# POLICY Document for ADAKVEO (crizanlizumab-tmca)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall, clinically appropriate use. This document provides specific information to each of the three sections of the overall policy.

**Section 1: Site of Care**

- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

**Section 2: Clinical Criteria**

- Policy information specific to the clinical appropriateness for the medication

## Section 1: Site of Care

### Site of Care Criteria
### Administration of Intravenous Adakveo

**POLICY**

**I. CRITERIA FOR APPROVAL FOR ADMINISTRATION IN OUTPATIENT HOSPITAL SETTING**

This policy provides coverage for administration of Adakveo in an outpatient hospital setting for up to 45 days when a member is new to therapy or is reinitiating therapy after not being on therapy for at least 6 months.

This policy provides coverage for administration of Adakveo in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

A. The member has experienced an adverse reaction that did not respond to conventional interventions (eg, acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion.
B. The member is medically unstable (e.g., respiratory, cardiovascular, or renal conditions).
C. The member has severe venous access issues that require the use of a special interventions only available in the outpatient hospital setting.
D. The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver.
E. Alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home.
F. The member is less than 14 years of age.

For situations where administration of Adakveo does not meet the criteria for outpatient hospital infusion, coverage for Adakveo is provided when administered in alternative sites such as; physician office, home infusion or ambulatory care.

**II. REQUIRED DOCUMENTATION**

The following information is necessary to initiate the site of care prior authorization review (where applicable):

A. Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after an infusion

B. Medical records supporting the member is medically unstable
C. Medical records supporting the member has severe venous access issues that require specialized interventions only available in the outpatient hospital setting
D. Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
E. Records supporting alternative infusion sites are greater than 30 miles from the member's home
F. Medical records supporting the member is new to therapy

# Section 2: Clinical Criteria

# Specialty Guideline Management
# Adakveo

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over the counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
|---|---|
| Adakveo | crizanlizumab-tmca |

## Indications

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 vaso-occlusive crises (VOCs) in adults and pediatric patients aged 16 years and older with sickle cell disease.

All other indications are considered experimental/investigational and not medically necessary.

## Prescriber Specialties

This medication must be prescribed by or in consultation with a hematologist or specialist in sickle cell disease.

## Coverage Criteria

**Sickle cell disease, to reduce the frequency of vaso-occlusive crises**

Authorization of 12 months may be granted for use in reducing the frequency of vaso-occlusive crises (VOCs) in members 16 years of age or older with sickle cell disease when both of the following criteria are met:

The member has experienced at least one vaso-occlusive crisis within the previous 12 months
The member meets either of the following:
- Member has sickle hemoglobin C (HbSC), sickle $\beta^+$-thalassemia (HbS$\beta^+$), or other genotypic variants of sickle cell disease (e.g., HbS-O Arab, HbS-Lepore).
- Member has homozygous hemoglobin S (HbSS) or sickle $\beta^0$-thalassemia (HbS$\beta^0$) genotype AND meets any of the following:
  - Has experienced, at any time in the past, an inadequate response or intolerance to a trial of hydroxyurea
  - Has a contraindication to hydroxyurea
  - Will be using Adakveo with concurrent hydroxyurea therapy

## Continuation of Therapy

**Sickle cell disease, to reduce the frequency of vaso-occlusive crises**

Authorization of 12 months may be granted for continued treatment when the member has experienced a reduction in the frequency of vaso-occlusive crises, or has maintained such reduction, since initiating therapy with Adakveo.

## REFERENCES


**SECTION 1**

1. Adakveo [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation.; June 2024.

**SECTION 2**

1. Adakveo [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2024.
2. 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.
3. Evidence-Based Management of Sickle Cell Disease. Expert Panel Report, 2014. National Institutes of Health. Available at https://www.nhlbi.nih.gov/health-topics/evidence-based-management-sickle-cell-disease. Accessed July 1, 2024.