Givlaari (givosiran)
Effective 12/01/2020

Plan	☒ MassHealth ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit (NLX)		
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 is at least 18 years of age
2. The member has a diagnosis of acute hepatic porphyria as evidenced by at least ONE of the following:
    a. Elevated porphobilinogen (PBG) and/or aminolevulinic acid (ALA) within the past 12 months
    b. Genetic confirmation of mutation in an affected gene
3. Givlaari is being prescribed by or in consultation with, a hematologist, or a specialist with expertise in the diagnosis and management of AHPs
4. The member has not had a prior liver transplant
5. The member has active disease as defined by one of the following:
    a. At least 2 documented porphyria attacks within the past 6 months requiring hospitalization, urgent healthcare visit or IV administration of hemin.
    b. The member is currently receiving treatment with prophylactic hemin to prevent porphyria attacks

Continuation of Therapy

Reauthorization of Givlaari may be granted for 12 months when ALL the following is met:

1. The member has experienced a positive clinical response as evidenced by ALL of the following:
   a. Reduction in hemin administration requirements (if previously required, including prophylactic and/or treatment doses)
   b. Reduction in the frequency of acute porphyria attacks and/or hospitalizations or urgent care visits
   c. Improvement of signs and symptoms of AHP (e.g., pain, neurological, gastrointestinal, renal, quality of life, etc.)
2. The member has not had a liver transplant

Limitations

Initial approvals will be granted for 6 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.

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