Reference number(s)
2965-A

SPECIALTY GUIDELINE MANAGEMENT

BALVERSA (erdafitinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Balversa is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (mUC) that has:
1. susceptible FGFR3 or FGFR2 genetic alterations, and
2. progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

B. Compendial Use
Urothelial Carcinoma
1. Bladder cancer
2. Primary carcinoma of the urethra
3. Upper genitourinary (GU) tract tumors
4. Urothelial carcinoma of the prostate

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Fibroblast growth factor receptor 3 (FGFR3) or Fibroblast growth factor receptor 2 (FGFR2) mutation status

III. CRITERIA FOR INITIAL APPROVAL

A. Urothelial carcinoma – Bladder cancer
Authorization of 12 months may be granted for treatment of bladder cancer with FGFR3 or FGFR2 genetic alterations as a single agent when used as subsequent therapy for any of the following:
1. Stage II disease if tumor is present following reassessment of tumor status 2-3 months after primary treatment with bladder preserving concurrent chemoradiotherapy
2. Locally advanced or metastatic disease
3. Metastatic or local recurrence post-cystectomy
4. Muscle invasive local recurrence or persistent disease in a preserved bladder

B. Urothelial Carcinoma – Primary Carcinoma of the Urethra

© 2021 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Authorization of 12 months may be granted for the treatment of primary carcinoma of the urethra with FGFR3 or FGFR2 genetic alterations as a single agent when used as subsequent therapy for locally advanced, recurrent or metastatic disease.

C. Urothelial Carcinoma – Upper Genitourinary (GU) Tract Tumors
Authorization of 12 months may be granted for the treatment of upper genitourinary (GU) tract tumors with FGFR3 or FGFR2 genetic alterations as a single agent when used as subsequent therapy for locally advanced or metastatic disease.

D. Urothelial Carcinoma – Urothelial Carcinoma of the Prostate
Authorization of 12 months may be granted for the treatment of urothelial carcinoma of the prostate with FGFR3 or FGFR2 genetic alterations as a single agent when used as subsequent therapy for locally advanced or metastatic disease.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Balversa [package insert]. Horsham, PA: Janssen Products, LP; April 2020.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 6, 2021.

© 2021 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.