POLICY NUMBER: RX.PA.086.MPC
REVISION DATE: 09/2023

RX.PA.086.MPC Altuviiio™ (antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl)

The purpose of this policy is to define the prior authorization process for Altuviiio™ (intravenous infusion)

ALTUVIIIO [antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl] is a recombinant DNA-derived, Factor VIII concentrate indicated for use in adults and children with hemophilia A (congenital factor VIII deficiency) for:

- Routine prophylaxis to reduce the frequency of bleeding episodes
- On-demand treatment & control of bleeding episodes
- Perioperative management of bleeding

PROCEDURE

A. Initial Authorization Criteria:

1. **Hemophilia A (Congenital factor VIII deficiency). All requests must meet the following criteria:**
    - Must have a documented diagnosis of severe hemophilia A (less than 1% endogenous Factor VIII)
    - Must have documentation that Altiviiio will be prescribed for one of the following:
        a) Treatment of bleeding episodes
        b) Prevention of bleeding in surgical interventions or invasive procedures (surgical prophylaxis)
        c) Prevention of bleeding episodes/routine prophylaxis
    - Must not be using Altuviiio for the treatment of von Willebrand disease
    - If member has a past trial and failure with other Factor VIII agents (i.e. Adynovate, Eloctate, Jivi, etc.) must provide documentation that failure was not due to a decreased response (clinical signs or symptoms) to the product
    - Dose does not exceed FDA approved indication
    - Must not had a major surgery within 8 weeks
    - The medication is prescribed by or in consultation with a hematologist
    - Must not concurrently be using other factor VIII products or Hemlibra (emicizumab-kxwh)
    - Must monitor the member for potential development of neutralizing antibodies/inhibitors to Factor VIII throughout treatment

B. Reauthorization Criteria:

1. Hemophilia A (Congenital factor VIII deficiency).

MPC Renewal:

- All prior authorization renewals are reviewed on a 1 year interval basis to determine the Medical Necessity for continuation of therapy.
- Documentation of a positive clinical response, as determined by the prescriber
- The medication is prescribed by or in consultation with a hematologist
- Must not concurrently be using other factor VIII products or Hemlibra (emicizumab-kxwh)
- Must provide documentation of a platelet count ≥ 100,000 cells/µL (within 60 days)
- Must monitor the member for potential development of neutralizing antibodies/inhibitors to Factor VIII throughout treatment
- Surgical prophylaxis renewal requests: no reauthorization allowed

Non-MPC Renewal:

- Members who have previously been taking Altuviiio and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria).
- Member has not been receiving medication samples for Altuviiio
- Provider has a documented clinical response of the member's condition which has improved based or stabilized upon the prescriber's assessment

C. Altuviiio will be considered investigational or experimental for any other use and will not be covered.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• Up to 3 months
Reauthorization	• Up to 1 year • Surgical prophylaxis: no reauthorization allowed

Codes:

Code	Description
J7214	Injection, factorviii/von willebrand factor complex, recombinant (altuviiio), per factor viii

REFERENCES

1. Altuviiio™ [prescribing information]. Waltham, MA: Bioverativ Therapeutics Inc.; February 2023.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	*09/2023*