

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2024 P 1272-6 |
| Program | Prior Authorization/Notification |
| Medication | Jivi® (antihemophilic factor [recombinant], PEGylated-aucl) |
| P&T Approval Date | 1/2019, 2/2020, 2/2021, 2/2022, 2/2023, 2/2024 |
| Effective Date | 5/1/2024 |

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 prevent or 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. Jivi is being prescribed for **one** of the following:

- (1) Treatment of bleeding episodes
- (2) Prevention of bleeding in surgical interventions or invasive procedures (e.g., surgical prophylaxis)
- (3) Prevention of bleeding episodes (i.e., routine prophylaxis)

Authorization of therapy will be issued for 12 months.

B. Reauthorization

1. **Jivi** will be approved based on the following criterion:
 - a. Documentation of positive clinical response to **Jivi** 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.

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.
- Medical necessity may be in place.

4. References:

1. Jivi® [package insert]. Whippany, NJ: Bayer HealthCare, LLC., August 2018.
2. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. MASCA Document #280, August 20, 2023.

| Program | Prior Authorization/Notification - Jivi |
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| Change Control | |
| 1/2019 | New program. |
| 2/2020 | Annual update with no change to clinical coverage criteria. |
| 2/2021 | Annual review with no changes to clinical coverage criteria. |
| 2/2022 | Annual review with no changes to clinical coverage criteria. Updated references. |
| 2/2023 | Annual review with no changes to clinical coverage criteria. Added state mandate and updated references. |
| 2/2024 | Annual review with no changes to clinical coverage criteria. Updated references. |