

Balversa (erdafitinib)
Effective 01/15/2021

Plan	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

BALVERSA™ is a prescription medicine used to treat adults with bladder cancer (urothelial cancer) that has spread or cannot be removed by surgery:

- Which has a certain type of abnormal fibroblast growth factor receptor (FGFR) gene, **and**
- Who have tried at least one other chemotherapy medicine that contains platinum, and it did not work or is no longer working

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are currently receiving treatment with Balversa excluding when the product is obtained as samples or via manufacturer’s patient assistance programs

OR

Authorization may be granted if prescriber provides documentation that the member meets **ALL** following criteria and documentation has been submitted:

1. Diagnosis of FGFR3 or FGFR2-mutated locally advanced or metastatic urothelial carcinoma
2. Prescriber is an oncologist
3. Appropriate dosing
4. Member has received prior treatment with platinum-containing chemotherapy or is ineligible for platinum-containing chemotherapy (see Appendix for Chemotherapy regimens)

Continuation of Therapy

Reauthorization requires physician documentation of the following:

1. Appropriate dosing based on phosphate levels (The dose should have been increased to 9 mg once daily if the serum phosphate level is <5.5 mg/dL and drug is tolerable 14 to 21 days after start of therapy on 8 mg once daily.



Limitations

1. Initial approvals will be granted for 3 months
2. Reauthorization requests, if appropriate, will be granted for an additional 12 months
3. The following quantity limits apply:

Balversa 3mg	84 tablets per 28 days
Balversa 4mg	56 tablets per 28 days
Balversa 5mg	28 tablets per 28 days

Appendix

Chemotherapy Regimens for Bladder Cancer (First-line Setting)

For first-line systemic therapy for locally advanced or metastatic bladder cancer, patients who are cisplatin eligible may receive the following preferred regimens:

- Gemcitabine and cisplatin
- Dose-dense combination of methotrexate, vinblastine, doxorubicin, and cisplatin (DDMVAC) with growth factor support.

Patients who are cisplatin ineligible may receive the following regimens:

- Preferred
 - Gemcitabine and carboplatin
 - Atezolizumab (only for patients whose tumors express PD-L1 or who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 expression)
 - Pembrolizumab (only for patients whose tumors express PD-L1 or who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 expression)
- Other recommended regimen
 - Gemcitabine
 - Gemcitabine and paclitaxel
- Useful under certain circumstances
 - Ifosfamide, doxorubicin, and gemcitabine (for patients with good kidney function and good performance status)

References

1. Balversa [package insert]. Horsham, PA: Janssen Products, LP.; April 2020.

Review History

10/9/2020: Created criteria to be in compliance with the Masshealth partial unified formulary requirements effective 1/1/21.

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