

**Givlaari (givosiran)
Effective 08/01/2021**

Plan	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A		
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

Givosiran is an aminolevulinate synthase 1-directed small interfering RNA indicated for the treatment of adults with acute hepatic porphyria (AHPs).

Coverage Guidelines

Authorization may be granted for members who are currently receiving treatment with Givlaari, excluding when the product is obtained as samples or via manufacturer's patient assistance program
OR

Approval of Givlaari will be granted if the member meets all following criteria and documentation has been submitted:

1. The member has a diagnosis of acute hepatic porphyria
2. The member is ≥ 18 years of age
3. Member's current weight (use to verify correct dosing; may take this information over the phone if missing on PA request)
4. Appropriate dosing

Continuation of Therapy

Reauthorization of Givlaari may be granted when ALL the following is met:

1. The member has experienced a positive clinical response as evidenced by ALL of the following:
2. Updated member weight (use to verify correct dosing; may take this information over the phone if missing on PA request)

Limitations

Initial approvals and reauthorizations will be granted for 12 months.



References

1. Givlaari (givosiran) [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals; November 2019
2. Gouya L, Ventura P, Balwani M, et al. EXPLORE: A Prospective, Multinational, Natural History Study of Patients with Acute Hepatic Porphyria with Recurrent Attacks. *Hepatology* 2020; 71:1546
3. Sardh E, Harper P, Balwani M, et al. Phase 1 Trial of an RNA Interference Therapy for Acute Intermittent Porphyria. *N Engl J Med* 2019; 380:549
4. Balwani M, Sardh E, Ventura P, et al. Phase 3 Trial of RNAi Therapeutic Givosiran for Acute Intermittent Porphyria. *N Engl J Med* 2020; 382:2289
5. Sood GK, Anderson KE. Acute intermittent porphyria: Management. In: UpToDate, Post, TW (Ed), UpToDate, Waltham, MA, 2020.

Review History

09/16/2020: Created and Reviewed at Sept P&T Meeting. Effective 12/01/2020.

05/19/2021: Reviewed and Updated May P&T Meeting to meet MH UPPL for 7/1/2021; updated duration of approval. Effective 08/01/2021.

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