Clinical Policy Title:	erdafitinib
Policy Number:	RxA.23
Drug(s) Applied:	Balversa®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

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

Erdafitinib is prescribed based on the presence of FGFR genetic alterations confirmed by an FDA-approved test.

This indication was 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
erdafitinib (Balversa®)	Urothelial carcinoma	8 mg (two 4 mg tablets) PO once daily with a dose increase to 9 mg (three 3 mg tablets) once daily if serum phosphate level is less than 5.5 mg/dL at 14-21 days* and there are no ocular disorders or any other ≥Grade 2 adverse reactions	9 mg/day

*Monitor serum phosphate level at baseline, at 14-21 days after initiation of therapy and then monthly or as clinically necessary.

Dosage Forms

- Tablets: 3 mg, 4 mg, 5 mg

Clinical Policy

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

I. Initial Approval Criteria

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

1. Diagnosis of locally advanced or metastatic urothelial carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age 18 years or older;
4. Presence of susceptible FGFR3 or FGFR2 genetic alterations (*see Appendix D*);
5. Disease has progressed during or following at least one line of platinum-containing chemotherapy;*
   **Prior authorization may be required for platinum-containing chemotherapy*
6. Prescribed as monotherapy;
7. 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 guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance, or documentation supports that member is currently receiving erdafitinib for a covered indication and has received this drug for at least 30 days;
2. Member is responding positively to therapy (e.g., no disease progression);
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 guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FGFR: fibroblast growth factor receptor
NCCN: National Comprehensive Cancer Network
PO: by mouth

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
carboplatin	Varies	Varies
cisplatin	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

- Contraindication(s):

- None reported.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- The presence of FGFR genetic alterations should be confirmed prior to initiation of erdafitinib. Patients with at least one 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.
- NCCN Compendium lists erdafitinib as a category 2A recommendation as second-line therapy post-platinum therapy for locally advanced or metastatic disease upper genitourinary tract, bladder, and urothelial carcinoma of the prostate with susceptible FGFR3 or FGFR2 genetic alterations.

References

1. Balversa® Prescribing Information. Horsham, PA: Janssen Products, LP; April 2020. Available at: www.balversa.com. Accessed January 27, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed January 27, 2021.
3. Erdafitinib. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI; 2021. Accessed with subscription at: http://www.micromedexsolutions.com. Accessed January 27, 2021.
4. National Comprehensive Cancer Network. Bladder Cancer Version 6.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed January 27, 2021.
5. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2020. Accessed with subscription at: http://www.clinicalkey.com. Updated January 14, 2020. Accessed January 27, 2021.
6. Erdafitinib, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed January 27, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy reviewed & updated.	04/29/2020	05/20/2020
Policy was reviewed: 1. Policy title table was updated: Clinical Policy Title was updated to 'erdafitinib', Drug(s) Applied was updated to 'Balversa®', Line of business policy applies was updated to All lines of business. 2. Continued therapy approval criteria II.A.1 rephrased to "Currently receiving medication that has been authorized by RxAdvance…".	01/27/2021	03/09/2021

3. Appendix B header verbiage was updated to “Below are suggested therapeutic alternatives based...” 4. References were updated.		