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| POLICY NUMBER UM_ONC_1299 | SUBJECT Tecentriq™ (atezolizumab) | DEPT/PROGRAM UM Dept | PAGE 1 OF 3 |
| 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 | APPROVAL DATE July 8, 2020 | EFFECTIVE DATE July 31, 2020 | COMMITTEE APPROVAL DATES (latest version listed last) 07/26/16, 08/10/17, 09/13/17, 08/08/18, 07/10/19, 12/11/19, 03/11/20, 07/08/20 |
| PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler | 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 All | |

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 is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century 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

1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

- 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**
- 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**
- 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**
- Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
- When available, generic drug alternatives are preferred over Brand name drugs.

2. Urothelial carcinoma of the bladder, and other urothelial carcinomas

NOTE: Per NCH Policy & NCH Pathway, Keytruda (pembrolizumab) is the preferred agent over other PD-1 or PD-L1 inhibitors [i.e. Opdivo (nivolumab), Tecentriq (atezolizumab), Bavencio (avelumab), Imfinzi (durvalumab)], for initial and subsequent therapy in the recurrent/metastatic setting.

- For members with locally advanced, metastatic, or recurrent urothelial cancer Tecentriq (atezolizumab) may be used as a single agent in **ANY** of the following:



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- i. First line treatment in members who are ineligible for cisplatin chemotherapy **AND** whose tumors express PD-L1 (CPS or TPS of $\geq 1\%$) **OR**
- ii. As subsequent therapy after progression on previous platinum-based chemotherapy.

3. Non-Small Cell Lung Cancer (NSCLC)

NOTE: Per NCH Policy & NCH Pathway, Keytruda- given with or without chemotherapy as appropriate- is the preferred immunotherapy agent over other PD-1 or PD-L1 inhibitors [e.g. Opdivo (nivolumab), Tecentriq (atezolizumab)], for initial and subsequent therapy in metastatic/recurrent NSCLC.

- a. 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.

4. Small Cell Lung Cancer (SCLC)

- a. 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.

5. Breast Cancer

- a. Tecentriq (atezolizumab) may be used in combination with Abraxane (albumin-bound paclitaxel) in members with recurrent/metastatic triple negative breast cancer whose tumors are PD-L1 positive (PD-L1 testing on patient's breast cancer shows a score (TPS or CPS) of $\geq 1\%$) and who have not received prior therapy with a checkpoint inhibitor, e.g. Keytruda (pembrolizumab).

6. Hepatocellular Carcinoma

- a. 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), Tecentriq (atezolizumab) may be used in combination with Avastin (bevacizumab) as first line therapy in the metastatic setting.

III. EXCLUSION CRITERIA

1. 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.
2. 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.
3. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY



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1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Tecentriq prescribing information. Genentech, Inc. South San Francisco, CA. 2020.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.