

Givlaari™ (givosiran)

When requesting Givlaari™ (givosiran), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Givlaari is indicated for the treatment of adults with acute hepatic porphyria (AHP).

Coverage Guidelines

Treatment of acute hepatic porphyria (AHP)

Patient must meet **all** of the following criteria:

- Is 18 years of age or older;
- Diagnosis of acute hepatic porphyria was confirmed by both of the following
 - o Patient demonstrated clinical features associated with acute hepatic porphyria. Examples of clinical features include neurovisceral symptoms, blistering lesions, hepatic involvement, peripheral neuropathy, abdominal pain, constipation, muscle weakness, pain in the arm and legs;
 - o Patient has elevated urinary aminolevulinic acid (ALA) or elevated porphobilinogen (PBG);
- Prior to starting treatment, the patient has a history of one porphyria attack in the last 6 months that required a hospitalization, urgent healthcare visit, or intravenous hemin administration at home;
- Givlaari is prescribed by or in consultation with one of the following specialists: gastroenterologist, hepatologist, a physician who specializes in acute hepatic porphyria

Approval duration: 12 months

Dosing Recommendation

The recommended dose of Givlaari is 2.5 mg/kg administered via subcutaneous injection once monthly.

References

1. Givlaari™ injection solution [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals; April 2024.

2. Porphyria. U.S. National Library of Medicine; National Institutes of Health; Department of Health and Human Services. Available at: <https://ghr.nlm.nih.gov/condition/porphyria>. Accessed on October 19, 2023.
3. Wang B, Rudnick S, Cengia B, et al. Acute hepatic porphyrias: Review and recent progress. *Hepatol Commun*; 2018;3(2):193-206.
4. Bissell DM, Wang B. Acute hepatic porphyria. *J Clin Transl Hepat*. 2015;3(1):17-26.
5. Balwani M, Wang B, Anderson K, et al. Acute hepatic porphyrias: Recommendations for evaluation and long term management. *Hepatology*. 2017;66(4):1314-1322.