Clinical Policy Title:	erdafitinib
Policy Number:	RxA.023
Drug(s) Applied:	Balversa®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Urothelial Carcinoma (must meet all)**:**

1. Diagnosis of at least one of the following (a, b, c or d):
   a. Bladder Cancer;
   b. Locally advanced or metastatic urothelial carcinoma;
   c. Upper GU Tract Tumors;
   d. Primary Carcinoma of the Urethra;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Presence of susceptible FGFR3 or FGFR2 genetic alterations;
5. Disease has progressed during or following at least one line of platinum-containing chemotherapy;*
   *Prior authorization may be required for platinum-containing chemotherapy
6. Prescribed as monotherapy;
7. Request meets one of the following (a or b):
   a. Dose does not exceed 9 mg per day;
   b. Dose* is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Urothelial Carcinoma (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance, or documentation supports that member is currently receiving erdafitinib for a covered indication and has received this drug for at least 30 days;
2. Member is responding positively to therapy (e.g., no disease progression);
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 9 mg per day;
   b. New dose* is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

References

1. National Comprehensive Cancer Network. Bladder Cancer Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed September 28, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy reviewed & updated.	04/29/2020	05/20/2020
Policy was reviewed: 1. Policy title table was updated: Clinical Policy Title was updated to 'erdafitinib', Drug(s) Applied was updated to 'Balversa®', Line of business policy applies was updated to All lines of business. 2. Continued therapy approval criteria II.A.1 rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 3. References were updated.	01/27/2021	03/09/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of locally advanced or metastatic urothelial carcinoma to Diagnosis of at least one of the following: Locally advanced or metastatic urothelial carcinoma, Bladder Cancer, Upper GU Tract Tumors and Primary Carcinoma of the Urethra. 2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. References were reviewed and updated.	11/23/2021	01/17/2022
Policy was reviewed: 1. References were reviewed and updated.	09/28/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023