



Drug Coverage Policy

Effective Date5/1/2026
Coverage Policy Number.....IP0564
Policy Title..... Altuviio

Hemophilia – Altuviio

- Altuviio™ (antihemophilic factor [recombinant] Fc-VWF-XTEN fusion protein-ehtl intravenous infusion - Bioverativ/Sanofi)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Altuviio, a recombinant DNA-derived Factor VIII concentrate, is indicated for use in **hemophilia A** in adults and children for:¹

- **Routine prophylaxis** to reduce the frequency of bleeding episodes.
- **On-demand treatment and control** of bleeding episodes.

- **Perioperative management** of bleeding.

It is notable that Altuviio has demonstrated a 3- to 4-fold prolonged half-life relative to other standard and extended half-life products.¹

Disease Overview

Hemophilia A is an X-linked bleeding disorder primarily impacting males caused by a deficiency in Factor VIII.²⁻⁴ The prevalence of hemophilia A in males is 1:5,000 live births.⁴ The condition is characterized by bleeding in joints, either spontaneously or in a provoked joint by trauma.²⁻⁴ Bleeding can occur in many different body areas as well (e.g., muscles, central nervous system). The bleeding manifestations can lead to substantial morbidity such as hemophilic arthropathy.²⁻⁴ Disease severity is usually defined by the plasma levels or activity of Factor VIII. Normal plasma levels of Factor VIII range from 50% to 150%.³ The disease is classified based on reduced levels. Mild, moderate, and severe hemophilia A is characterized by Factor VIII levels ranging from 6% up to 49%, 1% up to 5%, and < 1%, respectively.³ Approximately 60% of patients with hemophilia A are categorized as having severe disease.

Guidelines

Guidelines for hemophilia from the National Bleeding Disorders Foundation (October 2024)⁵ recognize Altuviio as a product with a prolonged half-life that differs from other recombinant Factor VIII concentrates.

Dosing Considerations

Dosing of clotting factor concentrates is highly individualized. The National Hemophilia Foundation's Medical and Scientific Advisory Council (MASAC) provides recommendations regarding doses of clotting factor concentrate in the home (2016).⁶ The number of required doses varies greatly and is dependent on the severity of the disorder and the prescribed regimen. Per MASAC guidance, patients on prophylaxis should also have a minimum of one major dose and two minor doses on hand for breakthrough bleeding in addition to the prophylactic doses used monthly. The guidance also notes that an adequate supply of clotting factor concentrate is needed to accommodate weekends and holidays. Therefore, maximum doses in this policy allow for prophylactic dosing plus three days of acute bleeding or perioperative management per 28 days. Doses exceeding this quantity will be reviewed on a case-by-case basis by a clinician.

Coverage Policy

Policy Statement

Prior Authorization is recommended for medical benefit coverage Altuviio. Approval is recommended for those who meet the Criteria and Dosing for the listed indication. Extended approvals are allowed if the patient continues to meet the criteria and dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Altuviio, as well as the monitoring required for adverse events and long-term efficacy, the agent is required to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Altuviio is considered medically necessary when the following is met:

FDA-Approved Indication

1. Hemophilia A. Approve for 1 year if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve if the patient meets ALL of the following (i, ii, and iii):

- i. Altuviio is being used in at least ONE of the following scenarios (a, b, or c).
 - a) Routine prophylaxis; OR
 - b) On-demand treatment and control of bleeding episodes; OR
 - c) Perioperative management of bleeding; AND
- ii. Patient meets ONE of the following (a or b):
 - a) Patient meets BOTH of the following [(1) and (2)]:
 - (1) Factor VIII inhibitor testing has been performed within the past 30 days; AND
 - (2) Patient does not have a positive test for Factor VIII inhibitors ≥ 1.0 Bethesda units/mL; OR
 - b) Patient has not received Factor VIII therapy in the past; AND
- iii. Medication is prescribed by or in consultation with a hemophilia specialist; OR

B) Patient is Currently Receiving Altuviio or Has Received Altuviio in the Past. Approve if the patient meets the ALL of following (i, ii, and iii):

- i. Altuviio is being used in at least ONE of the following scenarios (a, b, or c):
 - a) Routine prophylaxis; OR
 - b) On-demand treatment and control of bleeding episodes; OR
 - c) Perioperative management of bleeding; AND
- ii. Patient meets ONE of the following (a or b):
 - a) Patient meets BOTH of the following (1 and 2):
 - (1) Factor VIII inhibitor testing has been performed within the past 365 days; AND
 - (2) Patient does not have a positive test for Factor VIII inhibitors ≥ 1.0 Bethesda units/mL; OR
 - b) According to the prescriber, patient does not have clinical manifestations suggesting the presence of Factor VIII inhibitors; AND
Note: Inhibitors may be present if bleeding is not well controlled, there is decreased responsiveness to Factor VIII therapy, and/or if expected Factor VIII activity plasma levels are not achieved.
- iii. Medication is prescribed by or in consultation with a hemophilia specialist.

Dosing. Approve the following dosing regimens (A, B, and/or C):

- A) Routine prophylaxis:** approve up to 50 IU per kg intravenously no more frequently than once weekly; AND/OR
- B) On demand treatment and control of bleeding episodes:** approve up to 50 IU per kg intravenously with additional doses once every 2 to 3 days for up to 10 days per episode; AND/OR
- C) Perioperative management of bleeding:** approve up to 50 IU per kg intravenously and provide for additional doses once every 2 to 3 days for up to 10 days per procedure.

Conditions Not Covered

Altuviio for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

Coding Information

- Note:** 1) This list of codes may not be all-inclusive.
 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J7214	Injection, Factor VIII/von Willebrand factor complex, recombinant (Altuviiiio), per Factor VIII IU

References

1. Altuviiiio® intravenous infusion [prescribing information]. Waltham, MA: Bioverativ/Sanofi; December 2025.
2. Konkle BA, Nakaya Fletcher S. Hemophilia A. 2000 Sep 21 [Updated 2025 Aug 7]. In: Adam MP, Bick S, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2026.
3. National Bleeding Disorders Foundation. Hemophilia A: An overview of symptoms, genetics, and treatments to help you understand hemophilia A. Available at: <https://www.bleeding.org/bleeding-disorders-a-z/types/hemophilia-a>. Accessed on April 5, 2025.
4. Chowdary P, Carcao M, Kenet G, Pipe SW. Haemophilia. *Lancet*. 2025;405:736-750.
5. National Bleeding Disorders Foundation. MASAC (Medical and Scientific Advisory Council) recommendations concerning products licensed for the treatment of hemophilia and selected disorders of the coagulation system (endorsed October 2, 2024). MASAC Document #290. Available at: <https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf>. Accessed on February 8, 2026.
6. National Hemophilia Foundation. MASAC (Medical and Scientific Advisory Council) recommendations regarding doses of clotting factor concentrate in the home (Revised June 7, 2016). MASAC Document #242. Adopted on September 3, 2020. Available at: <https://www.hemophilia.org/sites/default/files/document/files/242.pdf>. Accessed on February 8, 2026.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	Updated the scenarios for Altuviiiio use. Added Factor VIII testing requirements. Updated the specialist prescribing requirement. Added criteria for a patient currently receiving Altuviiiio or has received Altuviiiio in the past.	08/15/2024
Selected Revision	In Hemophilia A, for Initial therapy, the threshold for a positive inhibitor test was changed to ≥ 1.0 Bethesda units/mL; previously, it was ≥ 0.6 Bethesda units/mL. It was added that a patient who has not received Factor VIII therapy in the	01/15/2025

	<p>past is not required to meet the inhibitor testing requirements.</p> <p>For a Patient Currently Receiving Altuviiiio or has received Altuviiiio in the past, the Factor VIII inhibitor testing timeframe was changed to within the past 365 days; previously, the timeframe was within the last 30 days. The wording "prescribing physician" was replaced with "prescriber."</p>	
Selected Revision	<p>Updated CPT Coding: Removed: J7205 Added: J7214</p>	01/15/2025
Annual Revision	No criteria changes.	5/15/2025
Annual Revision	<p>Updated from "0.6" to "1.0" Bethesda units/mL in the following criteria: Patient does <u>not</u> have a positive test for Factor VIII inhibitors \geq 1.0 Bethesda units/mL; under <u>Patient is Currently Receiving Altuviiiio or Has Received Altuviiiio in the Past</u></p>	5/1/2026

The policy effective date is in force until updated or retired.

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