



## UTILIZATION MANAGEMENT MEDICAL POLICY

**POLICY:** Sickle Cell Disease – Adakveo Utilization Management Medical Policy

- Adakveo® (crizanlizumab-tmca intravenous infusion– Novartis)

**REVIEW DATE:** 12/07/2022

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### OVERVIEW

Adakveo, a monoclonal antibody, is indicated to **reduce the frequency of vasoocclusive crises** in patients 16 years and older with **sickle cell disease**.<sup>1</sup>

Adakveo is given by intravenous infusion over a period of 30 minutes at Week 0, Week 2, and every 4 weeks thereafter; the dose is 5 mg/kg.

### Guidelines

The American Society of Hematology guidelines for sickle cell disease: management of acute and chronic pain associated with sickle cell disease (2020) does not address the use of Adakveo.<sup>2</sup> The National Institutes of Health – National Heart, Lung, and Blood Institute issued the Evidence-Based Management of Sickle Cell Disease, Expert Panel Report in 2014.<sup>3</sup> These guidelines were published prior to the approval of Adakveo. Hydroxyurea has been shown to reduce the frequency of painful episodes, the incidence of acute coronary syndrome events, and the need for transfusions and hospitalizations.

### POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Adakveo. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Adakveo as well as the monitoring required for adverse events and long-term efficacy, approval requires Adakveo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Adakveo is recommended in those who meet the following criteria:

#### FDA-Approved Indication

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- I. Sickle Cell Disease.** Approve for 1 year if the patient meets the following criteria (A or B):
  - A) Initial Therapy.** Approve if the patient meets ALL of the following criteria (i, ii, iii, and iv):
    - i.** Patient is  $\geq 16$  years of age; AND
    - ii.** Patient has had at least one sickle cell-related crisis in the previous 12-month period; AND
    - iii.** Patient meets ONE of the following criteria (a, b, or c):
      - a)** Patient is currently receiving a hydroxyurea product; OR

- b) According to the prescriber, patient has tried a hydroxyurea product and has experienced inadequate efficacy or significant intolerance; OR
  - c) According to the prescriber, patient is not a candidate for hydroxyurea therapy; AND  
Note: Examples of patients who are not candidates for hydroxyurea therapy include patients who are pregnant or who are planning to become pregnant and patients with an immunosuppressive condition (such as cancer).
  - iv. The medication is prescribed by or in consultation with a physician who specializes in sickle cell disease (e.g., a hematologist).
- B) Patient is Currently Receiving Adakveo.** Approve if the patient meets ALL of the following criteria (i, ii, and iii):
- i. Patient is  $\geq 16$  years of age; AND
  - ii. According to the prescriber, patient is receiving clinical benefit from Adakveo therapy; AND  
Note: Examples of clinical benefit include reduction in the number of vasoocclusive crises/sickle cell-related crises; delay in time to sickle cell-related crises; and reduction in the number of days in the hospital.
  - iii. The medication is prescribed by or in consultation with a physician who specializes in sickle cell disease (e.g., a hematologist).

**Dosing.** Approve the following dosing regimens (A and B):

A) Up to 5 mg/kg given by intravenous infusion at Weeks 0 and 2; AND

B) Up to 5 mg/kg given by intravenous infusion for up to once every 4 weeks.

#### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Adakveo is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

#### REFERENCES

1. Adakveo<sup>®</sup> intravenous infusion [prescribing information]. East Hanover, NJ: Novartis; September 2022.
2. Brandow AM, Carroll CP, Creary S, et al. American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. *Blood Adv.* 2020;4:2656-2701.
3. The National Institutes of Health – National Heart, Lung, and Blood Institute Evidence-Based Management of Sickle Cell Disease, Expert Panel Report 2014. Available at: [https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816\\_0.pdf](https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf). Accessed on November 28, 2022.

#### HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/01/2021
Annual Revision	No criteria changes.	12/07/2022