Reference number(s)
4898-A

Specialty Guideline Management Welireg

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Welireg	belzutifan

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

Von Hippel-Lindau (VHL) Disease

Adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery

Advanced Renal Cell Carcinoma (RCC)

Adult patients with advanced renal cell carcinoma (RCC) following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI)

Pheochromocytoma or Paraganglioma (PPGL)

Adult and pediatric patients 12 years and older with locally advanced, unresectable, or metastatic pheochromocytoma or paraganglioma (PPGL)

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: genetic testing confirming germline VHL alteration (where applicable)

Coverage Criteria

Von Hippel-Lindau (VHL) Disease[1-3]

Authorization of 12 months may be granted for treatment of VHL disease when all of the following criteria are met:

- Diagnosis has been confirmed by genetic testing
- Member does not require immediate surgery
- Requested medication is being used to treat any of the following VHL-associated tumors:
    - Renal cell carcinoma (RCC), as a single agent
    - Central nervous system (CNS) hemangioblastomas, as a single agent
    - Pancreatic neuroendocrine tumors (pNET)

Renal Cell Carcinoma[1,2]

Authorization of 12 months may be granted for treatment of renal cell carcinoma when all of the following criteria are met:

- Disease is advanced, stage IV, or relapsed
- Histology is clear cell
- The requested medication will be used as a single agent
- Member has been previously treated with a PD-1/PD-L1 inhibitor (e.g., nivolumab [Opdivo], pembrolizumab [Keytruda]) and a VEGF-TKI (e.g., axitinib [Inlyta], cabozantinib [Cabometyx], lenvatinib [Lenvima])

Pheochromocytoma or Paraganglioma[1,2]

Authorization of 12 months may be granted for treatment of pheochromocytoma or paraganglioma when all of the following criteria are met:

- Member is 12 years of age or older
- Disease is locally advanced, unresectable, or metastatic
- Tumors are secreting
- The requested medicatin will be used as a single agent

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Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Welireg [package insert]. Rahway, NJ: Merck Sharp & Dohme Corp.; May 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed August 19, 2025.
3. Jonasch E, Donskov F, Iliopoulos O, et al. Belzutifan for Renal Cell Carcinoma in von Hippel-Lindau Disease. N Engl J Med. 2021;385(22):2036-2046. doi:10.1056/NEJMoa2103425.