

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Balversa Prior Authorization Policy

- Balversa® (erdafitinib tablets – Janssen)

**REVIEW DATE:** 03/26/2025

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### 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.<sup>1</sup>

Select patients for therapy based on an FDA-approved companion diagnostic for Balversa.<sup>1</sup>

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.<sup>1</sup>

### Guidelines

Balversa is addressed in National Comprehensive Cancer Network (NCCN) guidelines:

- **Bladder Cancer:** Guidelines (version 7.2024 – February 28, 2025) recommend Balversa for second-line and subsequent treatment as a single agent, post-platinum, other chemotherapy, 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.<sup>2,3</sup>
- **Pancreatic Adenocarcinoma:** Guidelines (version 2.2025 – February 3, 2025) recommend Balversa as a single agent for subsequent therapy of locally advanced, recurrent or metastatic disease with FGFR genetic alterations (category 2A).<sup>4</sup>
- **Non-Small Cell Lung Cancer:** Guidelines (version 3.2025 – January 14, 2025) recommend Balversa for FGFR alterations in those with metastatic NSCLC (category 2A).<sup>5</sup>

### 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 one of the following criteria:

#### FDA-Approved Indication

1. **Urothelial Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
  - A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has locally advanced or metastatic disease; AND
  - C) Patient has susceptible fibroblast growth factor receptor (FGFR)3 genetic alterations; AND

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- D)** Patient has progressed during or following prior platinum-containing chemotherapy, other chemotherapy, or checkpoint inhibitor therapy; AND

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).

- E)** Medication is used as a single agent.

#### **Other Uses with Supportive Evidence.**

- 2. Pancreatic Adenocarcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):

- A)** Patient is  $\geq 18$  years of age; AND
- B)** Patient has a fibroblast growth factor receptor (FGFR) genetic alterations; AND
- C)** Patient has locally advanced, recurrent or metastatic disease; AND
- D)** Medication is used for subsequent therapy; AND
- E)** Medication is used as a single agent.

- 3. Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):

- A)** Patient is  $\geq 18$  years of age; AND
- B)** Patient has metastatic disease; AND
- C)** Patient has fibroblast growth factor receptor (FGFR) alterations.

#### **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; October 2024.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 7.2024 – February 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed March 11, 2025.
3. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on March 11, 2025. Search term: erdafitinib.
4. The NCCN Pancreatic Adenocarcinoma Clinical Practice Guidelines in Oncology (version 2.2025 – February 3, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed March 11, 2025.
5. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – January 14, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed March 11, 2025.