Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Adakveo® (crizanlizumab-tmca)

Effective: December 9, 2025

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration - Approved Indications

Adakveo (crizanlizumab-tmca) is a selectin blocker indicated to reduce the frequency of vaso-occlusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease

Clinical Guideline Coverage Criteria

The plan may authorize Adakveo for Members when **ALL** the following clinical criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of sickle cell disease

AND

2. Patients is at least 16 years of age or older

AND

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

AND

4. Documentation the Member experienced at least one (1) sickle cell-related vaso-occlusive crises within the previous 12 months

AND

5. Documentation of **one (1)** 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. Patient is at least 16 years of age or older

AND

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

AND

4. Documentation of **one (1)** 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 (1)** of the following:
    a. Reduction in sickle cell-related vaso-occlusive crises from pretreatment baseline
    b. Decrease in severity of sickle cell-related vaso-occlusive crises from pretreatment baseline

Limitations

- Initial approval of Adakveo will be authorized for 12 months. Reauthorization of Adakveo will be provided in 12- month intervals.
- Members new to the plan stable on Adakveo should be reviewed against the Reauthorization Criteria.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0791	Injection, crizanlizumab-tmca, 5 mg

References

1. Adakveo (crizanlizumab) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2025.
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 the 2014 Expert Panel Report. Am Fam Physician. 2015 Dec 15;92(12):1069-76A.
5. Vichinsky, E et al. Disease-modifying therapies to prevent pain and other complications of sickle cell disease. UpToDate. October 21, 2021. Accessed online January 31, 2022 at https://www.uptodate.com/contents/disease-modifying-therapies-to-prevent-pain-and-other-complications-of-sickle-cell-disease?search=adakveo&source=search_result&selectedTitle=2~11&usage_type=default&display_rank=1#H80649345

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- November 14, 2023: No changes
- November 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024
- November 2024: No changes
- December 9, 2025: No clinical changes. Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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