

Givlaari (givosiran)
Effective 06/01/2025

Plan	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

Givlaari (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 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 \geq 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

1. Initial approvals and reauthorizations will be granted for 12 months.

References

1. Givlaari [package insert] Cambridge (MA): Alnylam; 2024 Apr.
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.

05/15/25 – Reviewed and updated for P&T. Performed annual medical criteria review. Policy has been updated to better reflect agents with prior authorization on medical benefit. Updated formatting and references. Effective 6/1/25

