Clinical Policy: Erdafitinib (Balversa)

Reference Number: CP.PHAR.423
Effective Date: 09.01.19
Last Review Date: 08.24
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Erdafitinib (Balversa®) is a fibroblast growth factor receptor (FGFR) kinase inhibitor.

FDA Approved Indication(s)

Balversa is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC) with susceptible FGFR3 genetic alterations whose disease has progressed on or after at least one line of prior systemic therapy.

Select patients for therapy based on an FDA-approved companion diagnostic for Balversa.

Limitations(s) of use: Balversa is not recommended for the treatment of patients who are eligible for and have not received prior programmed cell death protein 1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor therapy.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Balversa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Urothelial Carcinoma (must meet all)**:**

1. Diagnosis of recurrent, locally advanced, or metastatic UC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Presence of susceptible FGFR3 genetic alterations (*see Appendix D*);
5. Prescribed as single-agent therapy;
6. Prescribed as subsequent therapy following platinum-containing chemotherapy (e.g., cisplatin, carboplatin), PD-1 or PD-L1 inhibitor therapy (e.g., Keytruda®), or other chemotherapy (*see Appendix B*);
   **Prior authorization may be required for chemotherapy and Keytruda*
7. For Balversa requests, member must use erdafitinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
8. Request meets one of the following (a or b):
   a. Dose does not exceed both of the following (i and ii):
      i. 9 mg per day;

ii. 3 tablets per day;
b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Urothelial Carcinoma (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Balversa for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Prescribed as single-agent therapy;
4. For Balversa requests, member must use erdafitinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed both of the following (i and ii):
      i. 9 mg per day;
      ii. 3 tablets per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
FGFR: fibroblast growth factor receptor
NCCN: National Comprehensive Cancer Network
PD-1: programmed cell death protein 1
PD-L1: programmed death-ligand
UC: urothelial carcinoma

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
carboplatin	Varies	Varies
cisplatin	Varies	Varies
gemcitabine	Varies	Varies
ddMVAC (dose dense methotrexate, vinblastine, doxorubicin, cisplatin)		
PD-1 inhibitors		
Keytruda (pembrolizumab)	UC (labeled use for locally advanced or metastatic disease): 200 mg IV once every 3 weeks for up to 24 months	200 mg/3 weeks
Opdivo® (nivolumab)	Varies	360 mg/3 weeks

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information
- The presence of FGFR3 genetic alterations should be confirmed prior to initiation of treatment with Balversa. Patients with at least 1 of the following genetic alterations: FGFR3 gene mutations (R248C, S249C, G370C, Y373C) or FGFR3 gene fusions (FGFR3-TACC3, FGFR3-BAIAP2L1) were studied in the confirmatory clinical study for approval.
- Information on FDA-approved tests for the detection of FGFR3 genetic alterations in UC is available at: http://www.fda.gov/CompanionDiagnostics.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
UC	8 mg (two 4 mg tablets) PO QD with a dose increase to 9 mg (three 3 mg tablets) QD if serum phosphate level is < 9.0 mg/dL at 14-21 days and there are no ocular disorders or Grade 2 or greater adverse reactions	9 mg/day

VI. Product Availability
Tablets: 3 mg, 4 mg, 5 mg

VII. References
1. Balversa Prescribing Information. Horsham, PA: Janssen Pharmaceutical Companies; February 2024. Available at: www.balversa.com. Accessed May 6, 2024.
2. Loriot Y, Matsubara N, Park SH, et al; THOR cohort 1 investigators. erdafitinib or chemotherapy in advanced or metastatic urothelial carcinoma. *N Engl J Med*. 2023 Nov 23;389(21):1961-1971. doi: 10.1056/NEJMoa2308849.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 22, 2024.
4. National Comprehensive Cancer Network. Bladder Cancer Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed May 22, 2024.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2020 annual review: recurrent disease and checkpoint inhibitor prior therapy option added per NCCN; references reviewed and updated.	05.12.20	08.20
3Q 2021 annual review: added gemcitabine-containing chemotherapy as a prior therapy option per NCCN; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	03.17.21	08.21

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less	01.20.22	05.22
3Q 2022 annual review: no significant changes, references reviewed and updated.	04.26.22	08.22
Template changes applied to other diagnoses/indications.	09.23.22	
3Q 2023 annual review: added monotherapy requirement per NCCN and New Century Health; references reviewed and updated.	04.13.23	08.23
RT4: updated FDA labeled indication for UC to remove accelerated approval language and include limitation of use; removed coverage of patients with FGFR2 genetic alterations to be consistent with revised FDA indication and NCCN recommendations; added initial and continued therapy criteria to use generic erdafitinib if available.	01.30.24	
3Q 2024 annual review: updated "gemcitabine chemotherapy" to "other chemotherapy" for previous therapies to align with NCCN Compendium; revised Commercial approval durations to align with Medicaid and HIM for this oral oncology agent; references reviewed and updated.	05.06.24	08.24

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a

discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.