
5.21.127

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Antineoplastic Agents	Original Policy Date:	April 26, 2019
Subject:	Balversa	Page:	1 of 4

Last Review Date: March 12, 2021

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 that has: (1)

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.

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).

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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** in patients 18 years of age or older who have locally advanced or metastatic urothelial carcinoma and if the conditions indicated below are met.

Balversa is considered **investigational** in patients less than 18 years of age and 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

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AND ALL of the following:

- a. Susceptible FGFR3 or FGFR2 genetic alterations
- b. Disease progression during or following at least one line of prior platinum-containing chemotherapy
- c. Prescriber agrees to monitor phosphate levels monthly for hyperphosphatemia
- d. Prescriber agrees to monitor for ocular disorders
- e. Females of reproductive potential and males with female partners of reproductive potential: 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 toxicities
- b. Prescriber agrees to monitor phosphate levels monthly for hyperphosphatemia
- c. Prescriber agrees to monitor for ocular disorders
- d. Females of reproductive potential and males with female partners of reproductive potential: 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

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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; April 2020.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.