Clinical Policy: Atezolizumab (Tecentriq)

Reference Number: CP.PHAR.235
Effective Date: 06/16
Last Review Date: 06/17

Coding Implications
Revision Log

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

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for atezolizumab (Tecentriq®).

Policy/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. Disease is locally advanced (stages II through IV), recurrent or metastatic;
3. Member is ineligible for cisplatin-containing chemotherapy OR disease has progressed during or following platinum-containing (e.g., cisplatin, carboplatin, oxaliplatin) chemotherapy;
4. 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 non-small cell lung cancer;
2. Disease has progressed during or following a first-line or subsequent systemic regimen for metastatic disease;
3. 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, alectinib or brigatinib;
   b. EGFR tumor aberration: erlotinib, afatinib, gefitinib or osimertinib;
4. Prescribed dose of Tecentriq does not exceed 1200 mg every 3 weeks.

Approval duration: 6 months

C. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

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

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;

2. Member is responding positively to therapy (e.g., no disease progression or unacceptable toxicity);
3. Prescribed dose of Tecentriq does not exceed 1200 mg every 3 weeks.

Approval duration: 12 months

B. Other diagnoses/indications (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.PHAR.57 - Global Biopharm Policy**.**

Background
Description/Mechanism of Action:
PD-L1 may be expressed on tumor cells, or tumor-infiltrating immune cells, and can contribute to the inhibition of the anti-tumor immune response. Atezolizumab is a monoclonal antibody that binds to PD-L1 and blocks its interactions with both PD-1 and B7.1 receptors. This releases the PD-L1/PD-1 mediated inhibition of the immune response, including the anti-tumor immune response, without inducing antibody dependent cellular cytotoxicity.

Formulations:
Solution for intravenous infusion:
- Tecentriq is supplied in single-dose vials: 1200 mg/20 mL (60 mg/mL)

FDA Approved Indications:
Tecentriq is a programmed death-ligand 1 (PD-L1) blocking antibody/intravenous formulation 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.

  Limitations 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 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.

Appendices
Appendix A: Abbreviation Key
ALK: anaplastic lymphoma kinase
EGFR: epidermal growth factor receptor

PD-L1: programmed death-ligand 1

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	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

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 May 11, 2017.
2. Atezolizumab. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed May 11, 2017.
3. Bladder cancer (Version 3.2017). In: National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed May 11, 2017.
4. Non-small cell lung cancer (Version 5.2017). In: National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed May 11, 2017.

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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs,

and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.