

Clinical Policy Title:	belzutifan
Policy Number:	RxA.715
Drug(s) Applied:	Welireg™
Original Policy Date:	12/07/2021
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Von Hippel-Lindau Disease (must meet all):

1. Diagnosis of Von Hippel-Lindau disease confirmed by germline VHL alteration;
2. Therapy is required for one of the following conditions (a, b or c):
 - a. Associated renal cell carcinoma;
 - b. Associated pancreatic neuroendocrine tumors;
 - c. Associated CNS hemangioblastoma;
3. Member is not eligible for immediate surgery.

B. Advanced Renal Cell Carcinoma (must meet all):

1. Diagnosis of advanced renal cell carcinoma;
2. Prescribed following treatment with a PD-1 or PD-L1 inhibitor and a VEGF tyrosine kinase inhibitor.

C. Pheochromocytoma or Paraganglioma (PPGL) (must meet all):

1. Diagnosis of locally advanced, unresectable, or metastatic pheochromocytoma or paraganglioma.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications:

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. Welireg. Package Insert. : Merck Sharp & Dohme LLC; 2025. Available at: [welireg_pi.pdf](#). Accessed June, 2025.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	11/15/2021	12/07/2021
Policy was reviewed:	09/07/2022	10/19/2022

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.

1. Initial Approval Criteria I.A.4: Updated to remove criteria patient must have ECOG performance status of 0 or 1.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed prescriber criteria. 2. Removed age criteria. 3. Removed dosing criteria. 4. Updated approval duration verbiage. 5. Updated continuation of therapy language. 6. Removed reauthorization requirement for positive response to therapy. 7. New indication added.	03/24/2025	04/10/2025
Policy was reviewed: 1. New indication added: Diagnosis of pheochromocytoma or paraganglioma.	6/9/2025	6/9/2025
Policy reviewed.	12/11/2025	12/11/2025