Clinical Policy: Atezolizumab (Tecentriq)

Reference Number: CP.PHAR.235
Effective Date: 06.01.16
Last Review Date: 02.19
Line of Business: Medicaid, HIM-Medical Benefit

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 ≥ 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

  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.
- Metastatic non-small cell lung cancer (NSCLC)
  - 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 patients with non-squamous disease with no EGFR or ALK genomic tumor aberrations

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, 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 1,200 mg every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

Approval duration: 6 months

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

1. Diagnosis of recurrent or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. If EGFR or ALK mutation status is negative or unknown, member meets one of the following (a or b):
   a. Disease is non-squamous and Tecentriq is prescribed in combination with bevacizumab, paclitaxel, and carboplatin;
   b. Member has previously received platinum-containing chemotherapy *(see Appendix B)*;
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 1,200 mg every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

C. Small Cell Lung Cancer (off-label) (must meet all)**:**

1. Diagnosis of extensive small cell lung cancer (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 1,200 mg every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

D. 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.PMN.53 for Medicaid and HIM-Medical Benefit.

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 or b):
   a. New dose does not exceed 1,200 mg every 3 weeks;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

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.PMN.53 for Medicaid and HIM-Medical Benefit.

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.PMN.53 and HIM-Medical Benefit, 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
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) Alecensa® (alectinib) Zykadia® (ceritinib)	NSCLC with ALK tumor aberration: Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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.
- The NCCN recommends Tecentriq in combination with carboplatin and etoposide as the preferred treatment option for extensive stage SCLC (category 1).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
UC, NSCLC	1,200 mg IV every 3 weeks	1,200 mg/3 weeks
SCLC*	1,200 mg IV day 1 every 3 weeks x 4 cycles (in combination with carboplatin and etoposide), followed by maintenance doses of 1,200 mg	1,200 mg/dose

**Off-label; dosing recommended by NCCN*

VI. Product Availability
Single-dose vial: 1,200 mg/20 mL

VII. References
1. Tecentriq Prescribing Information. South San Francisco, CA: Genentech, Inc.; December 2018. Available at: https://www.tecentriq.com. Accessed December 10, 2018.
2. Atezolizumab. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: nccn.org. Accessed December 10, 2018.
3. Bladder cancer (Version 5.2018). In: National Comprehensive Cancer Network Guidelines. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed September 27, 2018.
4. Non-small cell lung cancer (Version 2.2019). National Comprehensive Cancer Network Guidelines. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed December 10, 2018.
5. Small cell lung cancer (Version 1.2019). National Comprehensive Cancer Network Guidelines. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf. Accessed December 18, 2018.

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
C9483	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

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.

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.