PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Balversa Prior Authorization Policy
- Balversa® (erdafitinib tablets – Janssen Pharmaceuticals)

REVIEW DATE: 04/07/2021

OVERVIEW

Balversa, a kinase inhibitor, is indicated for the treatment of adult patients with **locally advanced or metastatic urothelial carcinoma** that has susceptible fibroblast growth factor receptor (FGFR)3 or FGFR2 genetic alterations, and progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of adjuvant or neoadjuvant platinum-containing chemotherapy.[1]

Patients are selected for treatment with Balversa based on the presence of susceptible FGFR genetic alterations in tumor specimens detected by an FDA-approved companion diagnostic.[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) clinical practice guidelines for bladder cancer (version 2.2021 – March 22, 2021) recommend Balversa as a single agent, post-platinum or –checkpoint inhibitor therapy in patients with bladder cancer, upper genitourinary tract tumors, primary carcinoma of the urethra, and urothelial carcinoma of the prostate with susceptible FGFR2 or FGFR3 genetic alterations.[2,3]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Balversa. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Urothelial Carcinoma.** Approve for 3 years if the patient meets the following criteria (A, B, and C):
   - **A)** Patient has locally advanced or metastatic disease; AND
   - **B)** Patient has susceptible fibroblast growth factor receptor 3 or fibroblast growth factor receptor 2 genetic alterations; AND
   - **C)** Patient has progressed during or following prior platinum-containing chemotherapy (i.e., cisplatin, oxaliplatin) or checkpoint inhibitor therapy.
     Note: Checkpoint inhibitors include: Keytruda® (pembrolizumab injection for intravenous use), Opdivo® (nivolumab injection for intravenous use), Tecentriq® (atezolizumab injection for intravenous use), Imfinzi® (durvalumab injection for intravenous use), and Bavencio® (avelumab injection for intravenous use).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Balversa is not recommended in the following situations:

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

REFERENCES

1. Balversa® tablets [prescribing information]. Horsham, PA: Janssen Pharmaceuticals; April 2020.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 2.2021 – March 22, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed March 24, 2021.
3. The NCCN Drugs and Biologics Compendium. © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 24, 2021. Search term: erdafitinib.