Reference number(s)
1766-A

SPECIALTY GUIDELINE MANAGEMENT

TECENTRIQ (atezolizumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Locally advanced or metastatic urothelial carcinoma
   Indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who:
   a. 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
   b. Are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.

2. Metastatic non-small cell lung cancer (NSCLC)
   a. Indicated as a single-agent for 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.
   b. Indicated 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.
   c. Indicated 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.
   d. Indicated 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.
   e. Indicated 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 the requested medication.

3. Small cell lung cancer (SCLC)
   Indicated in combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

4. Hepatocellular Carcinoma (HCC)
   Indicated in combination with bevacizumab for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy.

5. Melanoma

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

B. Compendial Uses
   1. Urothelial carcinoma
      a. Bladder cancer
      b. Primary carcinoma of the urethra
      c. Upper genitourinary tract tumors
      d. Urothelial carcinoma of the prostate
   2. Non-small cell lung cancer (NSCLC)

All other indications are considered experimental/investigational and not medically necessary.

II. REQUIRED DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Test results confirming PD-L1 tumor expression (where applicable)
B. Test results confirming tumor is positive for BRAF V600 mutation (where applicable)
C. Test results confirming the presence of EGFR, ALK, ROS1, and RET genomic aberration (where applicable)

III. EXCLUSIONS

Coverage will not be provided for members who have experienced disease progression while on PD-1 or PD-L1 inhibitor therapy

IV. CRITERIA FOR INITIAL APPROVAL

A. Urothelial Carcinoma - Bladder Cancer
Authorization of 6 months may be granted for treatment as a single agent for bladder cancer when the requested medication is used as first line therapy in cisplatin ineligible members whose tumors express PD-L1 (defined as PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to 5% of the tumor area) or in members who are not eligible for any platinum containing chemotherapy regardless of PD-L1 expression for any of the following:
1. Stage II or Stage IIIa disease if tumor is present following reassessment of tumor status 2-3 months after primary treatment with concurrent chemoradiotherapy
2. Stage IIIb disease as downstaging systemic therapy or following partial response or progression after primary treatment with concurrent chemoradiotherapy
3. Locally advanced or metastatic disease
4. Metastatic or local recurrence post-cystectomy
5. Muscle invasive local recurrence or persistent disease in a preserved bladder

B. Urothelial Carcinoma - Primary Carcinoma of the Urethra
Authorization of 6 months may be granted for treatment as a single agent for primary carcinoma of the urethra when the requested medication is used as first line therapy for recurrent, locally advanced or metastatic disease in cisplatin ineligible members whose tumors express PD-L1 (defined as PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to 5% of the tumor area) or in members who are not eligible for any platinum containing chemotherapy regardless of PD-L1 expression.

C. Urothelial Carcinoma - Upper Genitourinary Tract Tumors or Urothelial Carcinoma of the Prostate
Authorization of 6 months may be granted for treatment as a single agent for upper genitourinary tract tumors or urothelial carcinoma of the prostate when the requested medication is used as first line therapy for locally advanced or metastatic disease in cisplatin ineligible members whose tumors express PD-L1 (defined as PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to 5% of the tumor area) or in members who are not eligible for any platinum containing chemotherapy regardless of PD-L1 expression

D. Non-Small Cell Lung Cancer (NSCLC)
Authorization of 6 months may be granted for treatment of NSCLC when the tumor is negative for EGFR, ALK, and RET gene mutations (unless testing is not feasible due to insufficient tissue or if used in single agent subsequent therapy) and any of the following criteria are met:

1. Tecentriq will be used in combination with bevacizumab, carboplatin and paclitaxel or carboplatin and albumin-bound paclitaxel for nonsquamous cell histology, as first-line or subsequent treatment for recurrent, advanced, or metastatic disease (subsequent therapy only for ROS1 rearrangement positive tumors and prior crizotinib, entrectinib, or ceritinib therapy)
2. Tecentriq will be used in combination with bevacizumab if there is tumor response or stable disease following first-line atezolizumab, carboplatin, paclitaxel and bevacizumab regimen or atezolizumab, carboplatin, and albumin-bound paclitaxel regimen for nonsquamous cell histology, as maintenance therapy
3. Tecentriq will be used as a single agent if PD-L1 ≥50% as first-line treatment for recurrent, advanced, or metastatic disease
4. Tecentriq will be used as a single agent as subsequent treatment for recurrent, advanced, or metastatic disease
5. Tecentriq will be used as a single agent if there is tumor response or stable disease following first-line monotherapy, as maintenance therapy
6. Tecentriq will be used as a single agent as adjuvant treatment following resection and platinum-based chemotherapy for adult members with stage II to IIIA disease whose tumors have PD-L1 expression on ≥ 1% of tumor cells

E. Small Cell Lung Cancer (SCLC)
Authorization of 6 months may be granted for treatment of small cell lung cancer when the requested medication will be used as initial treatment in combination with etoposide and carboplatin (followed by single agent maintenance) for extensive-stage disease.

F. Hepatocellular Carcinoma (HCC)
Authorization of 6 months may be granted for treatment of unresectable or metastatic HCC when the requested medication will be used as initial treatment in combination with bevacizumab.

G. Melanoma
Authorization of 6 months may be granted for the treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma when the requested medication will be used in combination with cobimetinib (Cotellic) and vemurafenib (Zelboraf).

V. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section IV when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

VI. REFERENCES

1. Tecentriq [package insert]. South San Francisco, CA: Genentech, Inc.; October 2021.
2. The NCCN Drugs & Biologics Compendium™ © 2021 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed July 8, 2021.

DOCUMENT HISTORY

Created:	Specialty Clinical Development (JP) 05/2016
Revised:	JP 10/2016 (added NSCLC), 04/2017 (label update for urothelial ca), LP 07/2017 (annual review), JC 07/2018 (label update), JC 07/2018 (annual), JC 01/2019 (label update), TE/JC 03/2019 (label update), TE 07/2019, TE 12/2019 (label update), SP/TE 04/2020 (NCCN update), TE 05/2020 (label update), TE 07/2020 (annual and label update), 08/2020 (label update – melanoma), JW 4/2021 (indication withdrawal-subsequent therapy-urothelial), MN 07/2021 (annual), MN 10/2021 (remove TNBC; add adj NSCLC)
Reviewed:	CDPR/ME 05/2016; DNC 10/2016; ME 04/2017, SD 07/2017, EPA 07/2018, EPA 03/2019, CHART: 08/01/2019, 01/09/2020, 04/16/2020, 06/11/2020, 07/30/2020, 08/20/2020, 4/29/2021, 07/29/2021, 10/28/2021
External Review:	05/2016, 09/2017, 09/2018, 09/2019, 09/2020