Clinical Policy: Atezolizumab (Tecentriq)

Reference Number: CP.PHAR.235
Effective Date: 06.01.16
Last Review Date: 02.18
Line of Business: Medicaid

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 who:
  - Are not eligible for cisplatin-containing chemotherapy, or
  - Have disease progression during or following any platinum-containing therapy within 12 months of neoadjuvant or adjuvant chemotherapy.

  Limitation(s) of use: 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 EGFR or ALK genomic tumor aberrations should have disease progression on FDA approved therapy for these aberrations prior to receiving Tecentriq.

Policy/Criteria

Provider must submit documentation (including 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 urothelial carcinoma;
2. Age ≥18 years;
3. Disease is locally advanced (stages II through IV), recurrent or metastatic;
4. Member is ineligible for cisplatin-containing chemotherapy OR disease has progressed during or following platinum-containing (e.g., cisplatin, carboplatin, oxaliplatin) chemotherapy;
5. Prescribed dose of Tecentriq does not exceed 1200 mg every 3 weeks.

Approval duration: 6 months

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

1. Diagnosis of NSCLC;

2. Age ≥18 years;
3. Disease has progressed during or following a first-line or subsequent systemic regimen for metastatic disease;
4. If a known epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberration is present, history of disease progression during or following an NCCN-recommended therapy for the aberration:
   a. ALK tumor aberration: crizotinib, ceritinib, or alectinib;
   b. EGFR tumor aberration: erlotinib, afatinib, or gefitinib;
5. Prescribed dose of Tecentriq does not exceed 1200 mg every 3 weeks.

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 and has received this medication for at least 30 days;
2. Member is responding positively to therapy (e.g., no disease progression or unacceptable toxicity);
3. If request is for a dose increase, new dose does not exceed 1200 mg every 3 weeks.

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 CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
ALK: anaplastic lymphoma kinase
EGFR: epidermal growth factor receptor
NSCLC: non-small cell lung cancer
PD-L1: programmed death-ligand 1

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, carboplatin, oxaliplatin	Urothelial Carcinoma: Varies	Varies
Cisplatin or carboplatin containing regimens	NSCLC: Varies	Varies
Crizotinib, ceritinib, or alectinib	NSCLC with ALK tumor aberration: Varies	Varies
Erlotinib, afatinib, or gefitinib	NCSCLC 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.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Urothelial carcinoma, NSCLC	1200 mg IV every 3 weeks	1200 mg every 3 weeks

VI. Product Availability

Single-dose vial: 1200 mg/20 mL

VII. References

1. Tecentriq Prescribing Information. South San Francisco, CA: Genentech, Inc.; April 2017. Available at https://www.gene.com/download/pdf/tecentriq_prescribing.pdf. Accessed November 11, 2017.
2. Atezolizumab. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed November 10, 2017.
3. Bladder cancer (Version 5.2017). In: National Comprehensive Cancer Network Guidelines. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed November 10, 2017.
4. Non-small cell lung cancer (Version 9.2017). In: National Comprehensive Cancer Network Guidelines. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed November 10, 2017.

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

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.