AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Givlaari™ (givosiran) **Subcutaneous (J0223) (Medical)**
NDC: 71336-1001-01

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Quantity Limit: Givlaari 189 mg/mL in a single-dose vial for injection: 2 vials every month

Max Units (per dose): 288mg every month

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization Approval – 6 months

- ❑ Member is ≥ 18 years of age

AND

- ❑ Prescriber is a hepatologist, hematologist, oncologist or other specialist in treatment of acute hepatic porphyria (ICD 10 codes E80.21 or E80.29)

AND

- ❑ Member has a clinical diagnosis of acute hepatic porphyria associated with one of the following: **(please note that diagnosis of non-acute/chronic cutaneous porphyria is excluded from coverage)**
  - ❑ Acute intermittent porphyria (AIP)
  - ❑ Variegate Porphyria (VP)
  - ❑ Hereditary coproporphyria (HCP)
  - ❑ ALA dehydratase deficient porphyria (ADP)
  - ❑ Other: _____ **(must send literature to support safety and efficacy for off-label diagnosis/dosing)**

AND

- ❑ Diagnosis of AIP, HCP, VP, or ADP is based on the member having at least **ONE** of the following clinical features **(please note all symptoms present)**:
  - ❑ **Gastrointestinal:** abdominal pain, vomiting, constipation, diarrhea
  - ❑ **Neurologic:** pain extremities (back), Paresis, mental symptoms, respiratory paralysis
  - ❑ **Cardiovascular:** Tachycardia, systemic arterial hypertension
- ❑ Documentation of the following:
  - ❑ Member has had elevated urinary or plasma PBG (porphobilinogen) and ALA (delta-aminolevulinic acid) levels within the previous year (please submit recent levels of ALA OR PBG)

AND

  - ❑ Member has a history of at least two documented porphyria attacks within the past 6 months and **ONE** of the following:
    - ❑ Requirement of hospitalization (ICD E80.21 OR E80.29) that included IV hemin (J1640)
    - ❑ Urgent healthcare visit (ICD E80.21 OR E80.29) that included IV hemin (J1640)
    - ❑ Treatment with IV hemin monthly at home within the last 6 months from date of the request
    - ❑ Treatment with IV hemin due to severe CNS involvement including one of the following symptoms associated with porphyria attack **(please note)**:
      - ❑ Hallucination
      - ❑ Seizures

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AND

- ❑ Member will avoid concomitant use with CYP1A2 or CYP2D6 substrates (pharmacy claims will be verified), for which minimal concentration changes may lead to serious or life-threatening toxicities (e.g., clozapine, amitriptyline, theophylline, verapamil, clomipramine, clonidine, etc.). Providers may consult the website of the American Porphyria Foundation (www.porphyriafoundation.com) for additional information

AND

- ❑ Member will avoid known triggers of porphyria attacks (i.e., alcohol, smoking, exogenous hormones, hypocaloric diet/fasting, certain medications such as barbiturates, hydantoins, sulfa-antibiotics, anti-epileptics, etc.)

AND

- ❑ Members currently receiving prophylactic intravenous hemin (J1640) therapy will discontinue hemin within 3 to 6 months of initiation with givosiran

AND

- ❑ Member has not received or is awaiting liver transplant

Continuation of Therapy Approval – 12 months Approval. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ All criteria for initial approval continues to be met

AND

- ❑ Member has absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: anaphylactic reactions, severe hepatic toxicity, severe renal toxicity, severe injection site reactions, etc.

AND

- ❑ Member has had positive clinical response to givosiran as evidenced by a decrease in the frequency of acute porphyria attacks, and/or hospitalizations/urgent care visits, and/or a decreased requirement of hemin intravenous infusions **(ICD E80.21 OR E80.29 at ER visits will be verified with last approval)**

AND

- ❑ Member has a reduction of or normalization of biochemical markers (i.e., ALA, PBG) compared to baseline **(submit current lab results for documentation)**;

AND

- ❑ Member will not use givosiran in combination with prophylactic intravenous hemin therapy;

AND

- ❑ Member has not received a liver transplant

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Medication being provided by (check applicable box below):

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy - PropriumRx**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee:** 4/16/2020
REVISED/UPDATED: 6/12/2020