

Balversa (erdafitinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Balversa (erdafitinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Balversa (erdafitinib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of locally advanced or metastatic urothelial cancer and the following are met (Label, NCCN 2A):
 - A. Individual has confirmed disease susceptible to FGFR3 genetic alterations; **AND**
 - B. Individual is using in one of the following ways:
 1. Individual has progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy; **OR**
 2. As subsequent-line systemic therapy if individual has progressed on a checkpoint inhibitor and platinum-based therapy (Label, NCCN 2A); **OR**
 3. As subsequent-line systemic therapy if individual has progressed on first-line platinum-containing chemotherapy followed by avelumab maintenance therapy (NCCN 2A);
- AND**
- C. Individual is using as a single agent.

Key References:

1. Balversa [Package Insert]. Horsham, PA. Janssen Pharmaceutical Companies.; 2019. Updated 1/2024.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed on December 28, 2023.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
6. Loriot Y, Necchi A, Park SH, et.al. Erdafitinib in Locally Advanced or Metastatic Urothelial Carcinoma. N Engl J Med 2019; 381: 338-348.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on December 28, 2023.
 - a. Bladder Cancer. V3.2023. Revised May 25, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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