

5.85.36

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Hematological Agents	Original Policy Date:	December 13, 2019
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Last Review Date: March 12, 2021

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).

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

Related policies

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** in patients 16 years of age or older with vasoocclusive crises associated with sickle cell disease (SCD) and if the conditions indicated below are met.

Adakveo is considered **investigational** in patients less than 16 years of age and 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. Adakveo will be administered by a healthcare professional
2. Prescriber agrees to monitor for infusion-related reactions

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3. 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:

Vasocclusive crises associated with Sickle Cell Disease (SCD)

AND ALL of the following:

1. Reduction in the number of vasocclusive 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

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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; November 2019.
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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.