Medical Drug Clinical Criteria

Subject:	Anktiva (nogapendekin alfa inbakicept-pmln)		
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Overview

This document addresses the use of Anktiva (nogapendekin alfa inbakicept-pmln)). Anktiva is an interleukin-15 (IL-15) receptor agonist indicated with Bacillus Calmette-Guérin (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.

Definitions and Measures

ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:

- 0 = Fully active, able to carry on all pre-disease performance without restriction
- 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
- 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
- 5 = Dead

Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Anktiva (nogapendekin alfa inbakicept-pmln)

Requests for Anktiva (nogapendekin alfa inbakicept-pmln) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual is using as intravesical instillation; **AND**
III. Individual has a diagnosis of Bacillus Calmette-Guerin (BCG) unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without papillary tumors (Label); **AND**
IV. Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2; **AND**
V. Individual is using in combination with Bacillus Calmette-Guerin (BCG) treatment.

Requests for Anktiva (nogapendekin alfa inbakicept-pmln) may not be approved for the following:

I. Individual has muscle invasive (T2-T4), locally advanced, metastatic, or extra-vesical (i.e. urethra, ureter, or renal pelvis) urothelial carcinoma; **OR**
II. When the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9999	Not otherwise classified, antineoplastic drugs (Anktiva)
C9399	Unclassified drugs or biologics (Anktiva)

ICD-10 Diagnosis

All diagnoses pend.

Document History

New: 06/10/2024
Document History:

- 06/10/2024 – Select Review: New criteria document for Anktiva (nogapendekin alfa inbakicept-pmln) PA. Coding Reviewed: New document. Added HCPCS J9999, C9399. All diagnoses pend.

References

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3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on May 7, 2024.
    a. Bladder Cancer. V1.2024. Revised February 26, 2024.