CVS/caremark™

POLICY Document for GIVLAARI

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall, clinically appropriate use. This document provides specific information to each of the three sections of the overall policy.

Section 1: Site of Care

- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care

Site of Care Criteria
Administration of Subcutaneous Givlaari

POLICY

I. CRITERIA FOR APPROVAL FOR ADMINISTRATION IN OUTPATIENT HOSPITAL SETTING

This policy provides coverage for administration of Givlaari in an outpatient hospital setting for up to 45 days when a member is new to therapy or is reinitiating therapy after not being on therapy for at least 6 months.

This policy provides coverage for administration of Givlaari in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

A. The member has experienced an adverse reaction that did not respond to conventional interventions (eg, acetaminophen, steroids, diphenhydramine, fluids or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after administration.
B. The member is medically unstable (eg respiratory, cardiovascular, or renal conditions).
C. The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of drug administration AND the patient does not have access to a caregiver.
D. Alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home.
E. The member is less than 14 years of age.

For situations where administration of Givlaari does not meet the criteria for outpatient hospital administration, coverage for Givlaari is provided when administered in alternative sites such as; physician office, home infusion or ambulatory care.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the site of care prior authorization review (where applicable):

A. Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after administration

B. Medical records supporting the member is medically unstable
C. Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
D. Records supporting alternative infusion sites are greater than 30 miles from the member's home.
E. Medical records supporting the member is new to therapy

Section 2: Clinical Criteria

CAREFIRST: GIVLAARI

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:

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

All other indications are considered experimental/investigational and not medically necessary.

I. CRITERIA FOR INITIAL APPROVAL

Acute Hepatic Porphyria
Authorization of 6 months may be granted for treatment of acute hepatic porphyria when all of the following criteria are met:
1. The member is actively symptomatic
2. The member has an elevated urine porphobilinogen (PBG), or an elevated porphyrin level (plasma or fecal).
3. The patient is not the recipient of a liver transplant
4. Dosing is consistent with product labeling (2.5mg/kg once monthly; based on actual body weight)
5. The medication is prescribed by or in consultation with a neurologist, gastroenterologist, hematologist or physician specializing in the treatment of porphyria.

II. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment of an indication listed in Section III for members who are experiencing benefit from therapy while receiving Givlaari (e.g., reduction in porphyria attacks that required hospitalizations, urgent healthcare visit, or intravenous hemin administration).

REFERENCES

SECTION 1
1. Givlaari [package insert]. San Diego, CA: Ajinomoto Althea, Inc.; April 2024.