Harvard Pilgrim Health Care | TUFTS Health Plan

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

Effective: April 1, 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

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 in and pediatric patients weighing at least 40 kg.

Clinical Guideline Coverage Criteria

The plan may authorize Niktimvo when **ALL** the following criteria is 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; August 2024.
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)

March 2025: Joint Medical Policy and Health Care Services UM Committee review (eff 4/1/25).

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines 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.