Crizanlizumab-tmca (Adakveo®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

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 ~~FOR INITIAL APPROVAL~~

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 vasoocclusive 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 vasoocclusive crisis within the previous 12 months
- The member meets either of the following: ~~(1 or 2):~~
  - Member has sickle hemoglobin C (HbSC), ~~or~~ sickle β^+-thalassemia (HbSβ^+), 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 (HbSβ^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 vasoocclusive crises

Authorization of 12 months may be granted for continued treatment when the member has experienced a reduction in the frequency of vasoocclusive crises, or has maintained such reduction, since initiating therapy with Adakveo.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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.

EFFECTIVE DATE

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