Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 211.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Givlaari (givosiran)

I. Policy:
Givlaari (givosiran)

II. Purpose/Objective:
To provide a policy of coverage regarding Givlaari (givosiran)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Givlaari (givosiran) is a double-stranded small interfering RNA that causes degradation of aminolevulinate synthase 1 (ALAS1) mRNA in hepatocytes through RNA interference, reducing the elevated levels of liver ALAS1 mRNA. The reduction of ALAS1 mRNA decreases circulating levels of neurotoxic intermediates aminolevulinic acid (ALA) and porphobilinogen (PBG), which are factors associated with attacks and other disease manifestations of acute hepatic porphyria (AHP).

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Givlaari (givosiran) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Medical record documentation that Givlaari is prescribed by a specialist with experience managing porphyrias (including but not limited to a hematologist, hepatologist, or gastroenterologist) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of acute hepatic porphyria (AHP) [including acute intermittent porphyria (AIP), hereditary coproporphyria (HCP), variegate porphyria (VP), and aminolevulinic acid dehydratase (ALAD) porphyria (ADP)] by at least one of the following:
    - Elevated urinary or plasma aminolevulinic acid (ALA) **OR**
    - Elevated urinary or plasma porphobilinogen (PBG) **OR**
    - Genetic testing confirming a mutation associated with acute hepatic porphyria (AHP)

  AND
- Medical record documentation of the baseline number of porphyria attacks requiring hospitalization, urgent healthcare visit, or IV hemin treatment within the previous 6 months **AND**
- Medical record documentation of active disease with at least two documented porphyria attacks within the previous 6 months.

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months or less if the reviewing provider feels it is medically appropriate. After the initial six (6) month approval, subsequent approvals will be for a duration of twelve (12) months or less if the reviewing provider feels it is medically appropriate, and will require:

- Medical record documentation of a clinically significant positive response to Givlaari treatment as evidenced by:
    - a reduction in the number of porphyria attacks requiring hospitalization, urgent healthcare visit, or IV hemin treatment within the previous 6 months from baseline OR
    - decreased severity in the symptoms of acute hepatic porphyria OR
    - a reduction in the baseline levels of urinary or plasma aminolevulinic acid (ALA) OR urinary or plasma porphobilinogen (PBG)

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:
1. Givlaari [prescribing information]. San Diego, CA: Ajinomoto Althea Inc; February 2023.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 5/19/20

Revised: 3/22/23 (LOB carve out, Medicaid business segment), 12/28/23 (references added)

Reviewed: 4/30/21, 3/23/22 (Medicaid PARP statement), 3/18/24

MA UM Committee approval: 12/31/23