Clinical Policy Title:	belzutifan
Policy Number:	RxA.715
Drug(s) Applied:	Welireg™
Original Policy Date:	12/07/2021
Last Review Date:	12/07/2021
Line of Business Policy Applies to:	All lines of business

Background

Welireg™ is a hypoxia-inducible factor inhibitor indicated for 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
belzutifan (Welireg™)	Von Hippel-Lindau (VHL) disease	The recommended dosage of Welireg™ is 120 mg administered orally once daily with or without food.	120 mg

Dosage Forms

- Tablets: 40 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

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

1. Patient must have diagnosis of Von Hippel-Lindau disease confirmed by germline VHL alteration and require therapy for one of the following conditions (a, b or c):
   a. Associated renal cell carcinoma;
   b. Associated pancreatic neuroendocrine tumors;
   c. Associated CNS hemangioblastoma;
2. Prescribed by or in consultation with an oncologist;
3. Patient should not be eligible for immediate surgery;
4. Patient must have Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1;
5. Age ≥ 18 years;
6. Dose does not exceed 120 mg orally once daily.

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, 120 mg administered orally once daily.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
VHL: Von Hippel-Lindau
RCC: Renal cell carcinoma
ECOG: Eastern Cooperative Oncology Group
pNET: pancreatic neuroendocrine tumors
CNS: central nervous system

APPENDIX B: Therapeutic Alternatives
Not Applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - Embryo-fetal toxicity.

APPENDIX D: General Information

- Anemia: Monitor for anemia before initiation of and periodically throughout treatment with Welireg™. Withhold Welireg™ until hemoglobin ≥ 9g/dL, then resume at reduced dose or discontinue. For life threatening anemia, or for anemia requiring urgent intervention, withhold Welireg™ until hemoglobin ≥ 9g/dL and resume at a reduced dose or permanently discontinue Welireg™.
- Hypoxia: Monitor oxygen saturation before initiation of, and periodically throughout, treatment with Welireg™. For hypoxia at rest, withhold until resolved, resume at reduced dose, or discontinue depending on severity. For life-threatening hypoxia, permanently discontinue Welireg™.

References

1. Welireg™ Prescribing information. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; August 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215383s000lbl.pdf. Accessed November 15, 2021.
2. IPD Analytics Rx Insights_New Drug Review_ Welireg™ 08.2021. Avaliable at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Welireg. Accessed November 15, 2021.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Belzutifan. Available at www.nccn.org. Accessed November 15, 2021.

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4. Welireg™. Lexi-Drugs. Lexicomp. Wolters Kluwer. Hudson, OH. Available at https://online.lexi.com. Accessed November 15, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	11/15/2021	12/07/2021

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