# Pharmacy Medical Necessity Guidelines: Adakveo® (crizanlizumab-tmca)

*Effective: April 20, 2020*

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|---|---|---|---|
| Prior Authorization Required | √ | Type of Review – Care Management | |
| Not Covered | | Type of Review – Clinical Review | √ |
| Pharmacy (RX) or Medical (MED) Benefit | MED | Department to Review | PRECERT/ MM |

These pharmacy medical necessity guidelines apply to the following:

**Commercial Products**

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Tufts Health Public Plans Products**

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

**Fax Numbers:**

All plans except Tufts Health Public Plans:
PRECERT: 617.972.9409

Tufts Health Public Plans:
MM: 888.415.9055

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

## OVERVIEW

**FOOD AND DRUG ADMINISTRATION (FDA)-APPROVED INDICATIONS**

Adakveo (crizanlizumab-tmca) 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.

## COVERAGE GUIDELINES

The plan may authorize coverage of Adakveo (crizanlizumab-tmca) for Members, when the following criteria are met:

**Initial Therapy**

1. Documented diagnosis of sickle cell disease

**AND**

2. Member is at least 16 years of age

**AND**

3. Prescribed by or in consultation with a hematologist or sickle cell disease specialist

**AND**

4. Documentation the Member experienced at least two sickle cell-related vasoocclusive crises within the previous 12 months

**AND**

5. Documentation of one of the following:
   a. Member is currently receiving hydroxyurea therapy
   b. Member has a previous treatment failure, intolerance, or contraindication to hydroxyurea therapy

**Reauthorization Criteria**

1. Documented diagnosis of sickle cell disease

**AND**

2. The Member is at least 16 years of age

**AND**

3. Prescribed by or in consultation with a hematologist or sickle cell disease specialist

**AND**

4. Documentation of one of the following:
   a. Member is currently receiving hydroxyurea therapy
   b. Member has a previous treatment failure, intolerance, or contraindication to hydroxyurea therapy

**AND**

5. Documentation the Member has experienced a therapeutic response as defined by at least one of the following:
    a. Reduction in sickle cell-related vasoocclusive crises from pretreatment baseline
    b. Decrease in severity of sickle cell-related vasoocclusive crises from pretreatment baseline

## LIMITATIONS

- Initial approval by the plan will be limited to 6 months. Reauthorizations will be provided in 12-month intervals.
- Members new to the plan stable on Adakveo (crizanlizumab-tmca) should be reviewed against the Reauthorization Criteria.

## CODES

The following HCPCS/CPT code(s) are:

| Code | Description |
|---|---|
| J0791 | Injection, crizanlizumab-tmca, 5 mg |

## REFERENCES


1. Adakveo (crizanlizumab) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2019.
2. Ataga K, Kutlar A, Kanter J, et al. Crizanlizumab for the prevention of pain crises in sickle cell disease. N Engl J Med. 2017;376:429-39.
3. Kutlar A, Kanter J, Liles DK, et al. Effective of crizanlizumab on pain crises in subgroups of patients with sickle cell disease: A SUSTAIN study analysis. Am J Hematol. 2019 Jan;94(1):55-61.
4. Yawn BP, John-Sowah. Management of sickle cell disease: recommendations from he 2014 Expert Panel Report. Am Fam Physician. 2015 Dec 15;92(12):1069-76A.


## APPROVAL HISTORY

April 14, 2020: Reviewed by Pharmacy & Therapeutics Committee.

## BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.