## ERDAFITINIB

| Generic | Brand | HICL | GCN | Exception/Other |
|---|---|---|---|---|
| ERDAFITINIB | BALVERSA | 45687 | | |

### GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma (i.e., bladder cancer) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has susceptible Fibroblast growth factor receptor (FGFR3) or (FGFR2) genetic alterations as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test

   If yes, continue to #2.
   If no, do not approve.
   **DENIAL TEXT:** See the denial text at the end of the guideline.

2. Does the patient have **ONE** of the following criteria?
   - The patient has progressed during or following at least one line of prior platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
   - The patient has progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

   If yes, **approve for 12 months by GPID for all strengths as follows:**
   - **Balversa 3mg tablet (GPID 46189): #3 tablets per day.**
   - **Balversa 4mg tablet (GPID 46192): #2 tablets per day.**
   - **Balversa 5mg tablet (GPID 46193): #1 tablet per day.**

   If no, do not approve.
   **DENIAL TEXT:** The guideline named **ERDAFITINIB (Balversa)** requires a diagnosis of locally advanced or metastatic urothelial carcinoma (i.e., bladder cancer). In addition, the following criteria must be met:
   - The patient is 18 years of age or older
   - The patient has susceptible Fibroblast growth factor receptor (FGFR3) or (FGFR2) genetic alterations as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test
   - The patient meets ONE of the following:
     - The patient has progressed during or following at least one line of prior platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
     - The patient has progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

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## ERDAFITINIB

### RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Balversa.

### REFERENCES


- Balversa [Prescribing Information]. Horsham, PA: Janssen Products, LP; April 2019.


| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A
Commercial Effective: 05/06/19
Created: 04/19
Client Approval: 04/19
P&T Approval: 04/19