Mass General Brigham
Health Plan

Givlaari (givosiran)
Effective 08/01/2021

Plan	☐ MassHealth UPPL ☒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 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.