

crizanlizumab-tmca (Adakveo)

Commercial Medical Benefit Drug Policy

Place of Service

Home Infusion Administration

Infusion Center Administration

Office Administration

Outpatient Facility Infusion Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT

Mechanism of Action: P Selectin Blocker

HCPCS:

J0791:Injection, crizanlizumab-tmca, 5 mg

How Supplied:

100 mg (single-dose vial)

Condition(s) listed in policy (see coverage criteria for details)

- Sickle Cell Disease

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF ADAKVEO IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE
REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted*)

1. Patient is receiving their first two infusions of Adakveo or is being re-initiated on Adakveo after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Adakveo based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Adakveo based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Sickle Cell Disease

Meets medical necessity if all the following are met:

1. Patient is at least 16 years of age
2. Inadequate response, intolerable side effect, or contraindication to hydroxyurea or being added on to existing hydroxyurea therapy

Covered Doses:

Up to 5 mg/kg given intravenously at Week 0, Week 2, and every 4 weeks thereafter

Coverage Period:

Indefinitely

ICD-10:

D57.00, D57.01, D57.02, D57.1, D57.20, D57.211, D57.212, D57.219, D57.40, D57.411, D57.412, D57.419, D57.80, D57.811, D57.812, D57.819

References

1. Adakveo (crizanlizumab-tmca) Prescribing Information. Novartis, East Hanover, NJ: 6/2024.
2. AHFS. Available by subscription at <http://www.lexi.com>
3. DeBaun MR, Jordan LC, King AA, Schatz J, Vichinsky E, Fox CK, McKinstry RC, Telfer P, Kraut MA, Daraz L, Kirkham FJ, Murad MH. American Society of Hematology 2020 guidelines for sickle cell disease: prevention, diagnosis, and treatment of cerebrovascular disease in children and adults. *Blood Adv.* 2020 Apr 28;4(8):1554-1588.
4. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>

5. Yawn BP, Buchanan GR, Afenyi-Annan AN, et al. Management of sickle cell disease: summary of the 2014 evidence-based report by expert panel members. *JAMA*. 2014;312(10):1033-1048.

Review History

Date of Last Annual Review: 1Q2025

Changes from previous policy version:

- No clinical change following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity

Reviewed by P&T Committee