Reference number(s)
4898-A

SPECIALTY GUIDELINE MANAGEMENT

WELIREG (belzutifan)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Von Hippel-Lindau (VHL) Disease
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.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Von Hippel-Lindau (VHL) Disease
Authorization of 12 months may be granted for treatment of VHL-associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET) when all of the following criteria are met:
1. Member does not require immediate surgery
2. Member does not have metastatic disease
3. Medication will be used as single agent

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Welireg [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; August 2021.