

Pharmacy Medical Necessity Guidelines: Givlaari™ (givosiran)

Effective: February 17, 2020

Prior Authorization Required	✓	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	
Pharmacy (RX) or Medical (MED) Benefit	MED / RX	Department to Review	PRECERT /MM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan 		<p>Fax Numbers:</p> <p>All plans except Tufts Health Public Plans PRECERT: 617.972.9409</p> <p>Tufts Health Public Plans MM: 888.415.9055</p>	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Givlaari (givosiran) is an aminolevulinic acid synthase 1-directed small interfering RNA indicated for the treatment of adults with acute hepatic porphyria.

COVERAGE GUIDELINES

The plan may authorize the coverage of Givlaari (givosiran) for Members, when all of the following criteria are met:

Initial Therapy

1. Documented diagnosis of hepatic porphyria as evidenced by at least one of the following:
 - a. Elevated porphobilinogen (PBG) and/or aminolevulinic acid (ALA)
 - b. Genetic confirmation of mutation

AND

2. Prescribed by or in consultation with a dermatologist, geneticist, gynecologist, hematologist, hepatologist, gastroenterologist, neurologist, or any healthcare provider with experience managing acute hepatic porphyria

AND

3. Documentation the Member has not had a prior liver transplant

AND

4. Documentation of active disease as evidenced by at least two acute porphyria attacks requiring hospitalization, urgent healthcare visit, or administration of hemin in the previous 12 months

Reauthorization Criteria

1. Documented diagnosis of hepatic porphyria as evidenced by at least one of the following:
 - a. Elevated PBG and/or ALA
 - b. Genetic confirmation of mutation

AND

2. Prescribed by or in consultation with a dermatologist, geneticist, gynecologist, hematologist, hepatologist, gastroenterologist, neurologist, or any healthcare provider with experience managing acute hepatic porphyria

AND

3. Documentation the Member has not had a prior liver transplant

AND

4. Documentation of a positive clinical response as evidenced by a reduction of acute porphyria attacks requiring hospitalization, urgent healthcare visit, or administration of hemin

LIMITATIONS

- The plan will not cover Givlaari (givosiran) in Members without a history of attacks.
- The plan will not cover Givlaari (givosiran) in Members receiving prophylactic hemin.

- Initial approval of Givlaari (givosiran) will be given in 12 month intervals. Subsequent authorization requests may be given in 12 month intervals when Reauthorization Criteria above have been met.
- Members new to the plan stable on Givlaari (givosiran) must meet Initial Therapy criteria if on treatment for less than a year and must meet Reauthorization criteria if on treatment for more than a year.

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J0223	Injection, givosiran, 0.5 mg

REFERENCES

1. Sood GK, Anderson KE. Acute intermittent porphyria: Management. In: UpToDate, Post, TW (Ed), UpToDate, Waltham, MA, 2020.
2. Givlaari (givosiran) [prescribing information]. South San Francisco, CA: Genentech, Inc.; June 2019.
3. Wang B, Rudnick S, Cengia B, et al. Acute hepatic porphyrias: review and recent progress. *Hepatology Communications*. 2019;3:193-206.

APPROVAL HISTORY

February 11, 2020: Reviewed by Pharmacy & Therapeutics Committee.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.