

Policy Name: Givlaari (givosiran)

Policy #: 2792P

Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of Givlaari (givosiran).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Givlaari (givosiran) under the specialty medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of an acute hepatic porphyria (i.e., acute intermittent porphyria, hereditary coproporphyria, variegate porphyria, ALA dehydratase deficient porphyria)
- 1.2 One of the following:
 - Patient has had at least 2 documented porphyria attacks within the past 6 months, OR
 - Patient is currently receiving treatment with prophylactic hemin to prevent porphyria attacks
- 1.3 Age 18 years or older
- 1.4 Ordered by or in consultation with a hematologist (blood doctor) or specialist with expertise in the diagnosis or management of acute hepatic porphyria
- 1.5 Review of chart notes documenting diagnosis and confirming that patient has met all of the above requirements for treatment with Givlaari by both a pharmacist and a medical director

2. Exclusion Criteria

- 2.1 Prior liver transplant
- 2.2 Use of prophylactic hemin treatment while on Givlaari

3. Approval Period

- 3.1 Initial Approval: 12 months
- 3.2 Subsequent Approvals: 12 months with documentation of a positive clinical response including the following:
 - Reduction in hemin administration requirements
 - Reduction in the rate and/or number of porphyria attacks
 - Improvement in the signs and symptoms of AHPs (e.g., pain, neurological, gastrointestinal, renal, quality of life, etc.)

CPT Codes

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HCPCS Codes

J0223	Injection, givosiran, 0.5mg
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References

1. Givlaari (givosiran) [prescribing information]. San Diego, CA: Ajinomoto Althea Inc; April 2024.
2. Balwani M, Wang B, Anderson KE, et al. Acute hepatic porphyrias: Recommendations for evaluation and long-term management. *Hepatology*. 2017 Oct;66(4):1314-1322.
3. Gomá-Garcés E, Pérez-Gómez MV, Ortíz A. Givosiran for Acute Intermittent Porphyria. *N Engl J Med* 2020; 383:1989.
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.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.