Tecentriq (atezolizumab), Tecentriq Hybreza(atezolizumab and hyaluronidase-tqjs)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Tecentriq (atezolizumab) Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs)

APPROVAL CRITERIA

Requests for Tecentriq (atezolizumab) and Tecentriq Hybreza (atezolizumab and hyaluronidase-tgjs) may be approved if 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 cervical cancer adenocarcinoma; **AND**

1. Individual is using in combination with bevacizumab, paclitaxel, and cisplatin or carboplatin (NCCN 1);

OR

N. 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 (atezolizumab) or Tecentriq Hybreza (atezolizumab and hyaluronidase-tgjs) 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.

Key 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 ph 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.: 2024. 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. Updated periodically.
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-Teijido 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, Szczęsna 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&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed. Accessed April 5, 2023.
12. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; 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™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on March 12, 2024.
    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. V3.2023. Revised September 14, 2023.
    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.
15. 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.
16. 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.
17. 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.
18. 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.
19. 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.
20. 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.
21. 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 polices may take precedence over the application of this clinical criteria.