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5.85.036

Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Hematological Agents	**Original Policy Date:**	December 13, 2019
Subject:	Adakveo	**Page:**	1 of 4

Last Review Date: March 6, 2026

Adakveo

Description

Adakveo (crizanlizumab-tmca)

Background
Adakveo (crizanlizumab-tmca) is a first-in-class, humanized IgG2 kappa monoclonal antibody that binds to P-selectin and blocks interactions with its ligands including P-selectin glycoprotein ligand 1. Binding P-selectin on the surface of the activated endothelium and platelets blocks interactions between endothelial cells, platelets, red blood cells, and leukocytes. It is indicated to reduce the frequency of vasoocclusive crises in patients with sickle cell disease (SCD). Sickle cell disease is an inherited blood disorder in which the red blood cells are abnormally shaped (in a crescent, or "sickle," shape). This restricts the flow in blood vessels and limits oxygen delivery to the body’s tissues, leading to severe pain and organ damage (1).

Two effective disease-modifying therapies for SCD (hydroxyurea and chronic transfusion) are potentially widely available but remain underutilized. These are the only currently proven disease-modifying treatments for people with SCD. Both therapies are used in primary and secondary stroke prevention. Although neither has been shown to prevent all SCD-related organ damage, these treatment modalities can improve the quality of life for individuals with SCD. Currently, the only cure for sickle cell disease is a blood and bone marrow transplant though transplant is not for everyone (2).

Regulatory Status
FDA-approved indication: Adakveo is a selectin blocker indicated to reduce the frequency of vasoocclusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease (1).

Infusion-related reactions have occurred in patients treated with Adakveo. Patients should be monitored for signs and symptoms of infusion-related reactions, including fever, chills, nausea, vomiting, fatigue, dizziness, pruritus, urticarial, sweating, shortness of breath, or wheezing. Adakveo should be discontinued for severe reactions (1).

Adakveo should be prepared and administered by a healthcare professional (1).

The results of the efficacy analysis did not confirm the statistical superiority of Adakveo over placebo in reducing vasoocclusive crises leading to a healthcare visit over the first-year post randomization (1).

The safety and effectiveness of Adakveo in pediatric patients less than 16 years of age have not been established (1).

Related policies
Endari, Oxbryta, Siklos

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Adakveo may be considered **medically necessary** if the conditions indicated below are met.

Adakveo may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 16 years of age or older

Diagnosis

Patient must have the following:

Vasoocclusive crises associated with Sickle Cell Disease (SCD)

AND ALL of the following:

1. Inadequate treatment response, intolerance, or contraindication (i.e., renal, cardiovascular, GI) to a 3 month trial of generic hydroxyurea

2. Adakveo will be administered by a healthcare professional
3. Prescriber agrees to monitor for infusion-related reactions
4. Prescriber agrees to monitor for the development of late evolving antibodies

Prior – Approval *Renewal* Requirements

Age 16 years of age or older

Diagnosis

Patient must have the following:

Vasoocclusive crises associated with Sickle Cell Disease (SCD)

AND ALL of the following:

1. Reduction in the number of vasoocclusive crises since initiating therapy
2. Adakveo will be administered by a healthcare professional
3. Prescriber agrees to monitor for infusion-related reactions
4. Prescriber agrees to monitor for the development of late evolving antibodies

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Adakveo is used in the treatment for patients with sickle cell disease to reduce severe complications associated with the blood disorder. Sickle cell disease is an inherited blood disorder in which the red blood cells are abnormally shaped (in a crescent, or "sickle," shape). This restricts the flow in blood vessels and limits oxygen delivery to the body's tissues, leading to severe pain and organ damage. The safety and effectiveness of Adakveo in pediatric patients less than 16 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Adakveo while maintaining optimal therapeutic outcomes.

References

1. Adakveo [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2024.
2. Gibbons G, Shurin S, et al. Evidence-Based Management of Sickle Cell Disease: Expert Panel Report (EPR), 2014. U.S. Department of Health and Human Services National Institutes of Health.

Policy History

Date	Action
December 2019	Addition to PA
March 2020	Annual review. Addition of requirement to monitor for the development of late evolving antibodies per SME
March 2021	Annual review
March 2022	Annual review and reference update
June 2022	Annual review
March 2023	Annual review and reference update. Changed policy number to 5.85.036
June 2023	Annual review
March 2024	Annual review
June 2024	Annual review
March 2025	Annual review and reference update
June 2025	Annual review. Per SME, added requirement to t/f hydroxyurea and statement in regulatory section regarding the lack of statistical significance of Adakveo over placebo
March 2026	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.