UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2158-7
Program	Prior Authorization/Medical Necessity
Medication	Jivi® (antihemophilic factor [recombinant], PEGylated-aucl)
P&T Approval Date	1/2019, 2/2020, 9/2020, 9/2021, 9/2022, 9/2023, 9/2024
Effective Date	12/1/2024

1. Background

Jivi (antihemophilic factor [recombinant], PEGylated-aucl) is a recombinant DNA-derived, Factor VIII concentrate indicated for use in previously treated adults and adolescents (12 years of age and older) 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 of bleeding

Jivi is not indicated for use in children < 12 years of age due to a greater risk for hypersensitivity reactions. Jivi is not indicated for use in previously untreated patients (PUPs). Jivi is not indicated for the treatment of von Willebrand disease.

2. Coverage Criteria[a]:

A. Initial Authorization:

1. Jivi will be approved based on **all** of the following criteria:

   a. Diagnosis of hemophilia A

   -AND-

   b. Patient is 12 years of age or older

   -AND-

   c. Patient has previously received Factor VIII replacement therapy

   -AND-

   d. 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-

   e. Patient is not to receive routine infusions more frequently than 2 times per week

Authorization of therapy will be issued for 12 months.

B. Reauthorization

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

   a. Documentation of positive clinical response to **Jivi** therapy.

   -AND-

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

   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. Jivi® [package insert]. Whippany, BJ: Bayer HealthCare, LLC., August 2018.
2. MASAC 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 - Jivi
Change Control	
1/2019	New program.
2/2020	Annual review with no changes to clinical coverage criteria.
9/2020	Updated preferred standard half-life recombinant products. Updated reference.
9/2021	Annual review with no changes to clinical coverage criteria.
9/2022	Annual review with no changes to clinical coverage criteria. Updated background per prescribing information and updated references.
9/2023	Annual review. Modified physician attestation to prescriber attestation. Updated references.
9/2024	Annual review with no changes to clinical coverage criteria. Updated references.