Clinical Criteria

Subject:	Tecentriq (atezolizumab)		
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Overview

This document addresses the use of Tecentriq (atezolizumab). Tecentriq is an anti-programmed death ligand 1 (PD-L1) monoclonal antibody primarily used to treat urothelial carcinoma, non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC) and breast cancer under certain circumstances.

The FDA approved indications for Tecentriq (atezolizumab) includes:

- Individuals with metastatic or unresectable locally advanced, histologically documented triple-negative breast cancer (lack of estrogen-and progesterone-receptor expression and no overexpression of HER2)
- Individuals requiring first-line or maintenance therapy for metastatic nonsquamous NSCLC
- Individuals requiring subsequent therapy of metastatic nonsquamous and squamous NSCLC
- Individuals requiring first-line therapy as single agent for metastatic NSCLC
- Individuals with extensive-stage small cell lung cancer (SCLC)
- Individuals requiring first-line treatment of locally advanced or metastatic urothelial carcinoma who are ineligible for any platinum-containing chemotherapy
- Individuals requiring first-line treatment of unresectable or metastatic hepatocellular carcinoma (HCC)
- Individuals with unresectable or metastatic melanoma in combination with cobimetinib and vemurafenib with BRAF V600 mutation positive disease.

The National Comprehensive Cancer Network (NCCN) provides additional recommendations with a category 1 or 2A level of evidence for the use of:

- Individuals requiring first-line or maintenance therapy for recurrent or advanced nonsquamous NSCLC
- Individuals requiring subsequent therapy for recurrent or advanced nonsquamous and squamous NSCLC
- Individuals requiring subsequent treatment of locally advanced or metastatic urothelial carcinoma
- Individuals requiring first-line treatment of locally advanced or metastatic urothelial carcinoma who are ineligible for any platinum-containing chemotherapy (FDA approved indication)
- Individuals with metastatic or unresectable locally advanced, histologically documented triple-negative breast cancer (lack of estrogen-and progesterone-receptor expression and no overexpression of HER2) (FDA approved indication)
- Individuals requiring first-line treatment for metastatic or unresectable hepatocellular carcinoma (HCC)
- Individuals with extensive stage small cell lung cancer (SCLC).

Other Uses

Tecentriq has been investigated for other uses including treatment of gastric cancer, renal cancer, colorectal cancer, soft tissue sarcoma, diffuse large B cell lymphoma, hematological malignancies, multiple myeloma and myelodysplastic syndromes. These treatments have only been studied in phase I trials and require larger, randomized clinical trials for further evaluation. A recently completed phase III study for colorectal cancer showed that atezolizumab monotherapy and in combination with cobimetinib was not significant compared to current therapy, regorafenib. Currently there are ongoing clinical trials evaluating use for the other potential cancers. NCCN also gives a category 2A recommendation for use of Tecentriq in combination with carboplatin, paclitaxel/nab-paclitaxel, and with or without bevacizumab as first line therapy in those with NSCLC and BRAF or NTRK positive tumors in certain circumstances, however, published data is lacking.

Definitions and Measures

Adjuvant treatment: Additional cancer treatment given after the primary treatment to lower the risk that the cancer will come back. Adjuvant therapy may include chemotherapy, radiation therapy, hormone therapy, targeted therapy, or biological therapy.

ECOG Performance Status: A scale used to determine the individual's level of functioning. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:

- 0= Fully active, able to carry on all pre-disease performance without restriction
- 1= Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2= Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3= Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
- 4= Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
- 5= Dead

Extensive-stage small cell lung cancer: Cancer has spread to other parts of the body, and could include the fluid around the lungs.

Immune checkpoint inhibitor: A type of drug that blocks certain proteins made by some types of immune system cells, such as T cells, and some cancer cells. When these proteins are blocked, the “brakes” on the immune system are released and T cells are able to kill cancer cells better. Examples of checkpoint proteins found on T cells or cancer cells include programmed death (PD)-1, PD-ligand 1 (PD-L1), and cytotoxic T-lymphocyte–associated antigen (CTLA)-4/B7-1/B7-2 (NCI, 2018).

Kinase inhibitor: Type of drug which works by blocking several enzymes that promote cell growth, which has been found to be an effective approach to treat a variety of cancers.

Line of therapy:

- First-line therapy: The first or primary treatment for the diagnosis. This may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
- Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (second-line therapy) are not effective or there is disease progression.

Locally advanced cancer: Cancer that has spread from where it started to nearby tissue or lymph nodes.

Metastatic: The spread of cancer from one part of the body to another. A metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

Neoadjuvant treatment: Treatment given as a first step to shrink a tumor before the main treatment, which is usually surgery, is given. Examples of neoadjuvant therapy include chemotherapy, radiation therapy, and hormone therapy. It is a type of induction therapy.

Programmed death (PD)-1 proteins: PD-1 proteins are found on T-cells and attach to PD ligands (PD-L1) found on normal (and cancer) cells (see immune checkpoint inhibitor above). Normally, this process keeps T-cells from attacking other cells in the body. However, this can also prevent T-cells from attacking cancer cells in the body. Examples of FDA approved anti-PD-1 agents include Keytruda (pembrolizumab), Opdivo (nivolumab), and Libtayo (cemiplimab).

Programmed death ligand (PD-L)-1: The ligands found on normal (and cancer) cells to which the PD-1 proteins attach (see immune checkpoint inhibitor above). Cancer cells can have large amounts of PD-L1 on their surface, which helps them to avoid immune attacks. Examples of FDA approved anti-PD-L1 agents include Bavencio (avelumab), Tecentriq (atezolizumab), and Imfinzi (durvalumab).

Clinical Criteria

When a drug is being reviewed for coverage under a member’s medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Tecentriq (atezolizumab)

Requests for Tecentriq (atezolizumab) may be approved if the following criteria are met:

I. Individual has a diagnosis of one of the following:

A. First-line treatment of metastatic or unresectable, locally advanced, histologically confirmed triple-negative Breast Cancer (lack of estrogen- and progesterone-receptor expression and no overexpression of HER2) (NCCN 2A); **AND**
   1. Individual is using in combination with nab-paclitaxel (paclitaxel, protein-bound); **AND**
   2. Individual has PD-L1 expression on tumor-infiltrating immune cells [IC] covering greater than or equal to 1% [IC ≥ 1%] of the tumor area; **AND**
   3. Individual has a ECOG performance status of 0-2; **AND**
   4. Individual has not had previous treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
   5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

B. First-line treatment of advanced, unresectable, or metastatic hepatocellular carcinoma (HCC) (Label, NCCN 2A); **AND**
   1. Individual is using in combination with bevacizumab (or bevacizumab biosimilar); **AND**
   2. Individual has Child-Pugh Class A; **AND**
   3. Individual has an ECOG performance status of 0-2; **AND**
   4. Individual has not had previous treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
   5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

C. First-line treatment of recurrent, advanced or metastatic nonsquamous Non-Small Cell Lung Cancer (NSCLC) (Label, NCCN 2A); **AND**
   1. Individual is using in a combination regimen with nab-paclitaxel (paclitaxel, protein-bound) and carboplatin; **AND**
   2. Individual has confirmation of EGFR, ALK, ROS1 and BRAF mutations that are negative or unknown; **AND**
   3. Individual has a ECOG performance status of 0-2; **AND**
   4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
   5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

D. First-line treatment of recurrent, advanced or metastatic nonsquamous NSCLC (Label, NCCN 1, 2A); **AND**
   1. Individual is using in a combination regimen with carboplatin, paclitaxel, and bevacizumab (or bevacizumab biosimilar); **AND**
   2. Individual has confirmation of EGFR, ALK, ROS1, and BRAF mutations that are negative or unknown; **AND**
   3. Individual has a ECOG performance status of 0-1; **AND**
   4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
   5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

E. Continuation maintenance therapy for recurrent, advanced or metastatic nonsquamous NSCLC (Label, NCCN 1, 2A); **AND**
   1. Individual is using in combination with or without bevacizumab (or bevacizumab biosimilar); **AND**
   2. Individual has confirmation of achievement of tumor response or stable disease following initial cytotoxic therapy (first-line atezolizumab/carboplatin/paclitaxel/bevacizumab regimen **or** atezolizumab/carboplatin/nab-paclitaxel regimen); **AND**
   3. Individual has a ECOG performance status of 0-2; **AND**
   4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
   5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

F. Subsequent treatment of recurrent, advanced or metastatic NSCLC (nonsquamous or squamous) (Label); **AND**
   1. Disease has progressed during or following platinum-containing chemotherapy (e.g. cisplatin); **AND**
   2. When anaplastic lymphoma kinase (ALK) or epidermal growth factor receptor (EGFR) genomic tumor aberrations are present, must have demonstrated disease progression; **AND**
   3. Individual has a ECOG performance status of 0-2; **AND**
   4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1inhibitor; **AND**
   5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

G. Subsequent treatment of recurrent, advanced or metastatic nonsquamous NSCLC (NCCN 1, 2A); **AND**
   1. Disease has progressed during or following treatment with a targeted agent for the expressed oncogene (for example, kinase inhibitors that target EGFR, ALK, ROS1, BRAF, or NTRK mutations); **AND**
   2. Individual is using in a combination regimen with *one* of the following:
      a. Carboplatin, paclitaxel, and bevacizumab (or bevacizumab biosimilar); **OR**
      b. Carboplatin and nab-paclitaxel (albumin-bound paclitaxel); **AND**
   3. Individual has a ECOG performance status of 0-2; **AND**
   4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
   5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

H. First-line treatment of metastatic NSCLC; **AND**
   1. Individual is using as monotherapy; **AND**
   2. Individual has *one* of the following:
      a. Individual has PD-L1 expression on tumor cells [TC] that is greater than or equal to 50% [TC ≥ 50%], as confirmed through an FDA-approved test; **OR**
      b. Individual has PD-L1 expression on tumor-infiltrating immune cells [IC] covering greater than or equal to 10% [IC ≥ 10%] of the tumor area, as confirmed by an FDA-approved test; **AND**
   3. Individual has confirmation of EGFR or ALK mutations that are negative or unknown; **AND**
   4. Individual has a ECOG performance status of 0-2; **AND**
   5. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
   6. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

I. Treatment of unresectable or metastatic Melanoma; **AND**
1. Individual is using in combination with cobimetinib and vemurafenib; **AND**
2. Individual has BRAF V600 mutation positive disease with test result confirmed; **AND**
3. Individual has ECOG performance status of 0-2; **AND**
4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

~~J.~~K. First-line treatment of extensive-stage Small Cell Lung Cancer (SCLC) (Label, NCCN 1); **AND**
1. Individual is using in combination with etoposide and carboplatin (followed by maintenance atezolizumab monotherapy); **AND**
2. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
3. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

~~K.~~L. First-line treatment of locally advanced or metastatic Urothelial Carcinoma; **AND**
1. Individual is ineligible for any platinum-containing chemotherapy; **OR**
2. Individual is not eligible for cisplatin-containing chemotherapy, and tumor testing indicates that PD-L1 stained tumor-infiltrating immune cells [IC] covers greater than or equal to 5% [IC ≥ 5%] of the tumor area as confirmed through FDA-approved test; **AND**
3. Individual has a ECOG performance status of 0-2; **AND**
4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1inhibitor; **AND**
5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

~~L.~~M. Subsequent treatment of locally advanced or metastatic Urothelial Carcinoma; **AND**
1. Individual has disease progression during or following platinum-containing chemotherapy (e.g. cisplatin); **OR**
2. Individual has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; **AND**
3. Individual has a ECOG performance status of 0-2; **AND**
4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

Requests for Tecentriq (atezolizumab) may not be approved when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9022	Injection, atezolizumab, 10 mg [Tecentriq]

ICD-10 Diagnosis

C22.0-C22.9	Malignant neoplasm of liver and intrahepatic bile ducts
C34.00-C34.92	Malignant neoplasm of bronchus and lung
C43.0-C43.9	Malignant melanoma of skin
C50.011-C50.929	Malignant neoplasm of breast
C61	Malignant neoplasm of prostate
C65.1-C65.9	Malignant neoplasm of renal pelvis
C66.1-C66.9	Malignant neoplasm of ureter
C67.0-C67.9	Malignant neoplasm of bladder
C68.0	Malignant neoplasm of urethra
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.3	Personal history of malignant neoplasm of breast
Z85.51	Personal history of malignant neoplasm of bladder

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Z85.53-Z85.54	Personal history of malignant neoplasm of renal pelvis, ureter

Document History

Revised: 09/14/2020
Document History:

- 09/14/2020 – Select Review: Update criteria to add use in melanoma in combination with cobimetinib and vemurafenib in BRAF V600 mutation positive disease per label. Coding reviewed: Added ICD-10-CM C43.0-C43.9 for Melanoma of skin.
- 06/08/2020 – Select Review: Update criteria to add use in NSCLC for first line as monotherapy. Wording, formatting, and reference updates. Coding Review: No changes.
- 05/15/2020 – Annual Review: Update criteria to add use in hepatocellular carcinoma per NCCN. Update NSCLC criteria to include first-line therapy use in recurrent and advanced disease, and confirmation of negative ROS1 and BRAF mutations when using in combination with nab-paclitaxel and carboplatin. Add language regarding treatment with other anti-PD-1 or anti-PD-L1 inhibitors to NSCLC criteria. Update NSCLC maintenance therapy criteria to allow use after stable disease following first line atezolizumab/carboplatin/nab-paclitaxel. Add criteria to allow use as subsequent therapy after failure of targeted agents. Removed examples of non-approvable indications for consistency. Add bevacizumab biosimilar language. Remove ECOG status for extensive SCLC per NCCN. Coding Review: Added ICD-10-Dx: C22.0-C22.9
- 12/09/2019 – Select Review: Add new criteria for use in first line treatment of metastatic nonsquamous NSCLC with nab-paclitaxel and carboplatin. Update references, wording and formatting changes. Coding reviewed: No changes.
- 11/15/2019 – Select Review: Clarify use in first line treatment of urothelial carcinoma as ineligible for any platinum-containing chemotherapy OR ineligible for cisplatin-containing chemotherapy with PD-L1 tumor testing. Minor wording and formatting changes. Coding Reviewed: No changes.
- 08/16/2019 – Select Review: Update Tecentriq criteria for first line treatment of NSCLC to remove PD-L1 expression requirement, and change ECOG status to 0-2. Update wording with previous PD-1 and PD-L1 agent use for consistency. Add quantity limit. Minor wording and formatting changes. Coding Reviewed: No changes.
- 05/17/2019 – Annual Review: Initial review of Tecentriq (atezolizumab). Wording and formatting changes. Coding reviewed: No changes.

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    b. Breast Cancer. V3.2020. Revised March 6, 2020.
    c. Cutaneous Melanoma. V4.2020. Revised September 1, 2020.
    d. Hepatobiliary Cancers. V1.2020. Revised March 23, 2020.
    e. Non-Small Cell Lung Cancer. V5.2020. Revised May 27, 2020.

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.