Drug Policy:

Balversa™ (erdafitinib)

POLICY NUMBER UM ONC_1374	**SUBJECT** Balversa™ (erdafitinib)	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 11/13/19, 12/11/19, 05/13/20, 04/14/21, 11/15/21, 04/13/22, 05/11/22, 03/08/23	**APPROVAL DATE** March 8, 2023	**EFFECTIVE DATE** March 31, 2023	**COMMITTEE APPROVAL DATES** 11/13/19, 12/11/19, 05/13/20, 04/14/21, 11/15/21, 04/13/22, 05/11/22, 03/08/23
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 Balversa (erdafitinib) 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. Urothelial Carcinoma

1. 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:
    a. Documented FGFR3 mutation or FGFR2/3 fusion in tumor tissue (using the FDA approved companion diagnostic: therascreen or another appropriate genomic test) AND
    b. Member has had disease progression on/intolerance to platinum-based chemotherapy AND disease progression on/intolerance to Immune Check Point Inhibitor therapy (e.g., avelumab, nivolumab, or pembrolizumab) OR
    c. If ineligible for platinum containing therapy, the member had disease progression on/intolerance to Immune Check Point Inhibitor therapy (e.g., atezolizumab, avelumab, nivolumab, or pembrolizumab).

III. EXCLUSION CRITERIA

A. Disease progression while receiving Balversa (erdafitinib).

B. Lack of test results confirming a FGFR 3 or FGFR 2 genomic alteration in the tumor tissue.

C. Concurrent use with other chemotherapy, targeted therapies, or definitive radiotherapy.

D. Dosing exceeds single dose limit of Balversa (erdafitinib) 9 mg.

E. Treatment exceeds the maximum limit of 60 (4 mg), 30 (5mg), 90 (3mg) tablets/month.

F. Investigational use of Balversa (erdafitinib) 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. Loriot Y, et al. BLC2001 Clinical Trial. Erdafitinib in Locally Advanced or Metastatic Urothelial Carcinoma. N Engl J Med. 2019 Jul 25;381(4):338-348.

B. Balversa prescribing information. Janssen Products, LP. Horsham, PA 2023.

C. Clinical Pharmacology Elsevier Gold Standard. 2023.

D. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2023.

E. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.

F. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2023.

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.

I. NCQA UM 2023 Standards and Elements.

New Century Health