

## Clinical Policy: Atezolizumab (Tecentriq)

Reference Number: CP.PHAR.235

Effective Date: 06/16

Last Review Date: 05/17

[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 or metastatic;
3. Disease has progressed during or following platinum-containing (e.g., cisplatin, carboplatin) chemotherapy OR the patient is not eligible for platinum-containing 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 is metastatic;
3. Disease has progressed during or following platinum-containing (e.g., cisplatin, carboplatin) chemotherapy;
4. If a known epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberration, disease has progressed on FDA-approved therapy for these aberrations (ALK+ disease: crizotinib [Xalkori], alectinib [Alecensa]; EGFR+ disease: erlotinib [Tarceva], afatinib [Gilotrif], gefitinib [Iressa]);
5. 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 (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member has not had disease progression or unacceptable toxicity while on Tecentriq.

**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; 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:

- Single-dose vials: 1200 mg/20 mL (60 mg/mL)

*FDA Approved Indications:*

Tecentriq is a PD-L1 blocking antibody/intravenous injectable 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 chemotherapy, or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

*Limitations of use:* This indication is approved under accelerated approval based on tumor response rate and durability 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

ULN: upper limit of normal

**Coding Implications**

## CLINICAL POLICY

### Atezolizumab

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
New labeled indication added: first-line treatment of metastatic urothelial carcinoma in patients who are ineligible for cisplatin-containing chemotherapy.	04/17	05/17

#### References

1. Tecentriq Prescribing Information. South San Francisco, CA: Genentech, Inc.; April 2017. Available at [http://www.gene.com/download/pdf/tecentriq\\_prescribing.pdf](http://www.gene.com/download/pdf/tecentriq_prescribing.pdf). Accessed April 2017.
2. Bladder cancer (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed April 2017.
3. Non-small cell lung cancer (Version 5.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed April 2017.
4. Atezolizumab. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed April 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.

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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.

**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.

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