Reference number(s)
6477-A

Standard Medicare Part B Management Anktiva

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Anktiva	nogapendekin alfa inbakicept-pmln

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

Anktiva is indicated with Bacillus Calmette-Guérin (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.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Bladder Cancer[1]

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Authorization of 6 months may be granted for treatment of bladder cancer when all of the following criteria are met:

- The member has non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors
- The disease is Bacillus Calmette-Guerin (BCG)-unresponsive
- The requested medication will be used in combination with Bacillus Calmette-Guerin (BCG)
- The member will receive maintenance doses at months 4, 7, 10, 13 and 19 after induction therapy.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months [for a total of 24 maintenance doses (37 months of treatment)] may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat an indication listed in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen AND
    - No evidence of disease recurrence or progression while on the current regimen

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Anktiva.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Bladder Cancer

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

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References

1. Anktiva [package insert]. Bothell, WA: AGC Biologics; April 2024.

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