

STANDARD MEDICARE PART B MANAGEMENT

ADAKVEO (crizanlizumab-tmca)

POLICY

I. 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 vasoocclusive crises (VOCs) in adults and pediatric patients aged 16 years and older with sickle cell disease.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Sickle cell disease, to reduce the frequency of vasoocclusive crises

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

- A. The member has experienced at least one vasoocclusive crisis within the previous 12 months
- B. The member meets either of the following:
 - 1. Member has sickle hemoglobin C (HbSC) or sickle β^+ -thalassemia (HbS β^+) genotype
 - 2. Member has homozygous hemoglobin S (HbSS) or sickle β^0 -thalassemia (HbS β^0) genotype AND meets any of the following:
 - i. Has experienced, at any time in the past, an inadequate response or intolerance to a trial of hydroxyurea.
 - ii. Has a contraindication to hydroxyurea.
 - iii. Will be using Adakveo with concurrent hydroxyurea therapy.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- A. The member is currently receiving therapy with Adakveo.
- B. Adakveo is being used to treat an indication enumerated in Section II.
- C. The member is receiving benefit from therapy. Benefit is defined as reduction in the frequency of vasoocclusive crises, or maintenance of such reduction, since initiating therapy with Adakveo.

Reference number(s)
3416-A

IV. REFERENCES

1. Adakveo [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2021.
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.