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: 02/01/2022**
Policy Number: PA.CP.PHAR.235	**Effective Date: 01/01/2018** **Revision Date: 01/2022**
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:

1Q 2022 annual review: RT4 policy update to remove the indication, previously approved under accelerated approval, for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy; RT4: removed breast cancer indication and added NSCLC stage II to IIIA treatment indication per updated label; added criterion for use as single-agent therapy for urothelial carcinoma per NCCN; added criterion for Child-Pugh class A status in HCC per NCCN; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Atezolizumab (Tecentriq)

Reference Number: PA.CP.PHAR.235
Effective Date: 01/2018
Last Review Date: 01/2022

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:

- **Urothelial carcinoma (UC)**
  - For the treatment of adult 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.
    - are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.

    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 a confirmatory trial(s).
- **Non-small cell lung cancer (NSCLC)**
  - As a single agent and as adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage II to IIIA non-small cell lung cancer (NSCLC) whose tumors have PD-L1 expression on ≥ 1% of tumor cells, as determined by an FDA-approved test.
  - As a single agent for the first-line treatment of adult patients with metastatic NSCLC whose tumors have high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.
  - In combination with bevacizumab, paclitaxel, and carboplatin, for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.
  - 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.
  - As a single agent for the treatment of adult patients with metastatic 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 NSCLC harboring these aberrations prior to receiving Tecentriq.
- **Small cell lung cancer (SCLC)**
  - In combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).
- **Heptatocellular carcinoma (HCC)**

- In combination with bevacizumab for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy.

- **Melanoma**
  - In combination with cobimetinib and vemurafenib for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.

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 or b):
   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;
5. Prescribed as a single agent;
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

B. Non-Small Cell Lung Cancer (must meet all)**:**

1. Diagnosis of NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. For stage II to IIIA NSCLC, prescribed as a single agent and meets one of the following (a or b):
   a. Member has had previous resection;
   b. Member has all the following (i, ii, and iii):
      i. High-risk stage IIA NSCLC;
      ii. PD-L1 expression ≥ 1%;
      iii. Previously received platinum-containing chemotherapy *(see Appendix B)*;
5. For recurrent, advanced, or metastatic NSCLC: If EGFR or ALK mutation status is negative or unknown, member meets one of the following (a, b, c, or d):

a. Request is for use as a single agent as first-line therapy for tumors that have high PD-L1 expression (PD-L1 ≥ 50% [TC ≥ 50%] or tumor-infiltrating IC covering ≥ 10% of the tumor area [IC ≥ 10%]);
b. 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;
c. Member has previously received platinum-containing chemotherapy *(see Appendix B)*;
d. If no prior progression on a PD-1/PD-L1 inhibitor (i.e., Tecentriq as well as nivolumab, pembrolizumab, durvalumab), request is for single agent as subsequent therapy;

6. For recurrent, advanced, or metastatic NSCLC: 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)*;
7. 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. 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

D. Hepatocellular Carcinoma (must meet all):
1. Diagnosis of HCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with bevacizumab as first-line systemic therapy;
5. Confirmation of Child-Pugh class A status;
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

E. Melanoma (must meet all):

1. Diagnosis of melanoma with BRAF V600 mutation;
2. Disease is unresectable or metastatic;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Prescribed in combination with cobimetinib and vemurafenib;
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

F. 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. For HCC, UC, NSCLC, extensive-stage SCLC, melanoma: 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. 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
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

- NSCLC examples of high-risk factors: may include poorly differentiated tumors (including lung neuroendocrine tumors [excluding well-differentiated neuroendocrine tumors]), vascular invasion, wedge resection, tumors > 4 cm, visceral pleural involvement, and unknown lymph node status. These factors independently may or may not be an indication and may be considered when determining treatment with adjuvant chemotherapy.
- 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	840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks	1,680 mg/4 weeks
NSCLC	As a single agent: 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks When administering with chemotherapy with or without bevacizumab: 1,200 mg IV every 3 weeks prior to chemotherapy and bevacizumab Following completion of 4-6 cycles of chemotherapy, and if bevacizumab is discontinued, administer Tecentriq 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks	1,680 mg/4 weeks
SCLC	When administering with carboplatin and etoposide: 1,200 mg IV every 3 weeks prior to chemotherapy Following completion of 4 cycles of carboplatin and etoposide: administer Tecentriq 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks	1,680 mg/4 weeks
HCC	1,200 mg IV every 3 weeks plus bevacizumab 15 mg/kg IV on the same day If bevacizumab is discontinued for toxicity, the recommended dosage of Tecentriq is 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks	1,680 mg/4 weeks
Melanoma	Following completion of a 28 day cycle of cobimetinib and vemurafenib, administer Tecentriq 840 mg IV every 2 weeks with cobimetinib 60 mg PO QD (21 days on/7 days off) and vemurafenib 720 mg PO BID	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.; October 2021. Available at: https://www.tecentriq.com. Accessed November 4, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: nccn.org. Accessed November 13, 2021.
3. National Comprehensive Cancer Network Guidelines. Non-Small Cell Lung Cancer Version 7.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed October 15, 2020.
4. National Comprehensive Cancer Network Guidelines. Hepatobiliary Cancers Version 5.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed November 14, 2021.

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
J9022	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	
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	01/20	

Reviews, Revisions, and Approvals	Date	Approval Date
with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations; references reviewed and updated.		
1Q 2021 annual review: update to add criteria for newly FDA-approved indications: 1) first-line therapy for metastatic NSCLC with high PD-L1 expression, and 2) first-line therapy for HCC in combination with bevacizumab; update to add criteria for newly FDA-approved indication for melanoma in combination with cobimetinib and vemurafenib, for HCC, unresectable or metastatic removed to accommodate local disease per NCCN; references reviewed and updated.	01/21	
1Q 2022 annual review: RT4 policy update to remove the indication, previously approved under accelerated approval, for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy; RT4: removed breast cancer indication and added NSCLC stage II to IIIA treatment indication per updated label; added criterion for use as single-agent therapy for urothelial carcinoma per NCCN; added criterion for Child-Pugh class A status in HCC per NCCN; references reviewed and updated.	01/22	