

Givlaari (givosiran)
Effective 04/01/2023

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			
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			

Overview

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

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication 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:

1. The member has a diagnosis of acute hepatic porphyria (AHP)
2. The member is ≥ 18 years of age
3. Member's current weight
4. Appropriate dosing based on weight

Continuation of Therapy

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

1. The member has experienced a positive clinical response to therapy
2. Updated member weight

Limitations

Initial approvals and reauthorizations will be granted for 12 months.

References

1. Givlaari® [package insert] Cambridge (MA): Alnylam; 2020 Dec.
2. Balwani M, Wang B, Anderson KE, et al. Acute hepatic porphyrias: Recommendations for evaluation and longterm management. *Hepatology*. 2017 Oct;66(4):1314-1322.
3. Neeleman RA, Wagenmakers MAEM, Koole-Lesuis RH, et al. Medical and financial burden of acute intermittent porphyria. *J Inherit Metab Dis*. 2018 Sep;41(5):809-817

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.

02/08/2023 - Reviewed and updated for Feb P&T. Matched MH UPPL criteria. Updated references. Clarified criteria. Effective 4/1/23.

