.
- Metastatic non-small cell lung cancer (NSCLC)
 - as a single agent for the first-line treatment of adult patients whose tumors have high PD-L1 expression (PD-L1 stained $\geq 50\%$ of tumor cells [TC $\geq 50\%$] or PD-L1 stained tumor-infiltrating IC covering $\geq 10\%$ of the tumor area [IC $\geq 10\%$]), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, or
 - who have disease progression during or following platinum-containing chemotherapy. Patients with epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations should have disease progression on FDA approved therapy for these aberrations prior to receiving Tecentriq, or
 - in combination with bevacizumab, paclitaxel, and carboplatin for the first-line treatment of adult patients with non-squamous disease with no EGFR or ALK genomic tumor aberrations, or
 - 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.
- Unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) in combination with paclitaxel protein-bound in adult patients whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] of any intensity covering $\geq 1\%$ of the tumor area), as determined by an FDA-approved test.[†]
- Extensive-stage small cell lung cancer (SCLC) in combination with carboplatin and etoposide for the first-line treatment of adult patients.
- Hepatocellular carcinoma (HCC) in combination with bevacizumab for patients with unresectable or metastatic disease who have not received prior systemic therapy.

†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 confirmatory trials.

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 \geq 18 years;
4. One of the following (a, b, or c):
 - 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;
 - c. Disease has progressed during or following platinum-containing chemotherapy;
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

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

1. Diagnosis of recurrent, advanced, or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. If EGFR or ALK mutation status is negative or unknown, member meets one of the following (a, b, c, or d):
 - a. Request is for use as a single agent as first-line therapy for tumors that have high PD-L1 expression (PD-L1 \geq 50% [TC \geq 50%] or tumor-infiltrating IC covering \geq 10% of the tumor area [IC \geq 10%]);
 - b. Disease is non-squamous, and Tecentriq is prescribed in combination with one of the following (i or ii):
 - i. Bevacizumab, paclitaxel, and carboplatin;
 - ii. Paclitaxel protein-bound (Abraxane[®]) and carboplatin;
 - c. Member has previously received platinum-containing chemotherapy (*see Appendix B*);

- d. 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;
 5. If a known EGFR or ALK genomic tumor aberration is present, history of disease progression during or following an NCCN-recommended therapy for the aberration (*see Appendix B*);
 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

C. Breast Cancer (must meet all):

1. Diagnosis of unresectable, locally advanced, recurrent, or metastatic breast cancer;
 2. Prescribed by or in consultation with an oncologist;
 3. Age \geq 18 years;
 4. Documentation of triple negative (i.e., estrogen, progesterone, and human epidermal growth factor receptor 2 [HER2] negative) disease;
 5. Tumor expresses PD-L1;
 6. Prescribed in combination with protein-bound paclitaxel (nab-paclitaxel);
 7. 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

D. Small Cell Lung Cancer (must meet all):

1. Diagnosis of extensive-stage SCLC;
 2. Prescribed by or in consultation with an oncologist;
 3. Age \geq 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

E. Hepatocellular Carcinoma (must meet all):

1. Diagnosis of unresectable or metastatic HCC;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Prescribed in combination with bevacizumab as first-line systemic therapy;
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

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): HIM.PHAR.21 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: 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): HIM.PHAR.21 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 – HIM.PHAR.21 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

TNBC: triple-negative breast 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) Alecensa [®] (alectinib) Zykadia [®] (ceritinib)	NSCLC with ALK tumor aberration: Varies	Varies
Tarceva [®] (erlotinib) Gilotrif [®] (afatinib) 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

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	<p><u>As a single agent:</u> 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks</p> <p><u>When administering with chemotherapy with or without bevacizumab:</u> 1,200 mg IV every 3 weeks prior to chemotherapy and bevacizumab</p> <p>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</p>	1,680 mg/4 weeks

Indication	Dosing Regimen	Maximum Dose
SCLC	<p><u>When administering with carboplatin and etoposide:</u> 1,200 mg IV every 3 weeks prior to chemotherapy</p> <p>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</p>	1,680 mg/4 weeks
TNBC	For each 28 day cycle, 840 mg IV on days 1 and 15 followed by 100 mg/m ² nab-paclitaxel on days 1, 8, and 15	840 mg/2 weeks
HCC	<p>1,200 mg IV every 3 weeks plus bevacizumab 15 mg/kg IV on the same day</p> <p>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</p>	1,680 mg/4 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.; May 2020. Available at: <https://www.tecentriq.com>. Accessed June 8, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: nccn.org. Accessed December 29, 2019.
3. Bladder Cancer Version 4.2019. In: National Comprehensive Cancer Network Guidelines. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed November 13, 2019.
4. Non-Small Cell Lung Cancer Version 5.2020. National Comprehensive Cancer Network Guidelines. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed June 8, 2020.
5. Breast Cancer Version 3.2019. National Comprehensive Cancer Network Guidelines. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed November 13, 2019.
6. Small Cell Lung Cancer Version 1.2020. National Comprehensive Cancer Network Guidelines. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf. Accessed November 13, 2019.
7. Hepatobiliary Cancers Version 3.2020. National Comprehensive Cancer Network Guidelines. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed June 8, 2020.

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
Policy developed.	06.16	06.16
New labeled indication added: Non-small cell lung cancer.	01.17	01.17
Under urothelial carcinoma: a new FDA approved indication is added for cisplatin ineligible patients; defined “locally advanced” as “stages II through IV; added oxaliplatin as an example of platinum-containing chemotherapy. Under lung cancer: the FDA and NCCN uses are combined; ceritinib is added as an indicated therapy for ALK tumor aberrations and osimertinib for EGFR aberrations. Removed reasons to discontinue from the renewal section; added a general efficacy statement. Extended approval durations from 3 and 6 months to 6 and 12 months.	05.17	06.17
1Q18 annual review: Converted to new template No significant changes Added continuation of therapy for all covered indications 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	01.14.20	02.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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.		
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	

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.

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