

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

04/10/2024

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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.