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Ascension

Atezolizumab

(Tecentriq®) J9022 (10mg)

Covered with prior authorization

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

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

      OR
    - First-line treatment of recurrent, advanced or metastatic nonsquamous non-small cell lung cancer (NSCLC) (Label, NCCN 2A); **AND**
        - Individual is using in a combination regimen with nab-paclitaxel (paclitaxel, protein-bound) and carboplatin; **AND**
        - Individual does not have presence of actionable molecular markers*; **AND**
        - Individual has a ECOG performance status of 0-2; **AND**
        - Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
        - Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

      OR
    - First-line treatment of recurrent, advanced or metastatic nonsquamous NSCLC (Label, NCCN 1, 2A); **AND**
        - Individual is using in a combination regimen with carboplatin, paclitaxel, and bevacizumab (or bevacizumab biosimilar); **AND**
        - Individual does not have presence of actionable molecular markers*; AND Individual has a ECOG performance status of 0-2; **AND**
        - Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
        - Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

      OR

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

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

  OR
- Subsequent treatment of recurrent, advanced or metastatic nonsquamous NSCLC (NCCN 1, 2A); **AND**
  - 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**
  - Individual is using in a combination regimen with one of the following:
    - Carboplatin, paclitaxel, and bevacizumab (or bevacizumab biosimilar); **OR**
    - Carboplatin and nab-paclitaxel (albumin-bound paclitaxel); **AND**
  - Individual has a ECOG performance status of 0-2; **AND**
  - Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
  - Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

  OR
- First-line treatment of recurrent, advanced, or metastatic NSCLC (Label, NCCN 1); **AND**

- Individual is using as monotherapy; **AND**
- Individual has one of the following:
  - 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**
  - 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**
- Individual does not have presence of actionable molecular markers*; **AND**
- Individual has a ECOG performance status of 0-2; **AND**
- Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
- Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

- Treatment of stage II to IIIA NSCLC; **AND**
  - Individual is using as adjuvant therapy following resection and platinum-based chemotherapy; **AND**
  - Individual has PD-L1 expression on tumor cells [TC] that is greater than or equal to 1% [TC ≥ 1%], as confirmed through an FDA-approved test; **AND**
  - Individual has a ECOG performance status of 0-2; **AND**
  - Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
  - Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

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

OR

- First-line treatment of extensive-stage small cell lung cancer (SCLC) (Label, NCCN 1); **AND**
  - Individual is using in combination with etoposide and carboplatin (followed by maintenance atezolizumab monotherapy); **AND**

- Individual has not received treatment with another anti-PD-1 or anti-PD-L1 inhibitor; **AND**
- Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

- First-line treatment of locally advanced or metastatic Urothelial Carcinoma; **AND**
  - Individual is ineligible for any platinum-containing chemotherapy; **OR**
  - 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**
  - Individual has a ECOG performance status of 0-2; **AND**
  - Individual has not received treatment with another anti-PD-1 or anti-PD-L1inhibitor; **AND**
  - Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

***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).

Initial and renewal authorizations are for up to 12 months.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

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

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Exclusion criteria:

- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage. Tecentriq® is an anti-programmed death ligand 1 (PD-L1) monoclonal antibody primarily used to treat urothelial carcinoma, 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 non squamous NSCLC
- Individuals requiring subsequent therapy of metastatic non squamous 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
- 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 ≥ 1% of tumor cells

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 of locally advanced or metastatic urothelial carcinoma
- Individuals requiring first-line treatment for metastatic or unresectable hepatocellular carcinoma (HCC)
- Individuals with extensive-stage small cell lung cancer (SCLC)

Tecentriq® is supplied as an 840mg/14mL vial or 1200mg/20mL vial.

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Key References Accessed 8/2022:

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. 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.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
4. 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.
5. 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.
    a. Bladder Cancer. V1.2022. Revised February 11, 2022.
    b. Breast Cancer. V2.2022. Revised December 20, 2021.
    c. Melanoma: Cutaneous. V2.2022. Revised January 26, 2022.
    d. Hepatobiliary Cancers. V5.2021. Revised September 21, 2021.
    e. Malignant Peritoneal Mesothelioma V1.2022. Revised December 22, 2021.
    f. Non-Small Cell Lung Cancer. V2.2022. Revised March 7, 2022.
    g. Small Cell Lung Cancer. V2.2022. Revised November 24, 2021.
6. 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 randomized controlled trial. Lancet. 2018; 391(10122):748-757.
7. 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.
8. 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.
9. 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.

10. 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, randomized, open-label, phase 3 trial. Lancet Oncol. 2019 Jul;20(7):924-937. Epub 2019 May 20.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or
email your questions to smarthealthspecialty@ascension.org.