UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1284-7
Program	Prior Authorization/Notification
Medication	Balversa® (erdafitinib)
P&T Approval Date	6/2019, 5/2020, 5/2021, 5/2022, 5/2023, 5/2024, 5/2025
Effective Date	8/1/2025

1. Background:

Balversa (erdafitinib) is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (mUC) with susceptible fibroblast growth factor receptor 3 (*FGFR3)* genetic alterations whose disease has progressed on or after at least one line of prior systemic therapy.

Limitations of Use:
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.

The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium also recommends the use of Balversa in the treatment of salivary gland tumor, pancreatic adenocarcinoma, non-small cell lung cancer, invasive breast cancer, and cholangiocarcinoma.

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) Disease is **one** of the following:

(a) Locally advanced
(b) Metastatic

-AND-

(3) Presence of *FGFR3* genetic alterations

-AND-

(4) Disease has progressed on or after at least **one** line of prior systemic therapy [e.g., platinum-based chemotherapy (e.g., cisplatin, carboplatin), immune checkpoint inhibitor (e.g., pembrolizumab, nivolumab, avelumab)]

-AND-

(5) **One** of the following:

(a) Patient has received prior systemic therapy containing an immune checkpoint inhibitor (e.g., pembrolizumab, nivolumab, avelumab)

OR-

(b) Patient is not eligible for immune checkpoint inhibitor therapy (e.g., pembrolizumab, nivolumab, avelumab)

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. Salivary Gland Tumor

1. **Initial Authorization**

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

(1) Diagnosis of salivary gland tumor

-AND-

(2) Disease is **one** of the following:

(a) Recurrent
(b) Unresectable
(c) Metastatic

-AND-

(3) Presence of *FGFR* genetic alterations

-AND-

(4) Disease has progressed on or after at least **one** line of prior systemic therapy [e.g., platinum-based chemotherapy (e.g., cisplatin, carboplatin)]

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.

D. Pancreatic Adenocarcinoma

1. **Initial Authorization**

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

(1) Diagnosis of pancreatic adenocarcinoma

-AND-

(2) Disease is **one** of the following:

(a) Locally advanced
(b) Metastatic
(c) Recurrent

-AND-

(3) Presence of *FGFR* genetic alterations

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.

E. Non-Small Cell Lung Cancer

1. **Initial Authorization**

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

(1) Diagnosis of non-small cell lung cancer

-AND-

(2) Disease is metastatic

-AND-

(3) Presence of *FGFR* genetic alterations

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.

F. Breast Cancer

1. **Initial Authorization**

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

(1) Diagnosis of invasive breast cancer

-AND-

(2) Disease is metastatic

-AND-

(3) Presence of *FGFR1-3* genetic alterations

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.

G. Cholangiocarcinoma

1. **Initial Authorization**

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

(1) Diagnosis of cholangiocarcinoma

-AND-

(2) Disease is **one** of the following:

(a) Unresectable
(b) Metastatic

-AND-

(3) Presence of *FGFR2* genetic alterations

-AND-

(4) Disease has progressed on or after **both** of the following:

(a) Lytgovi (futibatinib)
(b) Pemazyre (pemigatinib)

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.

H. 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; October 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 21, 2025

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.
5/2024	Annual review. Removed coverage for *FGFR2* genetic alterations. Added that first line of prior systemic therapy should contain an immune checkpoint inhibitor, if eligible. Updated background and references.
5/2025	Annual review. Added coverage criteria for salivary gland tumor, pancreatic adenocarcinoma, non-small cell lung cancer, breast cancer, and cholangiocarcinoma. Updated background and references.