Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Anktiva® (nogapendekin alfa inbakicept-pmln)

Effective: January 1, 2026

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

Public Plans Products

☒ 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

Bladder cancer is a malignancy involving the urinary system, with abnormal tissue developing in the lining of the bladder. Approval of Anktiva is based on the Phase 2/3 QUILT-3.032 trial which is a single-arm trial that enrolled 77 patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk non-muscle invasive bladder cancer **(**NMIBC) with carcinoma in situ (CIS) with or without Ta/T1 papillary disease following transurethral resection. BCG unresponsiveness was defined as persistent or recurrent CIS alone or with Ta/T1 disease within 12 months of completion of adequate BCG therapy. Adequate BCG therapy was defined as administration of at least 5 of 6 doses of an initial induction course plus either of at least 2 of 3 doses of maintenance therapy or at least 2 of 6 doses of a second induction course. Results demonstrated a complete response (CR) rate of 62% with Anktiva. The final median duration of response (DOR) has yet to be determined but DUR as of the November 2023 cut-off was more than 47 months and ongoing.

Within QUILT-3.032 adverse events in patients who received Anktiva were consistent with those reported with BCG alone.

Anktiva is approved as induction and maintenance therapy in combination with BCG.

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 nonmuscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Anktiva for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of nonmuscle 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 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T).

September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24).

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).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

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.