

## Atezolizumab (Tecentriq®)

### Prior Authorization Drug Coverage Policy

Effective Date: 3/1/2021

Revision Date: n/a

Review Date: 10/6/2021

Lines of Business: Commercial

Policy type: Prior Authorization

This Drug Coverage Policy provides parameters for the coverage of atezolizumab. Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine.

### Drug Description<sup>1</sup>

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 activation of the anti-tumor immune response without inducing antibody-dependent cellular cytotoxicity.

### FDA Indications<sup>1</sup>

Atezolizumab is FDA indicated for the following:

- 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  $\geq 5\%$  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
- For the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (PD-L1 stained  $\geq 50\%$  of tumor cells [TC  $\geq 50\%$ ] or PD-L1 stained tumor-infiltrating immune cells [IC] covering  $\geq 10\%$  of the tumor area [IC  $\geq 10\%$ ]), as determined by an FDA-approved test and no EGFR or ALK genomic tumor aberrations.
  - In combination with bevacizumab, paclitaxel, and carboplatin
  - In combination with paclitaxel protein-bound and carboplatin

- 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 Atezolizumab.
- In combination with paclitaxel protein-bound for the treatment of adult patients with unresectable locally advanced or metastatic triple negative breast cancer (TNBC) whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] of any intensity covering  $\geq 1\%$  of the tumor area), as determined by an FDA approved test.
- In combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).
- In combination with bevacizumab for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy.
- In combination with cobimetinib and vemurafenib for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.

### Coverage Determinations<sup>1</sup>

Atezolizumab will require prior authorization. This agent is considered medically necessary for the following oncology indications if all criteria below are met.

#### Urothelial Carcinoma

- 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  $\geq 5\%$  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.

Recommended dosage: 840 mg every 2 weeks, 1200 mg every 3 weeks, or 1680 mg every 4 weeks.

#### Non-Small Cell Lung Cancer (NSCLC)

- For the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (PD-L1 stained  $\geq 50\%$  of tumor cells [TC  $\geq 50\%$ ] or PD-L1 stained tumor-infiltrating immune cells [IC] covering  $\geq 10\%$  of the tumor area [IC  $\geq 10\%$ ]), as determined by an FDA-approved test **AND**
  - No EGFR or ALK genomic tumor aberrations **AND**
  - In combination with bevacizumab, paclitaxel, and carboplatin **OR**
  - In combination with paclitaxel protein-bound and carboplatin
- For the treatment of adult patients with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy **AND**

- Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for NSCLC harboring these aberrations prior to receiving Atezolizumab.

Recommended dosage:

- 840 mg every 2 weeks, 1200 mg every 3 weeks, or 1680 mg every 4 weeks.
- When administering with chemotherapy with or without bevacizumab, administer Atezolizumab 1200 mg every 3 weeks prior to chemotherapy and bevacizumab
- Following completion of 4-6 cycles of chemotherapy, administer Atezolizumab 840 mg every 2 weeks, 1200 mg every 3 weeks, or 1680 mg every 4 weeks.

**Triple-Negative Breast Cancer (TNBC)**

- In combination with paclitaxel protein-bound for the treatment of adult patients with unresectable locally advanced or metastatic triple negative breast cancer (TNBC) whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] of any intensity covering  $\geq 1\%$  of the tumor area), as determined by an FDA approved test.

Recommended dosage: 840 mg on days 1 and 15 every 28 days

**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).

Recommended dosage:

- 1200 mg every 3 weeks prior to chemotherapy.
- Following completion of 4 cycles of carboplatin and etoposide, administer Atezolizumab 840 mg every 2 weeks, 1200 mg every 3 weeks, or 1680 mg every 4 weeks.

**Hepatocellular Carcinoma (HCC)**

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

Recommended dosage:

- Atezolizumab 1200 mg, followed by 15 mg/kg bevacizumab, on the same day every 3 weeks

**Melanoma:**

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

Recommended dosage: Following completion of a 28 day cycle of cobimetinib and vemurafenib, administer Atezolizumab 840 mg every 2 weeks, 1200 mg every 3 weeks, or 1680 mg every 4 weeks with cobimetinib 60 mg orally once daily (21 days on /7 days off) and vemurafenib 720 mg orally twice daily.

**All indications:**

- Atezolizumab will be approved through clinical review for up to a 6-month duration.

**Coverage Limitations**

Treatment with atezolizumab is not considered medically necessary for members with the following concomitant conditions:

- The member has experienced disease progression on atezolizumab.
- The member has experienced disease progression while on or following PD-1/PD-L1 therapy.
- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary

**Contraindications/Warnings/Precautions<sup>1</sup>**

- There are no contraindications listed in the US manufacturer's labeling.
- Warnings/precautions:
  - Immune-mediated pneumonitis
  - Immune-mediated hepatitis
  - Immune-mediated colitis
  - Immune-mediated endocrinopathies
  - Infections
  - Infusion-related reactions
  - Embryo-Fetal toxicity

For specific recommendations on contraindications, warnings and precautions, patient monitoring, and on dose adjustments and discontinuation, please refer to the current prescribing information.

**Billing**

- Description: Injection, Atezolizumab 10 mg
  - J9022

**Disclaimer**

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from Oncology Analytics, Inc.

## References

1. Tecentriq [package insert]. Genentech, Inc., South San Francisco, CA. Available at: [https://www.gene.com/download/pdf/tecentriq\\_prescribing.pdf](https://www.gene.com/download/pdf/tecentriq_prescribing.pdf)