Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:
Medical Benefit Drugs
Niktimvo™ (axatilimab-csfr)

Effective: February 10, 2026

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

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:

Niktimvo (axatilimab-csfr) is a colony stimulating factor-1 receptor-blocking antibody indicated for the treatment of chronic graft-versus-host disease after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg.

Clinical Guideline Coverage Criteria

The plan may authorize Niktimvo for Members, when the following criteria are met:

1. Documented diagnosis of chronic graft versus host disease

AND

2. The patient weighs at least 40 kg

AND

3. Documentation of failure with at least two prior lines of systemic therapies

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9038	INJ AXATILIMAB-CSFR 0.1 MG

References

1. Niktimvo (axatilimab-csfr) [package insert]. Wilmington, DE: Incyte Corporation; January 2025.
2. Ramachandran V, Kolli S, Strowd L. Review of graft-versus-host disease. Dermatol Clin. 2019;37(4):569-582. doi: 10.1016/j.det.2019.05.014.
3. Hamilton BK. Updates in chronic graft-versus-host disease. Hematology Am Soc Hematol Educ Program. 2021;2021(1):648–654.
4. Herzog S, et al. Chronic GVHD after steroid-sensitive, -dependent, and -refractory acute GVHD: incidence and clinical outcomes. Blood Adv. 2023;7(14):3644–3650.
5. Wolff D, et al. Safety and efficacy of axatilimab at 3 different doses in patients with chronic graft-versus-host disease (AGAVE-201). Blood. 2023;142(Suppl 1):1.

Approval And Revision History

February 11, 2025: Reviewed by Pharmacy and Therapeutics Committee (P&T) (eff 4/1/25)

February 10, 2026: No changes. Administrative update: removed Carelink from 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.