VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 04/12/2023

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 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 1.2023 – February 9, 2023) 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 Indication

1. **Urothelial Carcinoma.** Approve for 1 year 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 or checkpoint inhibitor therapy.
     Note: Examples of platinum-containing chemotherapy include cisplatin and carboplatin. 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; March 2023.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – February 9, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 10, 2023.
3. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 10, 2023. Search term: erdafitinib.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Urothelial carcinoma:** Removed cisplatin and oxaliplatin from criteria and added "examples of platinum-containing chemotherapy include cisplatin and carboplatin" to a Note.	04/06/2022
Selected Revision	**Urothelial carcinoma:** Changed approval duration from 3 years to 1 year.	06/22/2022
Annual Revision	No criteria changes.	04/12/2023