Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Anktiva (nogapendekin alfa inbakicept-pmln)

Effective: September 15, 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 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 (FDA) - Approved Indications:

Anktiva (nogapendekin alfa inbakicept-pmln) is an interleukin-15 (IL-15) receptor agonist indicated with Bacillus Calmette-Guerin (BCG) for the treatment of adult patients with BCG-unresponsive non muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

Note: Providers and Members enrolled with Harvard Pilgrim Health Care may reference the HPHC/OncoHealth guideline located at https://oncohealth.us/medicalpolicies/harvardpilgrim/.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Anktiva (nogapendekin alfa inbakicept-pmln) for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of non muscle invasive bladder cancer with carcinoma in situ

AND

2. Documentation of Bacillus Calmette-Guerin -unresponsive disease defined as persistent or recurrent disease following a regimen of BCG that consisted of at least five of six doses of an initial induction course plus either at least two of three doses of maintenance therapy or at least two of six doses of a second induction course

AND

3. Documentation of use in combination with Bacillus Calmette-Guerin

AND

4. Prescribed by or in consultation with a urologist or oncologist

Limitations

None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9028	INJECTION, NOGAPENDEKIN ALFA INBAKICEPT-PMLN, FOR INTRAVESICAL USE, 1 MICROGRAM

References

1. Anktiva (nogapendekin alfa inbakicept-pmln) [package insert]. Culver City, CA; ImmunityBio, Inc.: April 2024.
2. Chamie K, et al. IL-15 Superagonist NAI in BCG-unresponsive non-muscle-invasive bladder cancer. NEJM Evid. 2023;2(1):EVIDoa2200167.
3. Suderman J, et al. Re: IL-15 Superagonist NAI in BCG Unresponsive non-muscle-invasive bladder cancer. Eur Urol. 2023;83(6):581.

Approval And Revision History

September 10, 2024: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- Administrative update: November 2024: Added J code 9028 and removed expired C Code C9169 (effective 1/1/25).
- September 9, 2025: No clinical changes. Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- September 15, 2026: Administrative updates: Template updated to remove CareLink from the Medical Necessity Guideline template. Template updated from “Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans” to “Tufts Health Together- MassHealth Accountable Care Partnership Plans.”

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.