MEDICAL MUTUAL®

Drug Policy

Policy:	Balversa (erdafitinib)	Annual Review Date: 11/18/2021 Last Revised Date: 11/18/2021

OVERVIEW

Balversa is an oral fibroblast growth factor receptor (FGFR) inhibitor. Balversa is for targeted therapy. Patients must have an FDA-approved diagnostic test in order to identify the genetic alterations prior to starting therapy. The FDA has approved Qiagen's therascreen FGFR RGQ RT-PCR Kit for use as a companion test.

POLICY STATEMENT

This policy involves the use of Balversa. Prior authorization is recommended for pharmacy benefit coverage of Balversa. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Balversa as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Balversa be prescribed by or in consultation with an oncologist or hematologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Balversa is recommended in those who meet the following criteria:

1. **Urothelial Carcinoma, Locally Advanced, Metastatic, or Recurrent**
   Criteria. *Patient must meet the following criteria (A, B, C, and D):*
   - **A.** Patient is 18 years or older; AND
   - **B.** Disease has progressed during or following platinum-containing chemotherapy (i.e. cisplatin, oxaliplatin), including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy; AND
   - C. Patient has a susceptible genetic alteration in FGFR2 or FGFR3, as detected by an FDA-approved test; AND
   - D. Balversa will be used as a single agent.

2. **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
   Criteria. *Prescriber will provide specific diagnosis for documentation. Approve*

3. Patient has been started on Balversa
Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Balversa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Balversa™ tablets [prescribing information]. Horsham, PA: Janssen Pharmaceuticals; April 2020.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (Version 4.2019 – April 23, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed 19 November 2019.
3. The NCCN Drugs and Biologics Compendium. © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on 17 November 2021. Search term: erdafitinib.
4. Erdaftinib. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 4 October 2021. Accessed on 17 November 2021.