Mass General Brigham
Health Plan

Welireg (belzutifan)
Effective 03/01/2025

Plan	☐ MassHealth UPPL ☒ Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | 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.