

Welireg (belzutifan)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Welireg (belzutifan)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Welireg (belzutifan) may be approved if the following criteria are met:

- I. Individual has a diagnosis of von Hippel-Lindau (VHL) disease (Label); **AND**
 - II. Diagnosis of VHL is confirmed by genetic testing demonstrating germline *VHL* alteration (NCT03401788); **AND**
 - III. Individual requires therapy for one of the following associated conditions:
 - A. Renal cell carcinoma (RCC); **OR**
 - B. Central Nervous System (CNS) hemangioblastomas; **OR**
 - C. Pancreatic neuroendocrine tumors (pNET);**AND**
 - IV. Individual does not require immediate surgery; **AND**
 - V. Individual is using Welireg (belzutifan) as monotherapy;
- OR**
- VI. Individual is diagnosed with advanced clear cell renal cell carcinoma (Label; NCT04195750); **AND**
 - VII. Individual has progressed on or after receiving a vascular endothelial growth factor therapy; **AND**
 - VIII. Individual has progressed on or after receiving one of the following:
 - A. Programmed death receptor-1 (PD-1) inhibitor; **OR**
 - B. Programmed death-ligand (PD-L1) inhibitor.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.

5. A study of belzutifan (MK-6482) versus everolimus in participants with advanced renal cell carcinoma (MK-6482-005). ClinicalTrials.gov identifier: NCT04195750. Updated August 1, 2022. Accessed January 12, 2024. <https://classic.clinicaltrials.gov/ct2/show/NCT04195750>
6. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 4, 2024.
 - a. Kidney Cancer. V2.2024. Revised January 3, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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