BlueCross BlueShield Federal Employee Program

BALVERSA
(erdafitinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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.