Clinical Policy: Atezolizumab (Tecentriq)

Reference Number: PA.CP.PHAR.235
Effective Date: 01/18
Last Review Date: 04/19

Coding Implications
Revision Log

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 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 therapy 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.
- Locally Advanced or Metastatic Triple-Negative Breast Cancer (TNBC)
  - in combination with paclitaxel protein-bound, for the treatment of adult patients with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] of any intensity covering ≥ 1% of the tumor area), as determined by an FDA-approved test

  This indication is approved under accelerated approval based on progression free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s)
- 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, 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
It is the policy of Pennsylvania Health and Wellness® 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. 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 any platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant chemotherapy;

5. Request meets one of the following (a or b):
   a. Dose does not exceed one of the following dosing regimens (i,ii, or iii):
      i. 840 mg every 2 weeks;
      ii. 1200 mg every 3 weeks;
      iii. 1680 mg every 4 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. Triple-Negative Breast Cancer (must meet all)
1. Diagnosis of TNBC
2. Disease is (must meet a and b)
   a. Unresectable locally advanced or metastatic;
   b. Tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] of any intensity covering ≥ 1% of the tumor area), as determined by an FDA-approved test;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥18 years;
5. Is used in combination with paclitaxel protein-bound;
6. Request meets one of the following (a or b);
   a. Does not exceed 840 mg on days 1 and 15 of a 28-day cycle;
   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. Non-Small Cell Lung Cancer (must meet all):
1. Diagnosis of recurrent or metastatic non-small cell lung cancer (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 *(Appendix B)*;
6. Request meets one of the following (a or b):
   a. Dose does not exceed one of the following dosing regimens (i,ii, or iii):
      i. 840 mg every 2 weeks;
      ii. 1200 mg every 3 weeks;
      iii. 1680 mg every 4 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. Small Cell Lung Cancer (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 one of the following dosing regimens (i,ii, or iii):
      i. 840 mg every 2 weeks;
      ii. 1200 mg every 3 weeks;
      iii. 1680 mg every 4 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

E. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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 (i or ii):
      i. For TNBC: 840 mg on days 1 and 15 of each 28 day treatment cycle
      ii. For all other indications, dosing regimen does not exceed (1, 2, or 3):
         1. 840 mg every 2 weeks;
         2. 1200 mg every 3 weeks;
         3. 1680 mg every 4 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 (1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

   Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PMN.53

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.

III. 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
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
Xalkori® (crizotinib) Alecensa® (alectinib) Zykadia® (ceritinib)	NSCLC with ALK tumor aberration: Varies	Varies
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

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
UC, NSCLC, extensive-stage SCLC	840 mg IV every 2 weeks; 1200 mg IV every 3 weeks; 1680 mg IV every 4 weeks	840 mg IV every 2 weeks; 1200 mg/3 weeks; OR 1680 mg/4 weeks
TNBC	840 mg IV on days 1 and 15 of each 28-day treatment cycle	840 mg on days 1 and 15 of each 28-day treatment cycle

V. Product Availability
Single-dose vial: 840 mg/14ml; 1200 mg/20 mL

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
Ages added. References reviewed and updated.	02/18	
1Q 2019 annual review; 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.	01/19	
Q2 2019: New FDA indication for triple-negative breast cancer added; 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.	04/19	

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 April 11, 2019.
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.