

<b>Clinical Policy Title:</b>	belzutifan
<b>Policy Number:</b>	RxA.715
<b>Drug(s) Applied:</b>	Welireg™
<b>Original Policy Date:</b>	12/07/2021
<b>Last Review Date:</b>	10/19/2023
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Von Hippel-Lindau (VHL) disease (must meet all):

1. Patient must have diagnosis of Von Hippel-Lindau disease confirmed by germline VHL alteration and require therapy for one of the following conditions (a, b or c):
  - a. Associated renal cell carcinoma;
  - b. Associated pancreatic neuroendocrine tumors;
  - c. Associated CNS hemangioblastoma;
2. Prescribed by or in consultation with an oncologist;
3. Patient should not be eligible for immediate surgery;
4. Age ≥ 18 years;
5. Dose does not exceed 120 mg orally once daily.

#### Approval Duration

**Commercial:** 12 months

**Medicaid:** 12 months

### II. Continued Therapy Approval

#### A. Von Hippel-Lindau (VHL) disease (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, 120 mg administered orally once daily.

#### Approval Duration

**Commercial:** 12 months

**Medicaid:** 12 months

## References

Not Applicable

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	11/15/2021	12/07/2021
Policy was reviewed: 1. Initial Approval Criteria I.A.4:	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.

Updated to remove criteria patient must have ECOG performance status of 0 or 1.		
Policy was reviewed.	10/19/2023	10/19/2023