



Drug Policy:

Tecentriq™ (atezolizumab)

POLICY NUMBER UM ONC_1299	SUBJECT Tecentriq™ (atezolizumab)	DEPT/PROGRAM UM Dept	PAGE 1 of 4
DATES COMMITTEE REVIEWED 07/26/16, 08/10/17, 09/13/17, 08/08/18, 07/10/19, 12/11/19, 03/11/20, 07/08/20, 09/09/20, 04/14/21, 09/08/21, 11/10/21, 04/13/22, 05/11/22, 08/22/22, 11/09/22, 12/14/22, 02/08/23, 03/08/23, 05/10/23	APPROVAL DATE May 10, 2023	EFFECTIVE DATE May 26, 2023	COMMITTEE APPROVAL DATES 07/26/16, 08/10/17, 09/13/17, 08/08/18, 07/10/19, 12/11/19, 03/11/20, 07/08/20, 09/09/20, 04/14/21, 09/08/21, 11/10/21, 04/13/22, 05/11/22, 08/22/22, 11/09/22, 12/14/22, 02/08/23, 03/08/23, 05/10/23
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee	
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS	APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Tecentriq (atezolizumab) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this NCH policy provided:

1. The requested medication was used within the last year, **AND**
2. The member has not experienced disease progression and/or no intolerance to the requested medication, **AND**
3. Additional medication(s) are not being added to the continuation request.

B. Alveolar Soft Part Sarcoma (ASPS)

1. Tecentriq (atezolizumab) may be used as monotherapy in adult or pediatric members 2 years of age and older with unresectable or metastatic alveolar soft part sarcoma (ASPS).

C. Hepatocellular Carcinoma

1. In members with unresectable or metastatic hepatocellular carcinoma **AND** preserved liver function (Child-Pugh Class A), who have not received prior therapy with a checkpoint inhibitor, e.g., Keytruda (pembrolizumab) or Opdivo (nivolumab). Tecentriq (atezolizumab) may be used in combination with Avastin (bevacizumab)/bevacizumab biosimilar as first line therapy in the metastatic setting.

D. Malignant Melanoma

1. **NOTE:** The combination of [Cotellic (cobimetinib) + Zelboraf (vemurafenib) + Tecentriq (atezolizumab)] is not supported by NCH Policy for metastatic malignant melanoma. This policy position is based on the updated results of the IMspire 150 trial which showed no overall survival benefit with the above 3-drug regimen compared to [Cotellic(cobimetinib) + Zelboraf (vemurafenib)]. Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens available at <http://pathways.newcenturyhealth.com>.

E. Non-Small Cell Lung Cancer (NSCLC)

1. For members with metastatic/recurrent Non-Small Cell Lung Cancer, Tecentriq (atezolizumab) may be used as a single agent as subsequent therapy (if pembrolizumab/nivolumab/durvalumab/other checkpoint inhibitor not previously given) in members who have progressed during or following platinum-based chemotherapy or with prior use of an EGFR or ALK inhibitor for EGFR/ALK positive disease **OR**
2. For members with stage II-IIIa NSCLC whose tumors have PD-L1 expression of greater than or equal to 1% of tumor cells, Tecentriq (atezolizumab) may be used as adjuvant treatment and will be administered as monotherapy for up to 16 cycles (up to 1 year) following adjuvant platinum-based chemotherapy **OR**
3. For members with metastatic Non-Small Cell Lung Cancer, with negative EGFR and ALK, with a PDL-1 expression of greater than or equal to 50%, Tecentriq (atezolizumab) may be used as monotherapy as first line therapy.

F. Small Cell Lung Cancer (SCLC)

1. For members with extensive stage SCLC Tecentriq (atezolizumab) may be used as initial treatment in combination with etoposide and carboplatin or cisplatin followed by Tecentriq (atezolizumab) maintenance in members who have had a complete response/partial response/stable disease after completion of [atezolizumab + etoposide + carboplatin/cisplatin]. The above regimen may also be used in the second/subsequent line setting if the member has not received prior therapy with a checkpoint inhibitor, e.g., Keytruda (pembrolizumab) and has not progressed within 6 months of etoposide + platinum-based regimen.

G. Urothelial carcinoma of the bladder and other urothelial carcinomas

1. **NOTE:** Tecentriq (atezolizumab) is not supported by NCH Policy for the treatment of locally advanced or metastatic urothelial carcinoma in members who are not eligible for cisplatin or any platinum containing chemotherapy. This policy position is based on the voluntary withdrawal by the manufacturer of Tecentriq, which concluded that IMvigor130 confirmatory study did not meet the co-primary endpoint of overall survival (OS) for Tecentriq plus chemotherapy compared with chemotherapy alone. Please refer to the NCH recommended alternatives agents/regimens, including but not limited to regimens at <http://pathways.newcenturyhealth.com>.

III. EXCLUSION CRITERIA

- A. Tecentriq (atezolizumab) is being used after disease progression with the same regimen **OR** disease progression on prior anti-PD-1 or anti-PD-L1 therapy.
- B. Use of Tecentriq (atezolizumab) in combination with Cotellic (cobimetinib) + Zelboraf (vemurafenib) in metastatic/recurrent/unresectable BRAF V600 mutation positive malignant melanoma.
- C. Dosing exceeds single dose limit of Tecentriq (atezolizumab) 840 mg IV every 2 weeks, 1,200 mg every 3 weeks, or 1,680 mg every 4 weeks.
- D. Investigational use of Tecentriq (atezolizumab) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
 - 1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
 - 2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
 - 3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
 - 4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
 - 5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
 - 6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
 - 7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

- A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

- A. None

VII. REFERENCES

- A. Cheng AL, et al. Updated efficacy and safety data from IMbrave150: Atezolizumab plus bevacizumab vs. sorafenib for unresectable hepatocellular carcinoma. *J Hepatol*. 2022 Apr;76(4):862-873.
- B. Galsky MD, et al. IMvigor130 Clinical Trial. Atezolizumab with or without chemotherapy in metastatic urothelial cancer (IMvigor130): a multicentre, randomised, placebo-controlled phase 3 trial. *Lancet*. 2020 May 16;395(10236):1547-1557.
- C. Gutzmer R, et al. Atezolizumab, vemurafenib, and cobimetinib as first-line treatment for unresectable advanced BRAFV600 mutation-positive melanoma (IMspire150): primary analysis of the randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2020 Jun 13;395(10240):1835-1844.
- D. Herbst RS, et al. Atezolizumab for First-Line Treatment of PD-L1-Selected Patients with NSCLC. *N Engl J Med*. 2020 Oct 1;383(14):1328-1339.
- E. IMpower010 Investigators. et al. Adjuvant atezolizumab after adjuvant chemotherapy in resected stage IB-IIIA non-small-cell lung cancer (IMpower010): a randomised, multicentre, open-label, phase 3 trial. *Lancet*. 2021 Oct 9;398(10308):1344-1357.
- F. Tecentriq prescribing information. Genentech, Inc. South San Francisco, CA 2021.
- G. Clinical Pharmacology Elsevier Gold Standard 2023.
- H. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2023.
- I. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.
- J. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2023.
- K. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. *J Clin Oncol*. 2014 Apr 20;32(12):1277-80.
- L. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.
- M. NCQA UM 2023 Standards and Elements.