PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 03/26/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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 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

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.[2,3]**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).[4]

- **Non-Small Cell Lung Cancer:** Guidelines (version 3.2025 – January 14, 2025) recommend Balversa for FGFR alterations in those with metastatic NSCLC (category 2A).[5]

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 ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 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
   - **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 ≥ 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 ≥ 18 years of age; AND
   B) Patient has metastatic disease; AND
   C) Patient has fibroblast growth factor receptor (FGFR) alterations.

CONDITIONS NOT COVERED

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

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

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	04/12/2023
Annual Revision	**Urothelial carcinoma.** Removed "or fibroblast growth factor receptor 2" from criterion "Patient has susceptible fibroblast growth factor receptor 3 genetic alterations". Added "other chemotherapy" to criterion "Patient has progressed during or following prior platinum-containing chemotherapy, other chemotherapy, or checkpoint inhibitor therapy". Added examples of other chemotherapy to Note.	04/10/2024
Annual Revision	**Urothelial Carcinoma.** Added patient is ≥ 18 years of age and medication is used as a single agent as new requirements. **Non-small Cell Lung Cancer.** Added new condition of approval. **Pancreatic Adenocarcinoma.** Added new condition of approval.	03/26/2025