UnitedHealthcare Community Plan

# Clinical Pharmacy Program Guidelines for Balversa

| | |
|---|---|
| Program | Prior Authorization |
| Medication | Balversa™ (erdafitinib) |
| Markets in Scope | Arizona, Hawaii, Florida-CHIP, Maryland, New Jersey, Nevada, New York, New York EPP, Ohio, Pennsylvania, Rhode Island, California |
| Issue Date | 6/2019 |
| Pharmacy and Therapeutics Approval Date | 6/2019 |
| Effective Date | 8/2019 |

## 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.

Patients are selected for therapy based on an FDA-approved companion diagnostic for Balversa.

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.

## 2. Coverage Criteria:

**A. 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.**

**B. NCCN Recommended Regimens**

**1. Initial Authorization**

a. **Balversa** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

**Authorization will be issued for 12 months.**

**2. Reauthorization**

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

(1) Documentation of positive clinical response to Balversa therapy

**Authorization will be issued for 12 months.**

UnitedHealthcare Community Plan

**3. References:**

1. Balversa [package insert]. Horsham, PA: Janssen Products, LP. April 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed May 20, 2019.

| Program | Prior Authorization |
|---|---|
| **Change Control** | |
| Date | Change |
| 6/2019 | New program. |