VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Welireg Prior Authorization Policy
- Welireg™ (belzutifan tablets – Merck)

REVIEW DATE: 09/01/2021; selected revision 09/08/2021

OVERVIEW

Welireg, a hypoxia-inducible factor inhibitor, is indicated for the treatment of adult patients with **von Hippel-Lindau (VHL) disease** who require therapy for associated renal cell carcinoma, central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors, not requiring immediate surgery.[1] The pivotal trial included patients with VHL disease associated renal cell carcinoma, CNS hemangioblastoma, pancreatic neuroendocrine tumor, and retinal hemangioblastoma.[2]

Guidelines

Welireg is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):

- **CNS Cancers:** NCCN guidelines (version 2.2021 – September 8, 2021) recommend Welireg as useful in certain circumstances for VHL-associated CNS hemangioblastoma not requiring immediate surgery (category 2A).[3]
- **Kidney Cancer:** NCCN guidelines (version 2.2022 – September 8, 2021) recommend Welireg as a preferred regimen for VHL disease (category 2A)[4]
- **Neuroendocrine and Adrenal Tumors:** NCCN guidelines (version 3.2021 – August 13, 2021) list VHL disease as a hereditary endocrine neoplasia. Welireg is not addressed. The guidelines recommend screening for patients with VHL disease starting at age 2. Patients with VHL disease have an appreciable risk for bilateral tumors and the guidelines state that consideration should be given to cortical-sparing adrenalectomy.[5]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Welireg. All approvals are provided for 3 years.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Von Hippel-Lindau Disease.** Approve for 3 years if the patient meets the following (A, B, C and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has a von Hippel-Lindau (VHL) germline alteration as detected by genetic testing; AND
   - **C)** Patient does not require immediate surgery; AND
   - **D)** Patient requires therapy for ONE of the following conditions (i, ii, iii, or iv):
     - **i.** Central nervous system hemangioblastomas; OR
     - **ii.** Pancreatic neuroendocrine tumors; OR
     - **iii.** Renal cell carcinoma; OR

iv. Retinal hemangioblastoma.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Welireg is not recommended in the following situations:

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

REFERENCES

1. Welireg™ tablets [prescribing information]. Whitehouse Station, NJ: Merck; August 2021.
2. Srinivasan R, Donskov F, Iliopoulos O, et al. Phase 2 study of belzutifan (MK-6482), an oral hypoxia-inducible factor 2α inhibitor, for von Hippel-Lindau disease-associated clear cell renal cell carcinoma [abstract 4555]. Presented at: American Society of Clinical Oncology (ASCO) 2021 Annual Meeting; Virtual; June 4-8, 2021.
3. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 2.2021 – September 8, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 9, 2021.
4. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – September 8, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 9, 2021.
5. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 3.2021 – August 13, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 17, 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	09/01/2021
Selected Revision	**Von Hippel-Lindau Disease:** In the criterion regarding conditions for which the patient requires therapy, retinal hemangioblastoma was added as an option.	09/08/2021