POLICY NUMBER UM ONC_1374	SUBJECT Balversa™ (erdafitinib)		DEPT/PROGRAM UM Department	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 11/13/19, 12/11/19, 05/13/20	APPROVAL DATE May 13, 2020	EFFECTIVE DATE May 29, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 11/13/19, 12/11/19, 05/13/20	
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 Balversa (erdafitinib) 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:

a. 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**

b. 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**

c. 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**

d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**

e. When available, generic alternatives are preferred over brand-name drugs.

2. Urothelial Carcinoma

a. **NOTE: The preferred agents, per NCH policy and pathway, for subsequent line advanced/metastatic urothelial carcinoma are single agents GEMCITABINE or PEMBROLIZUMAB (if failed prior platinum based chemotherapy). Erdafitinib may be used per criteria described below.**

b. The member has unresectable or metastatic urothelial carcinoma and Balversa (erdafitinib) is being used as a single agent when **ALL** the following criteria are met:

i. Documented FGFR3 or FGFR2 genomic alterations in tumor tissue (using the FDA approved companion diagnostic: *therascreenR* or another appropriate genomic test) **AND**

ii. Disease progression on platinum-based chemotherapy **AND** disease progression on Check Point Inhibitor therapy (e.g. atezolizumab, avelumab, durvalumab, nivolumab, or pembrolizumab) **OR**

iii. If ineligible for platinum containing therapy, the member had disease progression on Check Point Inhibitor therapy (e.g. atezolizumab, avelumab, durvalumab, nivolumab, or pembrolizumab).

III. EXCLUSION CRITERIA

1. Disease progression while receiving Erdafitinib.
2. Lack of test results confirming a FGFR 3 or FGFR 2 genomic alteration in the tumor tissue.
3. Concurrent use with other chemotherapy, targeted therapies, or definitive radiotherapy.
4. Dosing exceeds single dose limit of Balversa (erdafitinib) 9 mg.
5. Treatment exceeds the maximum limit of 30 (4 mg), 30 (5mg), 90 (3mg) tablets/month.
6. 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

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

VI. ATTACHMENTS

None

VII. REFERENCES

1. Balversa PI prescribing information. Janssen Products, LP. Horsham, PA 2019.
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.