

| | |
|--------------------------------------------|-----------------------------------------|
| Clinical Policy Title: | erdafitinib |
| Policy Number: | RxA.023 |
| Drug(s) Applied: | Balversa® |
| Original Policy Date: | 02/07/2020 |
| Last Review Date: | 12/11/2025 |
| 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 locally advanced or metastatic urothelial carcinoma;
2. Presence of a susceptible FGFR3 genetic alteration;
3. Disease has progressed during or following at least one line of prior systemic therapy.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Urothelial Carcinoma (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 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 March 20,2025.

| 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: <ol style="list-style-type: none"> 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 | 01/27/2021 | 03/09/2021 |

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

| | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|------------|
| <p>medication that has been authorized by RxAdvance...".</p> <p>3. References were updated.</p> | | |
| <p>Policy was reviewed:</p> <ol style="list-style-type: none"> 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 |
| <p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. References were reviewed and updated. | 09/28/2022 | 01/17/2023 |
| <p>Policy was reviewed.</p> | 10/19/2023 | 10/19/2023 |
| <p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed prescriber criteria. 2. Removed age criteria. 3. Removed dosing criteria. 4. Updated continuation of therapy language. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. | 03/20/2025 | 04/10/2025 |
| <p>Policy reviewed.</p> | 12/11/2025 | 12/11/2025 |