MEDICAL MUTUAL®

Drug Policy

Policy:	Welireg (belzutifan)	Annual Review Date: 09/21/2023 Last Revised Date: 03/20/2024

OVERVIEW

Welireg (belzutifan) is an antitumor drug for adult patients with von Hippel-Lindau disease (VHL) who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNETs), not requiring immediate surgery.

POLICY STATEMENT

This policy involves the use of Welireg. Prior authorization is recommended for pharmacy benefit coverage of Welireg. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Welireg as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Welireg be prescribed by or in consultation with a physician who specializes in the condition being treated. To be considered for coverage, Welireg must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Welireg is recommended in those who meet the following criteria:

1. **Renal Cell Carcinoma**. Approved for 1 year if the patient meets the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has advanced disease; AND
   - **C)** Patient has tried at least one programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor; AND
     Note: Examples of PD-1 inhibitor or PD-L1 inhibitor include: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), and Bavencio (avelumab intravenous infusion).
   - **D)** Patient has tried at least one vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI).

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Note: Examples of VEGF-TKI include Cabometyx (cabozantinib tablets), Lenvima (lenvatinib capsules), Inlyta (axitinib tablets), Fotivda (tivozanib capsules), pazopanib, sunitinib, and sorafenib

2. **von Hippel-Lindau Disease (VHL) – associated conditions**
Criteria. *Patient must meet the following criteria*

A. The patient is 18 years of age or older; AND
B. The patient has a von Hippel-Lindau germline alteration as detected by genetic testing [Documentation required]; AND
C. The patient has ONE of the following VHL-associated conditions; renal cell carcinoma, pancreatic neuroendocrine tumors, or central nervous system hemangioblastoma; AND
D. The patient is not an eligible candidate for immediate surgery; AND
E. The patient has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 [Documentation required];
F. Welireg is prescribed by or in consultation with an oncologist or a provider that specializes in the treatment of genetic disorders**;**

3. **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
Criteria. *Prescriber will provide specific diagnosis for documentation. Approve.*

4. **Patient has been started on Welireg**
Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Welireg has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

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The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Welireg® [prescribing information]. Whitehouse Station, NJ: Merck and Co; December 2023.
2. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology

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