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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	April 26, 2019
Subject:	Balversa	**Page:**	1 of 5

Last Review Date: March 7, 2025

Balversa

Description

Balversa (erdafitinib)

Background
Balversa (erdafitinib) is a kinase inhibitor that binds to and inhibits enzymatic activity of FGFR1, FGFR2, FGFR3, and FGFR4. Balversa inhibits FGFR phosphorylation and signaling and decreased cell viability in cell lines expressing FGFR genetic alterations, including point mutations, amplifications, and fusions. Balversa demonstrates antitumor activity in FGFR-expressing cell lines and xenograft models derived from tumor types, including bladder cancer (1).

Regulatory Status
FDA-approved indication: Balversa is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma with susceptible FGFR3 genetic alterations whose disease has progressed on or after at least one line of prior systemic therapy (1).

Limitations of Use: (1)
Balversa is not recommended for the treatment of patients who are eligible for and have not received prior PD-1 or PD-L1 inhibitor therapy.

Balversa can cause ocular disorders, including central serous retinopathy/retinal pigment epithelial detachment resulting in visual field defect. Patients should receive dry eye prophylaxis with ocular demulcents as needed. Monthly ophthalmological examinations should be

performed monthly during the first 4 months of treatment and every 3 months afterwards, and urgently at any time for visual symptoms (1).

Increases in phosphate levels are a pharmacodynamics effect of Balversa. Patients should be monitored for hyperphosphatemia and the dose should be modified when required by the guidelines (1).

Balversa can cause fetal harm when administered to a pregnant woman. Pregnant women should be advised of the potential risk to the fetus. Female patients of reproductive potential should be advised to use effective contraception during treatment with Balversa and for one month after the last dose. Male patients with female partners of reproductive potential should be advised to use effective contraception during treatment with Balversa and for one month after the last dose (1).

The safety and efficacy of Balversa in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Balversa may be considered **medically necessary** if the conditions indicated below are met.

Balversa may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Locally advanced or metastatic urothelial carcinoma

AND ALL of the following:

a. Susceptible FGFR3 genetic alterations
b. Disease progression on or after at least one line of prior systemic therapy
c. Prescriber agrees to monitor phosphate levels monthly for hyperphosphatemia
d. Prescriber agrees to monitor for ocular disorders
e. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Balversa and for one month after the last dose
f. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Balversa and for one month after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Locally advanced or metastatic urothelial carcinoma

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor phosphate levels monthly for hyperphosphatemia
c. Prescriber agrees to monitor for ocular disorders
d. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Balversa and for one month after the last dose
e. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Balversa and for one month after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Duration 12 months

Rationale

Summary

Balversa (erdafitinib) is a kinase inhibitor that binds to and inhibits enzymatic activity of FGFR1, FGFR2, FGFR3, and FGFR4. Balversa inhibits FGFR phosphorylation and signaling and decreased cell viability in cell lines expressing FGFR genetic alterations, including point mutations, amplifications, and fusions. Balversa demonstrates antitumor activity in FGFR-expressing cell lines and xenograft models derived from tumor types, including bladder cancer. The safety and efficacy of Balversa in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Balversa while maintaining optimal therapeutic outcomes.

References

1. Balversa [package insert]. Horsham, PA: Janssen Products, LP; October 2024.
2. NCCN Drugs & Biologics Compendium® Erdafitinib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 21, 2025.

Policy History

Date	Action
April 2019	Addition to PA
June 2019	Annual review
September 2019	Annual review
June 2020	Annual review and reference update
March 2021	Annual review
March 2022	Annual review and reference update

March 2023	Annual review and reference update
December 2023	Annual review and reference update
February 2024	Per PI update, removed option to have FGFR2 genetic alterations. Also changed initiation requirement so patient must have disease progression on or after one line of prior systemic therapy. Modified contraception requirements
March 2024	Annual review and reference update
September 2024	Annual review and reference update
December 2024	Annual review and reference update
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.