

Welireg (belzutifan)
Effective 03/01/2025

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

Welireg (belzutifan) is indicated for the treatment of 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.

Welireg is also indicated for advanced renal cell carcinoma in adults following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI).

Coverage Guidelines

Authorization may be reviewed for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted if the member meets all following diagnosis-specific criteria:

Von Hippel-Lindau (VHL) Disease

1. The member has a diagnosis of von Hippel-Lindau (VHL) disease
2. Therapy is required for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET)
3. The member does not require immediate surgery

Advanced Renal Cell Carcinoma

1. The member has a diagnosis of advanced renal cell carcinoma
2. The member has had an inadequate response or adverse reaction to one, or contraindication to both, of the following:
 - a. Programmed death receptor-1 (PD-1) inhibitor
 - b. Programmed death-ligand 1 (PD-L1) inhibitor, with a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI)

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. Prescriber submits documentation of no evidence of unacceptable toxicity or disease progression while on treatment.

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months

References

1. Welireg (belzutifan) [prescribing information]. Rahway, NJ: Merck Sharp & Dohme LLC; December 2023.

Review History

03/16/2022 – Created for March P&T Effective 05/01/2022.

12/11/2024 – Updated and reviewed at December P&T. Added supplemental indication of advanced renal cell carcinoma. Updated criteria for von Hippel-Lindau disease to remove requirements that disease is not metastatic and that Welireg will be used as a single agent. Effective 03/01/2025.

