Clinical Policy: Erdafitinib (Balversa)

Reference Number: ERX.SPA.333
Effective Date: 09.01.19
Last Review Date: 08.21
Line of Business: Commercial, 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 that has:

- susceptible FGFR3 or FGFR2 genetic alterations and
- progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

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

This indication is approved under accelerated approval based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 urothelial carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Presence of susceptible FGFR3 or FGFR2 genetic alterations (*see Appendix D*);
5. Prescribed as subsequent therapy following platinum-containing chemotherapy (e.g., cisplatin, carboplatin), checkpoint inhibitor therapy (e.g., Tecentriq®, Keytruda®), or gemcitabine-containing chemotherapy (*see Appendix B*);
   **Prior authorization may be required for chemotherapy, Tecentriq, and Keytruda*
6. Request meets one of the following (a or b):
   a. Dose does not exceed 9 mg (3 tablets) per day;
   b. Dose is supported by practice guideline 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:
Commercial – Length of Benefit
Medicaid – 6 months

B. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Urothelial Carcinoma (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, 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. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 9 mg (3 tablets) per day;
   b. New dose is supported by practice guideline 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:
Commercial – Length of Benefit
Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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

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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
carboplatin	Varies	Varies
cisplatin	Varies	Varies
Tecentriq (atezolizumab)	UC (labeled use for locally advanced or metastatic disease): 840 mg IV once every 2 weeks or 1,200 mg once every 3 weeks or 1,680 mg once every 4 weeks.	Varies
Keytruda (pembrolizumab)	UC (labeled use for locally advanced or metastatic disease): 200 mg IV once every 3 weeks until disease progression, unacceptable toxicity, or (in patients without disease progression) for up to 24 months.	200 mg/3 weeks
gemcitabine	Varies	Varies

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 FGFR 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 FGFR gene fusions (FGFR3-TACC3, FGFR3-BAIAP2L1, FGFR2-BICC1, FGFR2-CASP7) were included in the clinical study for approval.
- Information on FDA-approved tests for the detection of FGFR genetic alterations in urothelial carcinoma is available at: http://www.fda.gov/CompanionDiagnostics.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Urothelial carcinoma	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 < 5.5 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; April 2020. Available at: www.balversa.com. Accessed March 17, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed March 16, 2021.
3. National Comprehensive Cancer Network. Bladder Cancer Version 3.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed May 3, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	05.07.19	08.19
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 reviewed and updated.	03.17.21	08.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.