

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) with susceptible FGFR3 genetic alterations whose disease has progressed on or after at least one line of prior systemic therapy.

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) 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 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 concurrent bladder preserving chemoradiotherapy, and maximal transurethral resection of bladder tumor (TURBT)
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**

Authorization of 12 months may be granted for the treatment of primary carcinoma of the urethra with FGFR3 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 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 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; February 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed June 12, 2024.