

belzutifan (WELIREG)

Diagnoses Considered for Coverage:

- Von Hippel-Lindau (VHL) disease in patients who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET)
- Advanced Renal Cell Carcinoma (RCC)

Coverage Criteria:

For diagnosis of von Hippel-Lindau (VHL) disease:

- Patient has VHL gene mutation, and
- One of the following VHL tumor types:
 - a. Renal cell carcinoma (RCC), or
 - b. Hemangioblastoma, or
 - c. Pancreatic neuroendocrine tumor (pNET), and
- One of the following:
 - o Being used as a single agent, or
 - o For pNET tumors: Being used as a single agent or concurrently with octreotide or lanreotide.

and

Dose does not exceed 120 mg per day.

For diagnosis of advanced renal cell carcinoma (RCC):

- Patient has been previously treated with:
 - a PD-1 (programmed death receptor-1) or PD-L1 (programmed death-ligand 1) inhibitor, and
 - a VEGF-TKI (vascular endothelial growth factor receptors-tyrosine kinase inhibitor)

and

- Being used as a single agent, and
- Dose does not exceed 120 mg per day

Coverage Duration: one year

REFERENCES:

- 1. Prescribing Information. Welireg. Merck Sharp & Dohme Corp. December 2023.
- 2. Welireg. National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium. February 2024. Available by subscription at: www.nccn.org.
- 1. National Comprehensive Cancer Network. Kidney Cancer (Version 2.2024 January 3, 2024). Available at www.nccn.org.

Effective Date: 02/28/2024