Adakveo (crizanlizumab-tmca)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Adakveo is indicated to reduce the frequency of vasoocclusive crises (VOCs) in adults and pediatric patients aged 16 years and older with sickle cell disease.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial therapy requests
   1. Documentation of baseline incidence of vasoocclusive crises
   2. Documentation of treatment failure, intolerance or contraindication to hydroxyurea if not currently receiving hydroxyurea

B. Continuation of therapy requests
   1. Documentation supporting the clinical benefit of Adakveo therapy (i.e., reduction in the frequency of vasoocclusive crises or the maintenance of the reduction of vasoocclusive crises, since initiating therapy with Adakveo)
   2. Documentation of treatment failure, intolerance or contraindication to hydroxyurea if not currently receiving hydroxyurea

Criteria for Initial Approval

A. Adakveo (crizanlizumab-tmca) may be considered medically necessary to reduce the frequency of vasoocclusive crises in members with sickle cell disease when the following criteria are met:
   1. The member is 16 years of age or older
   2. The member has a diagnosis of sickle cell disease of any genotype, including, but not limited to, homozygous hemoglobin S [HbSS], sickle hemoglobin C disease [HbSC], sickle beta^0 thalassemia, and sickle beta$^+$ thalassemia
   3. Adakveo is prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease
   4. The member has previously experienced 2 or more sickle cell-related vasoocclusive crises within the previous 12 months as determined by medical documentation
   5. The member is currently receiving and will continue to receive hydroxyurea in conjunction with Adakveo; OR the member has a documented history of treatment failure, intolerance or contraindication to hydroxyurea
   6. Adakveo will not be used in conjunction with Oxbryta (voxelotor)

Approval will be for **6 months**

Continuation of Therapy

A. Continued treatment with Adakveo (crizanlizumab-tmca) may be considered medically necessary to reduce the frequency of vasoocclusive crises in members with sickle cell disease when the following criteria are met:
   1. The member has a diagnosis of a sickle cell disease, including, but not limited to, homozygous hemoglobin S [HbSS], sickle hemoglobin C disease [HbSC], sickle beta^0 thalassemia, and sickle beta$^+$ thalassemia
   2. Adakveo is prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease
   3. The member has experienced a positive clinical benefit to Adakveo therapy as evidenced by a documented reduction in the frequency of vasoocclusive crises since baseline, or has maintained such reduction, since initiating therapy with Adakveo.
   4. The member is currently receiving hydroxyurea; OR the member has a documented history of treatment failure, intolerance or contraindication to hydroxyurea
   5. Adakveo will not be used in conjunction with Oxbryta (voxelotor)

Approval will be for **12 months**

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J0791 - Injection, crizanlizumab-tmca, 5 mg

REFERENCES

- Adakveo [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2022.

- Ataga KI, Kutlar A, Kanter J, et al. Crizanlizumab for the prevention of pain crises in sickle cell disease. N Engl J Med. 2017;376(5):429-439.
- Kutlar A, Kanter J, Liles DK, et al. Effect of Crizanlizumab on pain crises in subgroups of patients with sickle cell disease: A SUSTAIN study analysis. Am J Hematol. 2019;94:55-61.
- U.S. Food and Drug Administration (FDA). FDA approves first targeted therapy to treat patients with painful complication of sickle cell disease. Silver Spring, MD: FDA; November 15, 2019.
- Han J, Saraf SL, & Gordeuk VR. Systematic Review of Crizanlizumab: A New Parenteral Option to Reduce Vaso-occlusive Pain Crises in Patients with Sickle Cell Disease. *Pharmacotherapy.* 2020;40(6):535-543.

POLICY HISTORY

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