

Medical Drug Clinical Criteria

Subject:	Atezolizumab (Tecentriq, Tecentriq Hybreza)		
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Overview

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

The FDA approved indications for Tecentriq (atezolizumab) and Tecentriq Hybreza includes:

- 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 unresectable or metastatic hepatocellular carcinoma (HCC)
- Individuals with unresectable or metastatic melanoma in combination with cobimetinib and vemurafenib with BRAF V600 mutation positive disease.
- Individuals using as adjuvant treatment following resection and platinum-based chemotherapy for Stage II to IIIA NSCLC whose tumors have PD-L1 expression on $\geq 1\%$ of tumor cells
- Individuals with alveolar soft part sarcoma (ASPS)

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 first-line treatment for metastatic or unresectable hepatocellular carcinoma (HCC)
- Individuals with extensive stage small cell lung cancer (SCLC).

NCCN does not currently address Tecentriq Hybreza.

Definitions and Measures

Actionable molecular markers include EGFR, ALK, ROS1, BRAF, NTRK, MET and RET mutations. The NCCN panel recommends testing prior to initiating therapy to help guide appropriate treatment. If there is insufficient tissue to allow testing for all of these markers, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes (NCCN 1, 2A).

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 advanced, unresectable, or metastatic hepatocellular carcinoma (HCC) (Label, NCCN 2A); **AND**
 - 1. Individual is using in combination with bevacizumab (or bevacizumab biosimilar);
 - OR**
 - B. Adjuvant treatment of hepatocellular carcinoma (HCC) at high risk of recurrence (NCCN 2A); **AND**
 - 1. Individual is using in combination with bevacizumab;
 - 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 does not have presence of actionable molecular markers;
 - OR**
 - D. First-line, subsequent line, or maintenance therapy 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); **OR**
 - 2. Individual is using as monotherapy;
 - 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 tumor response or stable disease following initial cytotoxic therapy (first-line atezolizumab/carboplatin/paclitaxel/bevacizumab regimen **or** atezolizumab/carboplatin/nab-paclitaxel regimen);
 - 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
 - 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, NTRK, or MET mutations); **AND**
 - 2. Individual is using in combination with carboplatin and nab-paclitaxel (albumin-bound paclitaxel);
 - OR**
 - H. Treatment of stage II to IIIB NSCLC (NCCN 2A); **AND**
 - 1. Individual is using as adjuvant therapy following resection; **AND**
 - 2. Individual has PD-L1 expression on tumor cells [TC] that is greater than or equal to 1% [TC ≥ 1%];
 - OR**
 - I. Treatment of unresectable or metastatic Melanoma (Label); **AND**
 - 1. Individual is using in combination with cobimetinib and vemurafenib; **AND**
 - 2. Individual has BRAF V600 mutation positive disease;
 - OR**
 - J. First-line treatment of extensive-stage Small Cell Lung Cancer (ES-SCLC) (Label, NCCN 1); **AND**
 - 1. Individual is using in combination with etoposide and carboplatin (followed by maintenance atezolizumab monotherapy);
 - OR**
 - K. Treatment of alveolar soft part sarcoma (ASPS) (Label, NCCN 2A); **AND**
 - 1. Individual is 2 years of age or older; **AND**
 - 2. Individual is using as monotherapy;
 - OR**
 - L. Treatment of persistent, recurrent or metastatic small cell neuroendocrine carcinoma of the cervical cancer (NECC); **AND**
 - 1. Individual is using in combination with etoposide and platinum-therapy (NCCN 2A); **OR**
 - 2. Individual is using as a single agent maintenance therapy;
 - OR**
 - M. Treatment of mesothelioma including pericardial, tunica vaginalis, and testis (NCCN 2A); **AND**

1. Individual is using in combination with bevacizumab (or bevacizumab biosimilar); **AND**
2. Individual is using as subsequent therapy.

Tecentriq may not be approved for the following:

- I. Individual has disease progression with another PD-1 inhibitor or PD-L1 inhibitor (NCCN); **OR**
- II. Individual is receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant (NCCN); **OR**
- III. When the above criteria are not met and for all other indications.

Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs)

Requests for Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs) may be approved if the following criteria are met:

- I. Individual has a diagnosis of one of the following:
 - A. First-line treatment of unresectable or metastatic hepatocellular carcinoma (HCC) (Label); **AND**
 1. Individual is using in combination with bevacizumab (or bevacizumab biosimilar);
 - OR**
 - B. Treatment of stage II to IIIA NSCLC (Label); **AND**
 1. Individual is using as adjuvant therapy following resection and platinum based therapy; **AND**
 2. Individual has PD-L1 expression on tumor cells [TC] that is greater than or equal to 1% [TC ≥ 1%];
 - OR**
 - C. First-line treatment of metastatic NSCLC (nonsquamous or squamous) (Label); **AND**
 1. Individual does not have presence of actionable molecular markers; **AND**
 2. Individual has high PD-L1 expression on tumor cells [TC] (PD-L1 stained 50% or more of tumor cells [TC ≥ 50%] or PD-L1 stained tumor infiltrating immune cells [IC] covering 10% or more of the tumor area [IC ≥ 10%]); **AND**
 3. Individual is using as monotherapy;
 - OR**
 - D. First-line treatment of metastatic nonsquamous NSCLC (Label); **AND**
 1. Individual is using in a combination regimen with carboplatin, paclitaxel, and bevacizumab (or bevacizumab biosimilar); **AND**
 2. Individual does not have presence of actionable molecular markers;
 - OR**
 - E. First-line treatment of metastatic non-squamous Non-Small Cell Lung Cancer (NSCLC) (Label); **AND**
 1. Individual is using in a combination regimen with nab-paclitaxel (paclitaxel, protein-bound) and carboplatin; **AND**
 2. Individual does not have presence of actionable molecular markers;
 - OR**
 - F. Treatment of metastatic NSCLC (nonsquamous or squamous) (Label); **AND**
 1. Disease has progressed during or following platinum-containing chemotherapy; **AND**
 2. Individual is using as monotherapy;
 - OR**
 - G. Treatment of metastatic NSCLC (nonsquamous or squamous) (Label); **AND**
 1. Disease has progressed during or following treatment with a targeted agent for the expressed oncogene (for example, kinase inhibitors that target EGFR or ALK mutations); **AND**
 2. Individual is using as monotherapy;
 - OR**
 - H. First-line treatment of extensive-stage Small Cell Lung Cancer (ES-SCLC) (Label); **AND**
 1. Individual is using in combination with etoposide and carboplatin;
 - OR**
 - I. Treatment of unresectable or metastatic Melanoma (Label); **AND**
 1. Individual is using in combination with cobimetinib and vemurafenib; **AND**
 2. Individual has BRAF V600 mutation positive disease;

- J. Treatment of unresectable or metastatic alveolar soft part sarcoma (ASPS) (Label); **AND**
1. Individual is 18 years of age or older; **AND**
 2. Individual is using as monotherapy.

Tecentriq Hybreza may not be approved for the following:

- I. Individual has disease progression with another PD-1 inhibitor or PD-L1 inhibitor (NCCN); **OR**
- II. Individual is receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant (NCCN); **OR**
- III. Tecentriq Hybreza 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]
J9999	Not otherwise classified, antineoplastic drugs [Tecentriq Hybreza]
C9399	Unclassified drugs or biologicals [Tecentriq Hybreza]

ICD-10 Diagnosis

	All diagnosis pend [Tecentriq Hybreza]
C22.0	Liver cell carcinoma [Tecentriq]
C22.8	Malignant neoplasm of liver, primary, unspecified as to type [Tecentriq]
C22.9	Malignant neoplasm of liver, not specified as primary or secondary [Tecentriq]
C33	Malignant neoplasm of trachea [Tecentriq]
C34.00-C34.92	Malignant neoplasm of bronchus and lung [Tecentriq]
C43.0-C43.9	Malignant melanoma of skin [Tecentriq]
C45.0-C45.9	Mesothelioma [Tecentriq]
C49.0-C49.9	Malignant neoplasm of connective and soft tissue, unspecified [Tecentriq]
C53.0-C53.9	Malignant neoplasm of cervix uteri [Tecentriq]
Z85.118	Personal history of other malignant neoplasm of bronchus and lung [Tecentriq]
Z85.51	Personal history of malignant neoplasm of bladder [Tecentriq]

Document History

Revised: 11/15/2024

Document History:

- 12/17/2024 – Coding update only: Added HCPCS NOC C9399 for Tecentriq Hybreza.
- 11/15/2024 – Select Review: update hepatocellular cancer criteria, remove ECOG status from hepatocellular and NSCLC, update cervical cancer, update may not approve criteria, add Tecentriq Hybreza, wording and formatting. Coding Reviewed: Added HCPCS NOC J9999 and all diagnosis pend for Tecentriq Hybreza. Removed ICD-10-CM C22.1-C22.7, C50.011-C50.929, C61, C65.1-C65.9, C66.1-C66.9, C67.0-C67.9, C68.0-C68.9, Z85.53-Z85.54. Added ICD-10-CM C33, C49.0-C49.8. Updated diagnoses descriptions applicable to Tecentriq.
- 05/17/2024 – Annual Review: Modify non-squamous Non-Small Cell Cancer Lung Cancer (NSCLC) to allow use in actionable molecular markers and PDL-1 expression, Update NSCLC to allow for subsequent

line or maintenance therapy, update alveolar soft part sarcoma for all stages, Add mesothelioma criteria, update do not approve criteria, Wording and formatting. Coding Reviewed: Added ICD-10-CM C45.0-C45.9.

- 02/23/2024 – Annual Review: update child-pugh score for HCC, wording and formatting. Coding Reviewed: No changes.
- 11/17/2023 – Select Review: remove duplicate do not approve criteria for alveolar soft part sarcoma. Coding Reviewed: No changes.
- 05/19/2023 – Annual Review: modify NSCLC criteria to include stage IIIB, remove platinum requirement and ECOG, add cervical cancer criteria. Coding Reviewed: Added ICD-10-CM C53.0-C53.9.
- 02/24/2023 – Select review: Remove urothelial cancer indication, add do not approve criteria, add indication for alveolar soft part sarcoma, remove may not approve statements from all indications. Coding Reviewed: Added ICD-10-CM C49.9.
- 12/12/2022 – Select Review: Add new indication for alveolar soft part sarcoma. Coding Reviewed: No changes.
- 05/20/2022 – Annual review: No changes. Coding Reviewed: No changes.
- 11/19/2021 – Select Review: Update criteria to add indication for adjuvant therapy in stage II-IIIa NSCLC per label. Coding reviewed: No changes.
- 09/13/2021 – Select Review: Update criteria to remove use in TNBC in combination with nab-paclitaxel per FDA withdrawal. Coding reviewed: No changes.
- 05/21/2021 – Annual Review: Update criteria to remove use as subsequent treatment following platinum therapy for urothelial carcinoma per FDA withdrawal. Update NSCLC criteria to specify any actionable molecular marker with a note to further expand on definition and marker testing per NCCN. Update criteria for first line monotherapy use in NSCLC to include use in recurrent or advance disease per NCCN. Update criteria for subsequent therapy in NSCLC to include MET as oncogene examples. Retire quantity limits. Wording and formatting changes. Update references. Coding Reviewed: Added ICD-10-CM C68.0-C68.9.
- 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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 - a. Bladder Cancer. V1.2024. Revised January 30, 2024.
 - b. Cervical Cancer. V1.2024. Revised September 20, 2023.
 - c. Melanoma: Cutaneous. V3.2023. Revised October 27, 2023.
 - d. Mesothelioma: Peritoneal. V1.2024. Revised November 21, 2023.
 - e. Hepatocellular Carcinoma. V2.2024. Revised July 2, 2024.
 - f. Non-Small Cell Lung Cancer. V5.2023. Revised November 8, 2023.
 - g. Small Cell Lung Cancer. V2.2024. Revised November 21, 2023.
 - h. Soft Tissue Sarcoma. V3.2023. Revised December 12, 2023.
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