



Easy Choice Health Plan

Missouri Care

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona

OneCare (Care1st Health Plan Arizona, Inc.)

Staywell of Florida

WellCare (Arizona, Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

WellCare Prescription Insurance

WellCare Texan Plus (Medicare – Dallas & Houston markets)

JIVI®

Policy Number: HS-339

Original Effective Date: 9/6/2018

Revised Date(s): N/A

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

Hemophilia A, factor VIII deficiency, is a recessive X-chromosome linked inherited coagulation factor deficiency that result in a lifelong bleeding disorder. Eighty to eighty-five percent of people with hemophilia have hemophilia A and Factor VIII inhibitors have been reported in approximately 25 to 30 percent of patients with severe hemophilia A. People with this disease lack a protein that among others causes the blood to clot as part of the natural wound-healing process. The disorder primarily affects men and the severity and frequency of bleeding episodes varies from one person to another. Severe hemophilia is characterized by spontaneous bleeding into joints, muscles and various organs. This bleeding can lead to permanent disability and even death. With proper medical management patients are typically able to lead normal lives.^{1,2,3}

Optimal medical management of hemophilia A is complex and should not only include this prophylactic treatment but also methods to minimize bleeding risk, modifications to facilitate routine comprehensive care, and counseling

regarding psychosocial issues and disease inheritance. The goal of therapy is to reduce the risk of complications related to bleeding episodes. Prophylactic treatment involves regular intravenous injections of clotting factors to prevent regular spontaneous bleeds and joint damage. Some patients must receive these injections on an every other day basis from toddler age.^{1,3}

JIVI® [antihemophilic factor (recombinant), PEGylated-aucl] is an antihemophilic factor (recombinant) indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency). It is used to for on-demand treatment and control of bleeding episodes, perioperative management of bleeding and routine prophylaxis to reduce the frequency of bleeding episodes. JIVI® gained initial U.S. approval in 2018.⁴

JIVI® is for intravenous use after reconstitution only. It is recommended that JIVI® is initially infused at 30–40 IU/kg twice weekly. Based on the bleeding episodes it can be adjusted to 45–60 IU/kg every 5 days. The regimen may be further individually adjusted to less or more frequent dosing.⁴

The most frequently reported adverse reactions in clinical trials in previously treated patients 12 years of age and older were headache, cough, nausea and fever.⁴

POSITION STATEMENT

Applicable To:

- Medicaid – All Markets
- Medicare – All Markets

Exclusions

JIVI® is not considered medically necessary and **not a covered benefit** when any of the following apply:

1. Diagnosis of any bleeding disorder other than hemophilia A; **OR**,
2. Documented presence or history of FVIII inhibitor antibodies (≥ 0.6 BU/mL); **OR**,
3. Members under the age of 12 years old; **OR**,
4. Members who have not had any other previous treatment; **OR**,
5. Jivi is not indicated for the treatment of von Willebrand disease.

Coverage

JIVI® is **considered medically necessary** for treatment or prophylaxis of bleeds in members with severe hemophilia A when all of the following criteria are met:

Initial Authorization:

1. Member is age 12 or older; **AND**,
2. Member has documented therapy with any FVIII product for ≥ 150 exposure days; **AND**,
3. Member has documentation of platelet count $\geq 100,000/\text{mm}^3$.

Continuation of Care:

Continued therapy with JIVI® is **considered medically necessary** when the following criteria is met:

1. Member has shown one of the following responses to therapy:
 - A. Adequate decrease in bleeding events (if used for prophylaxis); **OR**,
 - B. Adequate response to therapy when used for treatment of bleeds.

CODING

Covered CPT Codes – None.

Covered HCPCS Code

J7196 Injection, antithrombin recombinant, 50 IU

Covered ICD-10 Codes – Any applicable.

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

1. Hoots, W.K., Shapiro, A.D. Hemophilia A and B: Routine management including prophylaxis. UpToDate Web Site www.uptodate.com. Published June 19, 2018. Accessed July 26, 2018.
2. Hoots, W.K., Shapiro, A.D. Factor VIII and factor IX inhibitors in patients with hemophilia. UpToDate Web Site www.uptodate.com. Published November 7 2017. Accessed July 26, 2018.
3. Research focus – hemophilia. Bayer Web site <http://pharma.bayer.com/en/innovation-partnering/research-focus/hemophilia/>. Accessed July 25, 2018.
4. Jivi package insert. Bayer HealthCare LLC. 2018

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

| Date | Action |
|-----------|---|
| 09/6/2018 | <ul style="list-style-type: none">• Approved by MPC. New. |