



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1284-5
Program	Prior Authorization/Notification
Medication	Balversa [®] (erdafitinib)
P&T Approval Date	6/2019, 5/2020, 5/2021, 5/2022, 5/2023
Effective Date	8/1/2023; Oxford only: 8/1/2023

1. Background:

Balversa[®] (erdafitinib) is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has susceptible FGFR3 or FGFR2 genetic alterations and progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

This indication is approved under accelerated approval based on tumor response rate. Continued approval for this medication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria^a:

A. Patients less than 19 years of age

1. **Balversa** will be approved based on the following criterion:

- a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. Urothelial Carcinoma

1. **Initial Authorization**

- a. **Balversa** will be approved based on **ALL** of the following criteria:

- (1) Diagnosis of urothelial carcinoma

-AND-

- (2) **One** of the following:

- (a) Locally advanced
- (b) Metastatic

-AND-

- (3) Patient has fibroblast growth factor receptor (FGFR) 3 or FGFR2 genetic alterations

-AND-

- (4) Patient has progressed during or following at least one line of prior chemotherapy or immunotherapy, or within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy

Authorization will be issued for 12 months.

2. Reauthorization

- a. **Balversa** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on **Balversa** therapy.

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Balversa [package insert]. Horsham, PA: Janssen Products, LP. January 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 23, 2023.

Program	Prior Authorization/Notification - Balversa
Change Control	
6/2019	New program.
5/2020	Annual review. Updated reference.
5/2021	Annual review. Updated references.
5/2022	Annual review. Updated references.
5/2023	Annual review with no changes to coverage criteria. Added state mandate footnote and updated references.