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	APPROVAL DATE April 13, 2022	EFFECTIVE DATE April 29, 2022	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	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 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. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR

3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When applicable, generic alternatives are preferred over brand-name drugs.

B. Urothelial carcinoma of the bladder and other urothelial carcinomas

1. For members with locally advanced, metastatic, or recurrent urothelial cancer Tecentriq (atezolizumab) may be used as a single agent in ANY of the following:
    a. First line treatment in members who are ineligible for cisplatin chemotherapy AND whose tumors express PD-L1 (CPS or TPS of >/=1%) OR for members who are not eligible for any platinum containing chemotherapy, regardless of PD-L1 tumor status.

C. 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 or ROS-1 inhibitor for EGFR/ALK/ROS-1 positive disease.
2. For members with stage II-IIIA NSCLC whose tumors have PD-L1 expression on ≥ 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 4 cycles of platinum-based chemotherapy.
3. NOTE: Per NCH Pathway & NCH Policy, [Atezolizumab + Carboplatin + Paclitaxel/Nab-Paclitaxel with or without Bevacizumab] is a Non-Preferred regimen for the treatment of NSCLC. This recommendation is based on the lack of Level 1 Evidence (randomized clinical trial and/or meta-analyses) to show superior outcomes compared to NCH Preferred regimens.

D. 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.

E. Breast Cancer

1. Metastatic Triple Negative Breast Cancer: The combination of Abraxane + Tecentriq (atezolizumab) is NOT recommended per NCH Policy and per NCH Pathway because of the voluntary withdrawal by the manufacturer of Tecentriq (atezolizumab), from the FDA, for the above indication.

F. 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/Avastin biosimilar (preferred) as first line therapy in the metastatic setting.

G. Malignant Melanoma

1. NOTE: The combination of [Cotellic (cobimetinib) + Zelboraf (vemurafenib) + Tecentriq (atezolizumab)] is not recommended for metastatic malignant melanoma. This position is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) showing the superiority of the above 3-drug combination over the recommended regimen [Opdivo (nivolumab) + Yervoy (ipilimumab)].

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, 1200 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 definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, in light of 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. 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.

B. Tecentriq prescribing information. Genentech, Inc. South San Francisco, CA 2021.

C. Clinical Pharmacology Elsevier Gold Standard 2022.

D. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2022.

E. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2022.

F. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2022.

G. 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.

H. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.