PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 04/12/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

- **Balversa® (erdafitinib tablets – Janssen)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

- **Balversa® (erdafitinib tablets – Janssen)**

is(are) considered experimental, investigational or unproven for ANY other use(s).

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