

# Medical Drug Clinical Criteria

<b>Subject:</b>	Tecentriq (atezolizumab)		
<b>Document #:</b>	CC-0128	<b>Publish Date:</b>	12/18/2023
<b>Status:</b>	Revised	<b>Last Review Date:</b>	11/17/2023

## Table of Contents

<a href="#">Overview</a>	<a href="#">Coding</a>	<a href="#">References</a>
<a href="#">Clinical criteria</a>	<a href="#">Document history</a>	

## 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 non-small cell lung cancer (NSCLC), and small cell lung cancer (SCLC).

The FDA approved indications for Tecentriq (atezolizumab) 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).

## 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 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;
  - OR**
  - B. 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\*; **AND**

3. Individual has a ECOG performance status of 0-2;
- OR**
- C. 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 does not have presence of actionable molecular markers\*; **AND**
  3. Individual has a ECOG performance status of 0-1;
- OR**
- D. 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;
- OR**
- E. 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. Individual has a ECOG performance status of 0-2;
- OR**
- F. 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 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;
- OR**
- G. First-line treatment of recurrent, advanced, or metastatic NSCLC (Label, NCCN 1); **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  $\geq$  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  $\geq$  10%] of the tumor area, as confirmed by an FDA-approved test; **AND**
  3. Individual does not have presence of actionable molecular markers\*; **AND**
  4. Individual has a ECOG performance status of 0-2;
- OR**
- H. Treatment of stage II to IIIB NSCLC; **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  $\geq$  1%], as confirmed through an FDA-approved test;
- 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;
- OR**
- J. 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);
- OR**
- K. Treatment of unresectable or metastatic alveolar soft part sarcoma (ASPS); **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).

Tecentriq may not be approved for the following:

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

**\*Note:** 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).

## 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
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C50.011-C50.929	Malignant neoplasm of breast
C53.0-C53.9	Malignant neoplasm of cervix uteri
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-C68.9	Malignant neoplasm of the urinary system
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
Z85.53-Z85.54	Personal history of malignant neoplasm of renal pelvis, ureter

## Document History

Revised: 11/17/2023

Document History:

- 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.

## References

1. Adams S, Diamond JR, Hamilton E, et al. Atezolizumab plus nab-paclitaxel in the treatment of metastatic triple-negative breast cancer with 2-year survival follow-up: a phase 1b clinical trial. *JAMA Oncol.* 2018 Oct 18; [Epub ahead of print]. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/30347025>.
2. Alsina M, Moehler M, Hierro C, et al. Immunotherapy for gastric cancer: a focus on immune checkpoints. *Target Oncol.* 2016; 11(4):469-477.
3. Balar AV, Galsky MD, Rosenberg JE, et al; IMvigor210 Study Group. Atezolizumab as first-line treatment in cisplatin-ineligible patients with locally advanced and metastatic urothelial carcinoma: a single-arm, multicentre, phase 2 trial. *Lancet.* 2017; 389(10064):67-76.
4. Cheng A-L, Qin S, Ikeda M, et al. Efficacy and safety results for a phase III study evaluating atezolizumab (atezo) + bevacizumab (bev) vs sorafenib (Sor) as first treatment (tx) for patients (pts) with unresectable hepatocellular carcinoma (HCC). *Ann Oncol.* 2019 Nov; 30 Suppl 9: ix86-ix87.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

6. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 6, 2023.
7. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
8. Emens LA, Cruz C, Eder JP, et al. Long-term clinical outcomes and biomarker analyses of atezolizumab therapy for patients with metastatic triple-negative breast cancer: a phase 1 study. *JAMA Oncol*. 2018 Sep 13; [Epub ahead of print]. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/30242306>.
9. García-Tejido P, Cabal ML, Fernández IP, Pérez YF. Tumor-infiltrating lymphocytes in triple negative breast cancer: the future of immune targeting. *Clin Med Insights Oncol*. 2016; 10(Suppl 1):31-39.
10. Hoffmann-La Roche. Study of atezolizumab as monotherapy and in combination with platinum-based chemotherapy in participants with untreated locally advanced or metastatic urothelial carcinoma (IMvigor130). NLM Identifier: NCT02807636. Last updated on November 16, 2018. Available at: <https://www.clinicaltrials.gov/ct2/show/NCT02807636?cond=NCT02807636&rank=1>.
11. Horn L, Mansfield AS, Szczesna A, et al. First-Line Atezolizumab plus Chemotherapy in Extensive-Stage Small-Cell Lung Cancer. *N Engl J Med*. 2018;379(23):2220-2229. doi:10.1056/NEJMoa1809064. Available at: [https://www.nejm.org/doi/10.1056/NEJMoa1809064?url\\_ver=Z39.88-2003&rft\\_id=ori:rid:crossref.org&rft\\_dat=cr\\_pub%20%20pubmed](https://www.nejm.org/doi/10.1056/NEJMoa1809064?url_ver=Z39.88-2003&rft_id=ori:rid:crossref.org&rft_dat=cr_pub%20%20pubmed). Accessed April 5, 2023.
12. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
13. McDermott DF, Sosman JA, Sznol M, et al. Atezolizumab, an anti-programmed death-ligand 1 antibody, in metastatic renal cell carcinoma: long-term safety, clinical activity, and immune correlates from a phase Ia study. *J Clin Oncol*. 2016; 34(8):833-842.
14. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 4, 2023.
15. Bladder Cancer. V1.2023. Revised February 9, 2023.
16. Cervical Cancer. V1.2023. Revised January 6, 2023.
17. Melanoma: Cutaneous. V2.2023. Revised March 10, 2023.
18. Mesothelioma: Peritoneal. V1.2023. Revised December 15, 2022.
19. Hepatocellular Carcinoma. V1.2023. Revised March 10, 2023.
20. Malignant Peritoneal Mesothelioma V1.2022. Revised December 22, 2021.
21. Non-Small Cell Lung Cancer. V2.2023. Revised February 17, 2023.
22. Small Cell Lung Cancer. V3.2023. Revised December 21, 2022.
23. Soft Tissue Sarcoma. V1.2023. Revised March 13, 2023.
24. Powles T, Durán I, van der Heijden MS, et al. Atezolizumab versus chemotherapy in patients with platinum-treated locally advanced or metastatic urothelial carcinoma (IMvigor211): a multicentre, open-label, phase 3 randomised controlled trial. *Lancet*. 2018; 391(10122):748-757.
25. Powles T, Eder JP, Fine GD, et al. MPDL3280A (anti-PD-L1) treatment leads to clinical activity in metastatic bladder cancer. *Nature*. 2014; 515(7528):558-562.
26. Rosenberg JE, Hoffman-Censits J, Powles T, et al. Atezolizumab in patients with locally advanced and metastatic urothelial carcinoma who have progressed following treatment with platinum-based chemotherapy: a single-arm, multicentre, phase 2 trial. *Lancet*. 2016; 387(10031):1909-1920.
27. Schmid P, Adams S, Rugo HS, et al. Atezolizumab and Nab-Paclitaxel in advanced triple-negative breast cancer. *N Engl J Med*. 2018; 379(22):2108-2121.
28. Socinski MA, Jotte RM, Cappuzzo F, et al. IMpower150 Study Group. Atezolizumab for First-Line Treatment of Metastatic Nonsquamous NSCLC. *N Engl J Med*. 2018 Jun 14;378(24):2288-2301.
29. Spigel D, de Marinis G, Giaccone N, et al., IMpower110: Interim overall survival (OS) analysis of a phase III study of atezolizumab (atezo) vs platinum-based chemotherapy (chemo) as first-line (1L) treatment (tx) in PD-L1–selected NSCLC. Abstract LBA78. *Ann Oncol*. 2019; 30 (suppl 5): doi:10.1093/annonc/mdz394 | v915. Available at [https://www.annalsofoncology.org/article/S0923-7534\(19\)60359-5/pdf](https://www.annalsofoncology.org/article/S0923-7534(19)60359-5/pdf).
30. West H, McCleod M, Hussein M, et al. Atezolizumab in combination with carboplatin plus nab-paclitaxel chemotherapy compared with chemotherapy alone as first-line treatment for metastatic non-squamous non-small-cell lung cancer (IMpower130): a multicentre, randomised, open-label, phase 3 trial. *Lancet Oncol*. 2019 Jul;20(7):924-937. Epub 2019 May 20.

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

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.