

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 recurrent or metastatic urothelial cancer and the following are met (Label, NCCN 1, 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 1, 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;

OR

- II. Individual has a diagnosis of metastatic Non-Small Cell Lung Cancer (NSCLC) (NCCN 2A); **AND**

A. Individual has confirmed disease susceptible to FGFR3 genetic alterations;

OR

- III. Individual has a diagnosis of locally advanced or metastatic pancreatic adenocarcinoma (NCCN 2A); **AND**

A. Individual has confirmed disease susceptible to FGFR3 genetic alterations; **AND**

B. Individual is using as subsequent therapy or resection as a single agent.

Key References:

1. Balversa [Package Insert]. Horsham, PA. Janssen Pharmaceutical Companies.; 2019. Updated 1/2024.
2. 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, 2024.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
5. Loriot Y, Necchi A, Park SH, et.al. Erdafitinib in Locally Advanced or Metastatic Urothelial Carcinoma. N Engl J Med 2019; 381: 338-348.

6. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 17, 2025.
- a. Bladder Cancer. V6.2024. Revised January 17, 2025.
 - b. Head and Neck Cancers. V2.2025. Revised January 17, 2025.
 - c. Non-small Cell Lung Cancer. V3.2025. Revised January 14, 2025.
 - d. Pancreatic Adenocarcinoma. V1.2025. Revised December 20, 2024.

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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