Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 144.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Tecentriq (atezolizumab)

I. Policy:
Tecentriq (atezolizumab)

II. Purpose/Objective:
To provide a policy of coverage regarding Tecentriq (atezolizumab)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Tecentriq (atezolizumab) is a humanized monoclonal antibody immune checkpoint inhibitor that binds to programmed death ligand 1 (PD-L1) to selectively prevent the interaction between the programmed cell death 1 (PD-1) and B7.1 (also known as CD80) receptors, while still allowing interaction between PD-L2 and PD-1. PD-L1 is an immune checkpoint protein expressed on tumor cells and tumor infiltrating cells and down regulates anti-tumor T-cell function by binding to PD-1 and B7.1; blocking PD-1 and B7.1 interactions restore antitumor T-cell function.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Tecentriq (atezolizumab) will be considered medically necessary for all lines of business when all of the following criteria are met:

1. **Non-Small Cell Lung Cancer:**
   - Prescription written by an oncologist **AND**
   - Medical record documentation of a diagnosis of non-small cell lung cancer meeting one of the following situations:
     - Medical record documentation of disease progression during or following platinum-containing chemotherapy

     OR
     - Medical record documentation of disease progression on at least one FDA-approved therapy targeting EGFR or ALK if the patient has EGFR or ALK genomic tumor aberrations (e.g. mutation, deletion, insertion, etc.)

     OR
     - Medical record documentation of a non-squamous histologic subtype **AND**
     - Medical record documentation that Tecentriq will be given as first-line treatment **AND**
     - Medical record documentation that Tecentriq will be given in combination with bevacizumab, paclitaxel, AND carboplatin **OR** paclitaxel protein-bound AND carboplatin **AND**
     - Medical record documentation that the patient does not have an EGFR or ALK genomic tumor aberration.

     OR

     - Medical record documentation that Tecentriq will be given as first-line treatment for metastatic disease **AND**
     - Medical record documentation that 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 **AND**
     - Medical record documentation that the patient does not have an EGFR or ALK genomic tumor aberration.

     OR

     - Medical record documentation of stage II to IIIA disease **AND**
     - Medical record documentation of use as adjuvant treatment following resection and platinum-based therapy **AND**
     - Medical record documentation that tumors have PD-L1 expression on ≥1% of tumor cells as determined by an FDA-approved test **AND**
     - Medical record documentation that Tecentriq is being given as a single agent.

2. **Small Cell Lung Cancer (SCLC):**
   - Prescription written by an oncologist **AND**
   - Medical record documentation of a diagnosis of extensive stage small cell lung cancer (ES-SCLC) **AND**
   - Medical record documentation that Tecentriq will be used in combination with carboplatin and etoposide **AND**
   - Medical record documentation of use as first-line treatment of extensive-stage disease.

3. **Unresectable or Metastatic Hepatocellular Carcinoma (HCC)**
    - Prescription written by an oncologist **AND**
    - Medical record documentation of diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) **AND**
    - Medical record documentation that Tecentriq will be given in combination with bevacizumab **AND**
    - Medical record documentation that patient has not received prior systemic treatment for hepatocellular carcinoma

4. **Melanoma**
    - Medical record documentation of unresectable or metastatic melanoma **AND**
    - Medical record documentation of BRAF V600 mutation as determined by an FDA-approved test **AND**
    - Medical record documentation that Tecentriq will be given in combination with Cotelliq (cobimetinib) and Zelboraf (vemurafenib)

5. **Alveolar Soft Part Sarcoma (ASPS)**
    - Prescription written by an oncologist **AND**
    - Medical record documentation of age greater than or equal to 2 years **AND**
    - Medical record documentation of diagnosis of unresectable or metastatic alveolar soft part sarcoma (ASPS)

Notes to reviewer:

- In clinical trials, contraindications to cisplatin-containing chemotherapy included: impaired renal function (CrCl greater than 30mL/min but less than 60mL/min), grade 2 or higher hearing loss or peripheral neuropathy, or ECOG performance status of 2.
- A therapeutic failure of platinum-containing chemotherapy is defined as disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant treatment.

AUTHORIZATION DURATION:

For adjuvant treatment of stage II to IIIA non-small cell lung cancer (NSCLC) following resection and platinum-based chemotherapy: One approval will be given for 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Tecentriq for adjuvant treatment of stage II to IIIA non-small cell lung cancer (NSCLC) following resection and platinum-based chemotherapy should not exceed the FDA-approved treatment duration of 1 year (12 months) in patients. For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

For all other indications: Initial approval will be for **12 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 7/19/16

Revised: 1/17/17 (NSCLC indication), 5/16/17 (updated urothelial indication), 9/18/18 (updated urothelial indication), 1/15/19 (non-squamous NSCLC), 5/21/19 (breast cancer, SCLC), 1/21/20 (NSCLC), 7/21/20 (HCC), 8/27/20 (NSCLC, melanoma), 9/24/21 (removal of urothelial progression following platinum indication per DHS), 10/27/21 (removal of TNBC), 11/16/21 (adjuvant stage II-IIIA NSCLC per DHS), 12/24/21 (adjuvant NSCLC auth duration), 12/24/22 (LOB carve out, PARP statement), 2/24/23 (urothelial removal, ASPS addition, Medicaid Business Segment)

Reviewed: 5/1/18, 8/20/21