Clinical Policy: Belzutifan (Welireg)

Reference Number: ERX.SPA.453
Effective Date: 12.01.21
Last Review Date: 11.21
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 in a member who requires therapy for associated RCC, CNS hemangioblastomas, or pNET, but does not require immediate surgery;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. For Welireg requests, member must use belzutifan, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 120 mg once daily and 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. For Welireg requests, member must use belzutifan, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 120 mg once daily and 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: August 2021. Available at www.accessdata.fda.gov. Accessed August 28, 2021.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com. Accessed August 28, 2021

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	08.30.21	11.21

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.