UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2110-9
Program	Prior Authorization/Medical Necessity
Medication	Adynovate® (antihemophilic factor [recombinant], pegylated)
P&T Approval Date	10/2016, 10/2017, 10/2018, 10/2019, 9/2020, 9/2021, 9/2022, 9/2023, 9/2024
Effective Date	12/1/2024

1. Background:

Adynovate (antihemophilic factor [recombinant], pegylated) is a recombinant antihemophilic factor indicated in adults and children with hemophilia A (congenital Factor VIII deficiency) for:[1]

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

Adynovate is not indicated for the treatment of von Willebrand disease.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Adynovate** will be approved based on **all** of the following criteria:[1-3]

   a. Diagnosis of hemophilia A

   -AND-

   b. Patient is not a suitable candidate for treatment with shorter acting half-life Factor VIII (recombinant) products [Advate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, or Recombinate] as attested by the prescriber

   -AND-

   c. **One** of the following:

      (1) **Both** of the following:

         (a) Patient is not to receive routine infusions more frequently than 2 times per week

         -AND-

         (b) Patient is not to receive a routine dose greater than 50 IU/kg

-OR-

(2) **All** of the following

(a) Patient is less than 12 years of age

-AND-

(b) Patient is not to receive routine infusions more frequently than 2 times per week

-AND-

(c) Patient is not to receive a routine dose greater than 70 IU/kg

Authorization of therapy will be issued for 12 months

B. Reauthorization

1. **Adynovate** will be approved based on **both** of the following criteria:

a. Documentation of positive clinical response to Adynovate therapy

-AND-

b. **One** of the following:

(1) **Both** of the following:

(a) Patient is not to receive routine infusions more frequently than 2 times per week

-AND-

(b) Patient is not to receive a routine dose greater than 50 IU/kg

-OR-

(2) **All** of the following

(a) Patient is less than 12 years of age

-AND-

(b) Patient is not to receive routine infusions more frequently than 2 times per week

-AND-

(c) Patient is not to receive a routine dose greater than 70 IU/kg

Authorization of therapy will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Adynovate® [package insert]. Lexington, MA: Baxalta US, Inc., August 2023.
2. Hoots WK, Shapiro AD. Hemophilia A and B: Routine management including prophylaxis. In: UpToDate, Waltham, MA, 2024.
3. Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. MASAC Document #284, April 11, 2024.

Program	Prior Authorization/Medical Necessity - Adynovate
Change Control	
10/2016	New program.
10/2017	Updated background and criteria to note updated indication. Revised formatting without changes to clinical intent outside of new indication. Updated state mandate verbiage. Updated references.
10/2018	Annual review with no changes to coverage criteria. Updated reference.
10/2019	Annual review with no changes to coverage criteria. Updated reference.
9/2020	Modified criteria aligning with coverage criteria for other covered extended half-life recombinant factors. Removed exclusion notation since addition to coverage. Updated references.
9/2021	Annual review with no changes to coverage criteria. Updated reference.
9/2022	Annual review with no changes to coverage criteria. Updated references.
9/2023	Annual review. Modified physician attestation to prescriber attestation. Updated references.
9/2024	Annual review with no changes to coverage criteria. Updated references.