Reference number(s)
4898-A

SPECIALTY GUIDELINE MANAGEMENT

WELIREG (belzutifan)

POLICY

I. 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

A. 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
B. 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)

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

II. DOCUMENTATION

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

III. CRITERIA FOR INITIAL APPROVAL

A. Von Hippel-Lindau (VHL) Disease
Authorization of 12 months may be granted for treatment of VHL disease when all of the following criteria are met:
1. Diagnosis has been confirmed by genetic testing
2. Member does not require immediate surgery
3. Requested medication is being used to treat any of the following VHL-associated tumors:
   i. Renal cell carcinoma (RCC), as a single agent
   ii. Central nervous system (CNS) hemangioblastomas, as a single agent
   iii. Pancreatic neuroendocrine tumors (pNET)

B. Advanced Renal Cell Carcinoma
Authorization of 12 months may be granted for treatment of renal cell carcinoma when all of the following criteria are met:
A. Disease is advanced
B. 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])

IV. CONTINUATION OF THERAPY

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

V. REFERENCES

1. Welireg [package insert]. Rahway, NJ: Merck Sharp & Dohme Corp.; December 2023.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 2, 2024.
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