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:
   A. Individual has confirmed disease susceptible to FGFR3 or FGFR2 genetic alterations; **AND**
   B. 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; **AND**
   C. Individual is using as a single agent.

Key References:

1. Balversa [Package Insert]. Horsham, PA. Janssen Pharmaceutical Companies.; 2022.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. 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 30, 2022.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; 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™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 20, 2022.
   a. Bladder Cancer. V3.2022. Revised December 21, 2022.