Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
# Givlaari (givosiran)

*Effective: September 15, 2026*

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|---|---|
| **Guideline Type** | ☒ Prior Authorization<br>☐ Non-Formulary<br>☐ Step-Therapy<br>☐ Administrative |

**Applies to:**

**Commercial Products**

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

**Public Plans Products**

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

**Senior Products**

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

## Overview

**Food and Drug Administration-Approved Indications**

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

## Clinical Guideline Coverage Criteria

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

### Initial Authorization Criteria

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

**AND**

2. Documentation the patient has actively symptomatic disease as evidenced by **one (1)** of the following:
    a. At least two (2) porphyria attacks within the past 6 months
    b. A history of one (1) severe attack with central nervous system, autonomic nervous system, or peripheral nervous system involvement (e.g., hallucinations, seizures, respiratory failure, paralysis)
    c. Significant chronic baseline disease activity with symptoms (e.g., abdominal pain, back pain, chest pain, mental status changes, memory loss)

**AND**

3. 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**

4. Documentation the patient has not had a prior liver transplant

### Reauthorization Criteria

1. Documented diagnosis of hepatic porphyria as evidenced by at least **one (1)** of the following:
    a. Elevated porphobilinogen (PBG) and/or aminolaevulinic 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 a positive clinical response as evidenced by a reduction of acute porphyria attacks requiring hospitalization, urgent healthcare visit, or administration of hemin

## Limitations

- Initial coverage of Givlaari will be authorized for 12 months. Reauthorization of Givlaari will be provided in 12-month intervals.
- Members new to the plan stable on Givlaari 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 code(s) require prior authorization:

**Table 1: HCPCS Codes**

| HCPCS Codes | Description |
|---|---|
| J0223 | Injection, givosiran, 0.5 mg |

## References


1. Givlaari (givosiran) [prescribing information]. South San Francisco, CA: Genentech, Inc.; September 2025.
2. Sood GK, Anderson KE. Acute intermittent porphyria: Management. In: UpToDate, Post, TW (Ed), UpToDate, Waltham, MA, 2020.
3. Wang B, Rudnick S, Cengia B, et al. Acute hepatic porphyrias: review and recent progress. Hepatology Communications. 2019;3:193-206.
4. Balwani M, et al. Acute hepatic porphyrias: Recommendations for evaluation and long-term management. Hepatology. Hepatology 2017;66:1314-1322.
5. Anderson KE, et al. Recommendations for the Diagnosis and Treatment of the Acute Porphyrias. Annals of Internal Medicine. 2005; Volume 142 (6): 439-450.
6. Balwani M, et al. Phase 3 Trial of RNAi Therapeutic Givosiran for Acute Intermittent Porphyria. N Engl J Med 2020; 382:2289-2301.


## Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T).

Subsequent endorsement date(s) and changes made:

1. September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC).
2. September 12, 2023: Removed “Submission of the following documentation is necessary to initiate the prior authorization review: Elevated urinary or plasma porphobilinogen (PBG) or aminolevulinic acid (ALA) values, or genetic testing” (effective 10/1/23).
3. August 13, 2024: Removed the Limitation The Plan will not cover Givlaari in patients without a history of attacks. Consolidated Tufts Health RITogether and Commercial Products coverage criteria into one Medical Necessity Guideline (eff 9/1/24).
4. June 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template
5. September 9, 2025: no changes.
6. September 15, 2026: Administrative updates: Template updated to remove CareLink from the Medical Necessity Guideline template. Template updated from “Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans” to “Tufts Health Together- MassHealth Accountable Care Partnership Plans.”

## Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines,

along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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