Clinical Policy Title:	givosiran
Policy Number:	RxA.623
Drug(s) Applied:	Givlaari®
Original Policy Date:	05/21/2020
Last Review Date:	8/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Acute Hepatic Porphyria (AHP) (must meet all):

1. Diagnosis of AHP (including acute intermittent porphyria (AIP), hereditary coproporphyria (HCP), variegate porphyria (VP), or aminolevulinic acid (ALA) dehydratase deficient porphyria) confirmed by one of the following (a or b):
   a. Genetic testing (i, ii, iii, or iv):
      i. AIP: positive HMBS (aka PBGD) mutation;
      ii. HCP: positive CPOX mutation;
      iii. VP: positive PPOX mutation;
      iv. ALAD porphyria: positive ALAD mutation;
   b. History of at least a four-fold increase of 5-aminolevulinic acid (ALA) or porphobilinogen (PBG) using a random urine sample within the past year;
2. Member has not had or is not anticipating a liver transplant;
3. Member will not receive concomitant prophylactic hemin treatment while on Givlaari®;
4. History of ≥ 2 porphyria attacks in a 6-month period requiring hospitalization, urgent healthcare visit, or intravenous Panhematin® (hemin for injection) administration at home, and (a or b):
   a. The porphyria attacks occurred within the last 6 months;
   b. The porphyria attacks occurred in any 6-month period, and member is currently receiving prophylactic Panhematin® therapy (e.g., once or twice a week on a regular basis).

   *Prior authorization may be required.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Acute Hepatic Porphyria (AHP) (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

Not Applicable

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	05/07/2020	05/21/2020
Policy was reviewed: 1. Line of Business Policy Applies to was updated to all lines of business. 2. Reference was updated.	1/28/2021	03/09/2021
Policy was reviewed: 1. Initial approval criteria I.A.3 and I.A.4 were updated to add ,"Patient has not had or is not anticipating a liver transplant" and "Patient will not receive concomitant prophylactic hemin treatment while on Givlaari". 2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. Continued Therapy Criteria II.A.2 was updated to add examples of positive response to therapy. 4. Continued Therapy Criteria II.A.3 and II.A.4 updated to add, "Patient has not had or is not anticipating a liver transplant" and "Patient will not receive concomitant prophylactic hemin treatment while on Givlaari". 5. References were reviewed and updated.	11/29/2021	01/17/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from The member has a diagnosis of AHP (including acute intermittent porphyria (AIP), hereditary coproporphyria (HCP), variegate porphyria, or aminolevulinic acid (ALA) dehydratase deficient porphyria) to The member has a diagnosis of AHP (including acute intermittent porphyria (AIP), hereditary coproporphyria (HCP), variegate porphyria, or aminolevulinic acid (ALA) dehydratase deficient porphyria) confirmed by one of the following (a or b):; a. Genetic testing (i, ii, iii, or iv): i. AIP: positive HMBS (aka PBGD) mutation; ii. HCP: positive CPOX mutation; iii. VP: positive PPOX mutation; iv. ALAD porphyria: positive ALAD mutation; 2. Initial Approval Criteria, I.A.5: "The member has	10/19/2022	01/17/2023

active disease which is defined as two documented porphyria attacks within the past 6 months. These can include: i. Hospitalization; ii. Urgent healthcare visit; iii. Intravenous hemin administration at home" was replaced with History of ≥2 porphyria attacks in a 6-month period requiring hospitalization, urgent healthcare visit, or intravenous Panhematin® (hemin for injection) administration at home, and (a or b): a. The porphyria attacks occurred within the last 6 months; b. The porphyria attacks occurred in any 6-month period, and member is currently receiving prophylactic Panhematin® therapy (e.g., once or twice a week on a regular basis). *Prior authorization may be required. 3. Continued Therapy Approval, II.A.2: "The member has responded positively to therapy with Givlaari® (e.g. reduction in hemin administration requirements, reduction in rate and/or number of porphyria attacks, improvement of signs and symptoms of AHP's (e.g. pain, neurological, gastrointestinal, renal, quality of life etc.)" was replaced with Member is responding positively to therapy as evidenced by one of the following (a or b): a. Decreased number of porphyria attacks requiring hospitalization, urgent healthcare visit, or intravenous Panhematin® administration at home; b. No increase in porphyria attacks requiring hospitalization, urgent healthcare visit, or intravenous Panhematin administration at home if member was receiving prophylactic Panhematin® therapy prior to Givlaari® initiation. 4. Approval duration: Commercial and Medicaid updated from 3 months to 6 months. 5. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed dose restrictions.	8/28/2024	9/13/2024

3. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 4. Removed other reauthorization requirements including positive response to therapy. 5. Updated approval duration verbiage.		