Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 304.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Altuviiio (antihemophilic factor (Recombinant [Fc-VWF-XTEN)-ehtl)

Applicable line of business:

Commercial	X	Medicaid	
Medicare		ACA	X
CHIP	X		

I. Policy:
Altuviiio (antihemophilic factor (Recombinant [Fc-VWF-XTEN)-ehtl)

II. Purpose/Objective:
To provide a policy of coverage regarding Altuviiio (antihemophilic factor (Recombinant [Fc-VWF-XTEN)-ehtl)

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 the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. 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

DESCRIPTION:
Altuviiio (antihemophilic factor (Recombinant [Fc-VWF-XTEN)-ehtl)) temporarily replaces the missing coagulation factor VIII needed for effective hemostasis. Altuviio has demonstrated a 3- to 4-fold prolonged half-life relative to other standard and extended half-life factor VIII products. This is achieved by covalent fusion of factor VIII to the Fc domain of human immunoglobulin G1, the inclusion of 2 XTEN polypeptides, and covalently linking the factor VIII-binding D'D3 domain of von Willebrand factor.

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

Altuviiio (antihemophilic factor (Recombinant [Fc-VWF-XTEN)-ehtl) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when ALL of the following criteria are met:

- Medical record documentation of a diagnosis of hemophilia A **AND**
- Prescribed by or in consultation with a hematologist **AND**
- Medical record documentation for use as a treatment for <u>one</u> of the following:
    - Routine prophylaxis to reduce the frequency of bleeding episodes
    - On-demand treatment and control of bleeding episodes
    - Perioperative management of bleeding

  AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Advate **AND**
- <u>If being used for routine prophylaxis of Hemophilia A</u>, medical record documentation of therapeutic failure on, intolerance to, or contraindication to Hemlibra.

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. Altuviiio [Prescribing Information]. Waltham, MA. Bioverativ Therapeutics Inc. February 2023.

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

Devised: 12/5/24 (per the 11/21/23 P&T)

Revised:

Reviewed:

MA UM Committee approval: pending