PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 09/07/2022

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.[1]

Guidelines

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

- **CNS Cancers:** NCCN guidelines (version 1.2022 – June 2, 2022) 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 – August 3, 2022) recommend Welireg as a preferred regimen for VHL disease (category 2A) and useful in certain circumstances as single-agent therapy for relapse or stage IV disease as subsequent therapy for clear cell histology (category 2B)[4]
- **Neuroendocrine and Adrenal Tumors:** NCCN guidelines (version 1.2022 – May 23, 2022) list VHL disease as a hereditary endocrine neoplasia. Welireg may be considered for the management of symptomatic clinically significant tumor burden and/or progressive recurrent, locoregional advanced disease and/or distant metastatic tumors in patients with progressive pancreatic neuroendocrine tumors in the setting of germline VHL alteration as an alternative front-line therapy or as subsequent therapy (category 2A).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Welireg. All approvals are provided for the duration noted below.

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 1 year 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):

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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; May 2022.
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 1. 2022 – June 2, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 5, 2022.
4. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 2.2022– August 3, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 5, 2022.
5. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 1.2022 – May 23, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 5, 2022.

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