PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 04/10/2024

OVERVIEW

Balversa, a kinase inhibitor, is indicated for the treatment of **locally advanced or metastatic urothelial carcinoma** in adults with susceptible fibroblast growth factor receptor (FGFR)3 genetic alterations whose disease has progressed on or after at least one line of prior systemic therapy.[1]

Select patients for therapy based on an FDA-approved companion diagnostic for Balversa.[1]

Limitation of Use: Balversa is not recommended for the treatment of patients who are eligible for and have not received prior programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor therapy.[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) clinical practice guidelines for bladder cancer (version 2.2024 – March 27, 2024) 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 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 Indication

1. **Urothelial Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient has locally advanced or metastatic disease; AND
   - **B)** Patient has susceptible fibroblast growth factor receptor 3 genetic alterations; AND
   - **C)** Patient has progressed during or following prior platinum-containing chemotherapy, other chemotherapy, or checkpoint inhibitor therapy.
     Note: Examples of platinum-containing chemotherapy include cisplatin and carboplatin. Examples of other chemotherapy include gemcitabine, paclitaxel, and doxorubicin. Examples of checkpoint inhibitors include: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Imfinzi (durvalumab intravenous infusion), and Bavencio (avelumab intravenous infusion).

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; January 2024.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 2.2024 – March 27, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 1, 2024.
3. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 1, 2024. Search term: erdafitinib.