

Clinical Policy: Belzutifan (Welireg)

Reference Number: ERX.SPA.453

Effective Date: 12.01.21

Last Review Date: 11.22

Line of Business: Commercial, Medicaid

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

Description

Belzutifan (Welireg[™]) is a hypoxia inducible factor inhibitor.

FDA Approved Indication(s)

Welireg 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.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions[™] that Welireg is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Von Hippel-Lindau Disease (must meet all):

1. Diagnosis of VHL disease requiring therapy for associated RCC, CNS hemangioblastomas, or pNET, but not requiring immediate surgery;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Request meets one of the following (a or b):*
 - a. Dose does meets both of the following (i and ii):
 - i. Dose does not exceed 120 mg once daily;
 - ii. Dose is at least 40 mg once daily;
 - b. Dose is supported by practice guideline or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:

Commercial – Length of Benefit

Medicaid – 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Von Hippel-Lindau Disease (must meet all):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Welireg for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;

3. If request is for a dose increase, request meets one of the following (a or b):*
 - a. New dose meets both of the following (i and ii):
 - i. Dose does not exceed 120 mg once daily;
 - ii. Dose is at least 40 mg once daily;
 - b. New dose is supported by practice guideline or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:

Commercial – Length of Benefit

Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CNS: central nervous system

FDA: Food and Drug Administration

pNET: pancreatic neuroendocrine tumors

RCC: renal cell carcinoma

VHL: von Hippel-Lindau

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): embryo-fetal toxicity

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
VHL disease	120 mg PO once daily	120 mg/day

VI. Product Availability

Tablet: 40 mg

VII. References

1. Welireg Prescribing Information. Whitehouse Station, NJ: Merck Sharp & Dohme Corp: May 2022. Available at www.accessdata.fda.gov. Accessed August 4, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 3, 2022.
3. National Comprehensive Cancer Network. Kidney Cancer Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf. Accessed August 2, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	08.30.21	11.21
4Q 2022 annual review: no significant changes; removed generic oral oncology redirection verbiage; references reviewed and updated.	08.04.22	11.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

This policy is the property of Envolve Pharmacy Solutions. Unauthorized copying, use, and distribution of this Policy or any information contained herein is strictly prohibited. By accessing this policy, you agree to be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.

©2021 Envolve Pharmacy Solutions. All rights reserved. All materials are exclusively owned by Envolve Pharmacy Solutions and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Envolve Pharmacy Solutions. You may not alter or remove any trademark, copyright or other notice contained herein.