POLICY Document for TECENTRIQ (atezolizumab)

The overall objective of this policy is to support the appropriate and cost effective use of the medication. This document provides specific information to each section of the overall policy.

Section 1: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 2: Oncology Clinical Policy
- Policy information specific to regimen review per NCCN Guidelines.

Section 1: Clinical Criteria

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:
   i. 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
   ii. Are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status, or
   iii. Have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy.

2. Metastatic non-small cell lung cancer (NSCLC)
   i. 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.
   ii. 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.
   iii. 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. Unresectable locally advanced or metastatic triple-negative breast cancer (TNBC)
   Indicated in combination with paclitaxel protein-bound for the treatment of adult patients with unresectable locally advanced or metastatic TNBC 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.

4. 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).

B. Compendial Uses
   1. Stage II or Stage IIIa bladder cancer
   2. Bladder cancer with metastatic or local recurrence post-cystectomy
   3. Subsequent therapy for urothelial carcinoma
   4. Subsequent therapy or continued maintenance therapy for non-small cell lung cancer
   5. Recurrent triple-negative breast cancer

All other indications are considered experimental/investigational and are 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 that the cancer cells are negative for the following receptors (where applicable):
   1. human epidermal growth factor receptor 2 (HER-2)
   2. estrogen
   3. progesterone

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 any of the following criteria are met:
1. The requested medication is used as first line therapy in cisplatin ineligible persons 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 persons who are not eligible for any platinum containing chemotherapy regardless of PD-L1 expression for any of the following:
   i. Stage II or Stage IIIa disease if tumor is present following reassessment of tumor status 2-3 months after primary treatment with concurrent chemoradiotherapy
   ii. locally advanced or metastatic disease

iii. metastatic or local recurrence post-cystectomy

2. The requested medication is used as subsequent systemic therapy following platinum containing chemotherapy for either of the following:
   i. locally advanced or metastatic disease
   ii. metastatic or local recurrence post-cystectomy

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 any of the following criteria are met:

1. The requested medication is used as first line therapy for recurrent, locally advanced or metastatic disease in cisplatin ineligible persons 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 persons who are not eligible for any platinum containing chemotherapy regardless of PD-L1 expression.
2. The requested medication is used as subsequent therapy for recurrent, locally advanced or metastatic disease following platinum-containing chemotherapy.

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 any of the following criteria are met:

1. The requested medication is used as first line therapy for locally advanced or metastatic disease in cisplatin ineligible persons 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 persons who are not eligible for any platinum containing chemotherapy regardless of PD-L1 expression
2. The requested medication is used as subsequent therapy for locally advanced or metastatic disease following platinum-containing chemotherapy

D. Non-Small Cell Lung Cancer (NSCLC)

Authorization of 6 months may be granted for treatment of NSCLC when any of the following criteria are met:

1. The requested medication is used as treatment for recurrent, advanced or metastatic nonsquamous NSCLC in combination with carboplatin, paclitaxel and bevacizumab (if EGFR or ALK positive, will be used following EGFR or ALK therapy)
2. The requested medication is used as treatment for recurrent, advanced or metastatic nonsquamous NSCLC in combination with paclitaxel protein-bound and carboplatin (if EGFR or ALK positive, will be used following EGFR or ALK therapy)
3. The requested medication is used as continuation maintenance therapy as a single agent or in combination with bevacizumab for recurrent, advanced or metastatic nonsquamous NSCLC following atezolizumab/carboplatin/paclitaxel/bevacizumab therapy when tumor response or stable disease is achieved
4. The requested medication is used as continuation maintenance therapy for recurrent, advanced or metastatic nonsquamous NSCLC following atezolizumab/carboplatin/paclitaxel protein-bound therapy when tumor response or stable disease is achieved
5. The requested medication is used as subsequent therapy as a single agent for recurrent, advanced, or metastatic disease

E. Breast Cancer

Authorization of 6 months may be granted for treatment of unresectable locally advanced, recurrent, or metastatic breast cancer when all of the following criteria are met:

1. The diagnosis of breast cancer is confirmed by the cancer cells testing negative for ALL of the following receptors:

i. human epidermal growth factor receptor 2 (HER-2)
ii. estrogen
iii. progesterone

2. Tumors must express programmed death ligand 1 (PD-L1) (i.e., PD-L1 stained tumor-infiltrating immune cells [IC] of any intensity covering greater than or equal to 1 percent of the tumor area).
3. The requested medication will be used in combination with protein-bound paclitaxel (Abraxane).

F. 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.

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 who have not experienced disease progression or an unacceptable toxicity.

Section 2: Oncology Clinical Policy

Oncology Clinical Policy

Program Description

The National Comprehensive Care Network® (NCCN®) is an alliance of leading cancer centers devoted to patient care, research and education dedicated to improving the quality, effectiveness and efficiency of cancer care so patients can live better lives.[1] It is comprised of oncology experts who convene regularly to establish the best treatments for patients. NCCN develops various resources for use by stakeholders in the health care delivery system. These resources include, but are not limited to, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), the NCCN Drugs & Biologics Compendium (NCCN Compendium®) and the NCCN Chemotherapy Order Templates (NCCN Templates®).

NCCN templates are based on NCCN Clinical Practice Guidelines and NCCN Compendium. The NCCN Compendium lists the appropriate drugs and biologics for specific cancers using U.S. Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category.

NCCN Categories of Evidence and Consensus[2]

- Category 1: Based on high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2A: Based on lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2B: Based on lower-level evidence, there is NCCN consensus that the intervention is appropriate.
- Category 3: Based any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

Policy for Regimen Prior Authorization

A regimen prior authorization allows submission of a single prior authorization request for all oncology drugs or biologics within an NCCN template that require prior authorization.

This policy provides coverage of a regimen review when *all* of the following criteria are met:

1. Regimen prior authorization reviews, based on NCCN templates, are initiated through the provider portal: https://provider.carefirst.com/providers/home.page
2. If the prior authorization request is submitted via phone or fax, each drug or biologic will need to be submitted and reviewed as a separate prior authorization request for review with drug-specific criteria.
3. The prior authorization review is requested for an oncology drug or biologic that requires prior authorization on the medical benefit.
4. The indication is for a cancer that is eligible for regimen review. Currently, the cancer types in scope for regimen review include breast, lung, colon and rectal cancer.
5. The member is eligible for regimen review.

In addition, the following criteria must be met for approval:

1. The requested regimen for the drug(s) or biologic(s) and indication is consistent with an NCCN recommendation with a level of evidence category of 1 or 2A.
2. The NCCN template must be accepted by the provider without modification.

Authorizations may be granted for 12 months.
Further review may be indicated where the above criteria are not met.

Continuation of Therapy

To submit a request for continuation of therapy, a new regimen prior authorization review must be requested. Upon template selection, the template must be modified to include the appropriate therapies being used for maintenance treatment. The regimen request will be submitted for further review.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia and/or evidence-based practice guidelines.

REFERENCES:

SECTION 1

1. Tecentriq [package insert]. South San Francisco, CA: Genentech, Inc.; December 2019.
2. The NCCN Drugs & Biologics Compendium™ © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed December 30, 2019.

SECTION 2

1. National Comprehensive Cancer Network. About NCCN website. https://www.nccn.org/about/default.aspx, accessed September 16, 2019.
2. National Comprehensive Cancer Network. NCCN Categories of Evidence and Consensus website. https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx, accessed September 16, 2019.

3. National Comprehensive Cancer Network. NCCN Guidelines website. http://www.nccn.org/professionals/physician_gls/f_guidelines.asp, accessed September 16, 2019. *(Note: An account may be required.)*
4. National Comprehensive Cancer Network. NCCN Drugs and Biologics Compendium® website. http://www.nccn.org/professionals/drug_compendium/content/contents.asp, accessed September 16, 2019. *(Note: A subscription may be required.)*
5. National Comprehensive Cancer Network. NCCN Chemotherapy Order Templates (NCCN Templates) website. https://www.nccn.org/professionals/OrderTemplates/Default.aspx, accessed September 16, 2019. *(Note: A subscription may be required.)*