UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 2110-3
Program	Prior Authorization/Medical Necessity
Medication	Adynovate (antihemophilic factor [recombinant], pegylated)*
P&T Approval Date	10/2016, 10/2017, 10/2018
Effective Date	2/1/2019; Oxford only: 2/1/2019

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:[1-6]

a. Diagnosis of hemophilia A

-AND-

b. **One** of the following:

(1) Submission of documentation showing failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level) after a trial of **three** of the following recombinant factor products:

i. Kogenate FS
ii. Kovaltry
iii. NovoEight
iv. Nuwiq

-OR-

(2) Submission of documentation showing history of hypersensitivity to **three** of the following recombinant factor products:

i. Kogenate FS
ii. Kovaltry
iii. NovoEight
iv. Nuwiq

-OR-

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

i. Patient is currently on **Adynovate**

-AND-

ii. Physician attestation that patient would preferentially benefit from **Adynovate** based on **one** of the following:

1. Patient is at high risk for the development of inhibitors (e.g., family history of inhibitors and success with product, current treatment less than 50 days, high risk genetic mutation, history of initial intensive therapy greater than 5 days)
2. Patient has developed inhibitors
3. Patient has undergone immune tolerance induction/immune tolerance therapy

Authorization of therapy will be issued for 12 months

B. Reauthorization

1. **Adynovate** will be approved based on the following criterion:

a. Documentation of positive clinical response to Adynovate therapy.

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

* Adynovate is excluded for the majority of our benefits

3. Additional Clinical Programs:
N/A

4. References:

1. Adynovate® [package insert]. Westlake Village, CA: Baxalta US, Inc., March 2017.
2. ter Avest PC, Fischer K, Mancuso ME, Santagostino E, Yuste VJ, van den Berg HM, van der Bom JG, on behalf of the CANAL Study Group. Risk stratification for inhibitor development at first treatment for severe hemophilia A: a tool for clinical practice. J Thromb Haemost. 2008; 6: 2048–54.
3. Hoots WK, Shapiro AD. Treatment of hemophilia. In: UpToDate, Waltham, MA, 2016.
4. Hoots WK, Shapiro AD. Factor VIII and factor IX inhibitors in patients with hemophilia. In: UpToDate, Waltham, MA, 2016.
5. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. MASAC Document #253, April 23, 2018.
6. MASAC Recommendation on SIPPET (Survey of Inhibitors in Plasma-Product-Exposed Toddlers): Results and Recommendations for Treatment Products for Previously Untreated Patients with Hemophilia A. MASAC Document #243, June 28 2016.

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.