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

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):

Coding Implications
Revision Log
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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/ Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>cisplatin-, oxaliplatin-</td>
<td>UC: Varies</td>
<td>Varies</td>
</tr>
<tr>
<td>(Eloxatin®) or</td>
<td></td>
<td></td>
</tr>
<tr>
<td>carboplatin-containing</td>
<td></td>
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<tr>
<td>chemotherapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>cisplatin-, or carboplatin-</td>
<td>NSCLC: Varies</td>
<td>Varies</td>
</tr>
<tr>
<td>containing chemotherapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Xalkori® (crizotinib)</td>
<td>NSCLC with ALK</td>
<td>Varies</td>
</tr>
<tr>
<td>Alecensa® (alectinib)</td>
<td>tumor aberration: Varies</td>
<td></td>
</tr>
<tr>
<td>Zykadia® (ceritinib)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug Name</td>
<td>Dosing Regimen</td>
<td>Dose Limit/Maximum Dose</td>
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<td>-----------</td>
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<td>------------------------</td>
</tr>
<tr>
<td>Tarceva® (erlotinib)</td>
<td>NSCLC with EGFR tumor aberration:</td>
<td>Varies</td>
</tr>
<tr>
<td>Gilotrif® (afatinib)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iressa® (gefitinib)</td>
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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

<table>
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<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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<tbody>
<tr>
<td>UC, NSCLC</td>
<td>1,200 mg IV every 3 weeks</td>
<td>1,200 mg/3 weeks</td>
</tr>
<tr>
<td>SCLC*</td>
<td>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</td>
<td>1,200 mg/dose</td>
</tr>
</tbody>
</table>

*Off-label; dosing recommended by NCCN

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

VII. References

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.

<table>
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<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>C9483</td>
<td>Injection, atezolizumab, 10 mg</td>
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### Reviews, Revisions, and Approvals

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<th>Date</th>
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#### 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.
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.