

Welireg® (belzutifan)
Effective 08/01/2022

Plan	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Welireg® (belzutifan) is the first hypoxia-inducible factor-2alpha (HIF-2α) inhibitor that results in the reduction of transcription and expression of HIF-2α target genes associated with cellular proliferation, angiogenesis, and tumor growth. It is indicated for the treatment of 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.

No PA	Drugs that require PA
Alternatives vary by specific malignancy	Welireg® (belzutifan)

Coverage Guidelines

Authorization may be granted for members who are currently receiving treatment with Welireg, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Treatment of von Hippel-Lindau (VHL) disease

Prescriber provides documentation of ALL of the following:

1. Appropriate diagnosis as confirmed by germline VHL alteration
2. Prescriber is an oncologist
3. Appropriate dosing



4. Physician documented of member having renal cell carcinoma, central nervous system hemangioblastomas, or pancreatic neuroendocrine tumors
5. Member is not a candidate for or does not require immediate surgery
6. Quantity requested is ≤ 3 units/day

Continuation of Therapy

Reauthorizations requires physician attestation of continuation of therapy and positive response to therapy.

Limitations

1. Initial approvals will be granted for 3 months.
2. Reauthorizations will be granted for 12 months.
3. The following quantity limits apply:

Welireg [®] (belzutifan)	90 tablets per 30 days
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Requests for over the quantity limit should be reviewed against the Global Quantity Limit criteria.

4. Dosing

Drug	Dosing
Welireg [®] (belzutifan)	120 mg once daily
Tablet: 40 mg	<i>Refer to package insert for dosage modifications due to adverse reactions</i>

References

1. Welireg[®] (belzutifan) [prescribing information]. Whitehouse Station (NJ): Merck Sharpe & Dohme Corp.; 2021 Aug.
2. Plon SE, Jonasch E. Clinical features, diagnosis, and management of von Hippel-Lindau disease. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Dec 16]. Available from: <http://www.utdol.com/utd/index.do>.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Central Nervous System Cancers. Version 2.2021. 2021 Sep 8 [cited 2021 Dec 17]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology Kidney Cancer. Version 4.2022. 2021 Dec 21 [cited 2021 Dec 29]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Neuroendocrine and Adrenal Tumors. Version 4.2021. 2021 Dec 14 [cited 2021 Dec 17]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf.

Review History

6/22/2022 – Created and Reviewed for June P&T; matched MH UPPL. Created criteria to be in compliance with Masshealth criteria Effective 8/1/22.

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