

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 β^+ -thalassemia (HbS β^+), or other genotypic variants of sickle cell disease (e.g., HbS-O Arab, HbS-Lepore).
 - Member has homozygous hemoglobin S (HbSS) or sickle β^0 -thalassemia (HbS β^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

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.