Reference number(s)
2965-A

Specialty Guideline Management
Balversa

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Balversa	erdafitinib

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.

FDA-approved Indications[1]

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.

Compendial Uses[2]

Urothelial Carcinoma

- Bladder cancer
- Primary carcinoma of the urethra
- Upper genitourinary (GU) tract tumors
- Urothelial carcinoma of the prostate

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

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Pancreatic Carcinoma

Biliary Tract Cancer

Non-Small Cell Lung Cancer

Documentation

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

Coverage Criteria

Urothelial carcinoma – Bladder cancer[1,2]

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:

- 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)
- Locally advanced disease
- Metastatic disease
- Local recurrence
- Persistent disease in a preserved bladder

Urothelial Carcinoma – Primary Carcinoma of the Urethra[1,2]

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.

Urothelial Carcinoma – Upper Genitourinary (GU) Tract Tumors[1,2]

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.

Urothelial Carcinoma – Urothelial Carcinoma of the Prostate[1,2]

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.

Pancreatic Carcinoma[2]

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

Biliary Tract Cancers (Cholangiocarcinoma)[2]

Authorization of 12 months may be granted for the treatment of intrahepatic or extrahepatic cholangiocarcinoma with FGFR2 fusions or rearrangements as a single agent when used as subsequent therapy for unresectable, resected gross residual (R2), or metastatic disease.

Non-Small Cell Lung Cancer[2]

Authorization of 12 months may be granted for the treatment of metastatic non-small cell lung cancer with FGFR alterations.

Continuation of Therapy

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

References

1. Balversa [package insert]. Horsham, PA: Janssen Products, LP; October 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 22, 2025.