Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2020**
Policy Number: PA.CP.PHAR.235	**Effective Date: 01/01/2018** **Revision Date: 01/15/2020**
Policy Name: Atezolizumab (Tecentriq)	

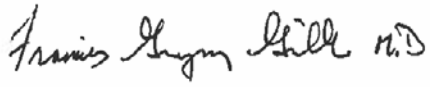
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

For NSCLC, added indication as subsequent therapy if no progression on other PD-1/PDL-1 inhibitors; added language to incorporate use in metastatic NSCLC in combination with paclitaxel protein-bound and carboplatin for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Atezolizumab (Tecentriq)

Reference Number: PA.CP.PHAR.235
Effective Date: 01/18
Last Review Date: 01.20

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.
- 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, or
  - in combination with paclitaxel protein-bound and carboplatin for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.
- Unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) in combination with paclitaxel protein-bound in adult patients 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).
- Extensive-stage small cell lung cancer (SCLC) in combination with carboplatin and etoposide for the first-line treatment of adult patients.

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 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 UC;
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 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. 1,200 mg every 3 weeks;
      iii. 1,680 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. Non-Small Cell Lung Cancer (must meet all)**:**

1. Diagnosis of recurrent, advanced, 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, b, or c):
   a. Disease is non-squamous and Tecentriq is prescribed in combination with one of the following (i or ii):
      i. Bevacizumab, paclitaxel, and carboplatin;
      ii. Paclitaxel protein-bound (Abraxane®) and carboplatin;
   b. Member has previously received platinum-containing chemotherapy *(see Appendix B)*;
   c. If no prior progression on a PD-1/PD-L1 inhibitor (i.e., Tecentriq as well as nivolumab, pembrolizumab, durvalumab) single agent as subsequent therapy;
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 one of the following dosing regimens (i, ii, or iii):
      i. 840 mg every 2 weeks;
      ii. 1,200 mg every 3 weeks;
      iii. 1,680 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

C. Breast Cancer (must meet all)**:**

1. Diagnosis of unresectable, locally advanced, recurrent, or metastatic breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Documentation of triple negative (i.e., estrogen, progesterone, and human epidermal growth factor receptor 2 [HER2] negative) disease;
5. Tumor expresses PD-L1;
6. Prescribed in combination with protein-bound paclitaxel (nab-paclitaxel);
7. Request meets one of the following (a or b):
   a. Dose does not exceed 840 mg every 2 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-stage 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. 1,200 mg every 3 weeks;
      iii. 1,680 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, b, or c):
   a. For UC, NSCLC, extensive-stage SCLC: New dose does not exceed one of the following dosing regimens (i, ii, or iii):
      i. 840 mg every 2 weeks;
      ii. 1,200 mg every 3 weeks;
      iii. 1,680 mg every 4 weeks;

b. For TNBC: New dose does not exceed 840 mg every 2 weeks;
c. 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

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALK: anaplastic lymphoma kinase
EGFR: epidermal growth factor receptor
SCLC: small cell lung cancer
FDA: Food and Drug Administration
NSCLC: non-small cell lung cancer
PD-L1: programmed death-ligand 1
TNBC: triple-negative breast 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.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Cisplatin-, oxaliplatin- (Eloxatin®) or carboplatin-containing chemotherapy	UC: Varies	Varies
cisplatin-, or carboplatin-containing chemotherapy	NSCLC: 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

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.

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
UC, NSCLC, SCLC	1,200 mg IV every 3 weeks	1,200 mg/3 weeks
TNBC	For each 28 day cycle, 840 mg IV on days 1 and 15 followed by 100 mg/m^2 nab-paclitaxel on days 1, 8, and 15	840 mg/2 weeks

V. Product Availability

Single-dose vial: 840 mg/14ml; 1200 mg/20 mL

VI. References

1. Tecentriq Prescribing Information. South San Francisco, CA: Genentech, Inc.; May 2019. Available at: https://www.tecentriq.com. Accessed November 13, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: nccn.org. Accessed November 13, 2019.
3. Bladder Cancer Version 4.2019. In: National Comprehensive Cancer Network Guidelines. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed November 13, 2019.
4. Non-Small Cell Lung Cancer Version 1.2020. National Comprehensive Cancer Network Guidelines. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed November 13, 2019.
5. Breast Cancer Version 3.2019. National Comprehensive Cancer Network Guidelines. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed November 13, 2019.
6. Small Cell Lung Cancer Version 1.2020. National Comprehensive Cancer Network Guidelines. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf. Accessed November 13, 2019.

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	01/19	

Reviews, Revisions, and Approvals	Date	Approval Date
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.		
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	
1Q 2020 annual review: For NSCLC, added indication as subsequent therapy if no progression on other PD-1/PDL-1 inhibitors; added language to incorporate use in metastatic NSCLC in combination with paclitaxel protein-bound and carboplatin for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations; references reviewed and updated.	01/20	