Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 268.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Amvuttra (vutrisiran)

I. Policy:
Amvuttra (vutrisiran)

II. Purpose/Objective:
To provide a policy of coverage regarding Amvuttra (vutrisiran).

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: Amvuttra (vutrisiran) is a double-stranded small interfering ribonucleic acid (siRNA)-N-acetylgalactosamine (GalNAc) conjugate that causes degradation of mutant and wild-type transthyretin (TTR) messenger RNA (mRNA) through RNA interference, which results in a reduction of serum TTR protein and TTR protein deposits in tissues.

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

Amvuttra (vutrisiran) will be considered medically necessary for the Medicaid and Medicare lines of business when all of the following criteria are met:

- Prescription written by or in consultation with a neurologist, board-certified medical geneticist, or specialist with experience in the treatment of hereditary transthyretin-mediated amyloidosis (hATTR) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of hereditary transthyretin-mediated amyloidosis as confirmed by genetic testing to confirm a pathogenic mutation in TTR AND one of the following:
    - Biopsy of tissue/organ to confirm amyloid presence **OR**
    - A clinical manifestation typical of hATTR (Neuropathy and/or CHF) without a better alternative explanation **AND**
- Medical record documentation of Amvuttra being used to treat polyneuropathy **AND**
- Medical record documentation of familial amyloid polyneuropathy (FAP) stage 1-2 and/or polyneuropathy disability score (PND) indicating the patient is not wheelchair bound or bedridden **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation that Amvuttra will not be used in combination with other RNA interference treatment

NOTE:
FAP stage:
1- unimpairmend ambulation
2- assistance with ambulation
3- wheelchair-bound or bedridden
Polyneuropathy disability score:
I- preserved walking, sensory disturbances
II- impaired walking without need for stick/crutches
IIIa- walking with 1 stick/crutch
IIIb- walking with 2 sticks/crutches
IV- wheelchair-bound or bedridden
Polyneuropathy disability score (used in Neuro-TTR trial for Tegsedi):
I- preserved walking, sensory disturbances
II- impaired walking without need for stick/crutches
III- walking with 1 stick/crutch
IV- walking with 2 sticks/crutches
V- wheelchair-bound or bedridden

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if the member progresses to FAP stage 3 and/or polyneuropathy disability score indicating the patient is wheelchair-bound or bedridden.

QUANTITY LIMIT: 0.5 mL per 84 days (Facets RX count: 25 units (J0225) per 84 days)

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.

Amvuttra (vutrisiran) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when all of the following criteria are met:

- Prescription written by or in consultation with a neurologist, board-certified medical geneticist, or specialist with experience in the treatment of hereditary transthyretin-mediated amyloidosis (hATTR) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of hereditary transthyretin-mediated amyloidosis as confirmed by genetic testing to confirm a pathogenic mutation in TTR AND one of the following:
    - Biopsy of tissue/organ to confirm amyloid presence **OR**
    - A clinical manifestation typical of hATTR (Neuropathy and/or CHF) without a better alternative explanation **AND**
- Medical record documentation of Amvuttra being used to treat polyneuropathy **AND**
- Medical record documentation of familial amyloid polyneuropathy (FAP) stage 1-2 and/or polyneuropathy disability score (PND) indicating the patient is not wheelchair bound or bedridden **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation that Amvuttra will not be used in combination with other RNA interference treatment **AND**
- Medical record documentation that the member has been evaluated and treated by a contracted Center of Excellence in amyloidosis management

Note: Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e., Northern Light Health).

NOTE:
FAP stage:
1-unimpairmend ambulation
2- assistance with ambulation
3- wheelchair-bound or bedridden
Polyneuropathy disability score:
I- preserved walking, sensory disturbances
II- impaired walking without need for stick/crutches
IIIa- walking with 1 stick/crutch
IIIb- walking with 2 sticks/crutches
IV-wheelchair-bound or bedridden
Polyneuropathy disability score (used in Neuro-TTR trial for Tegsedi):
I- preserved walking, sensory disturbances
II- impaired walking without need for stick/crutches
III- walking with 1 stick/crutch
IV- walking with 2 sticks/crutches
V-wheelchair-bound or bedridden

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if the member progresses to FAP stage 3 and/or polyneuropathy disability score indicating the patient is wheelchair-bound or bedridden.

QUANTITY LIMIT: 0.5 mL per 84 days (Facets RX count: 25 units (J0225) per 84 days)

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.

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

Devised: 11/15/22
Revised: 12/23/22 (specialist, genetic testing, ambulatory, note, Medicaid Business Segment), 12/19/23 (AND before COE)
Reviewed:
MA UM Committee approval: 12/31/23