Mass General Brigham
Health Plan

Givlaari (givosiran)
Effective 04/01/2023

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
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 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

<u>Continuation of Therapy</u>
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.