Anktiva® (nogapendekin alfa inbakicept-pmln)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

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

FDA-Approved Indications

Anktiva is 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.

POLICY

Prescriber Specialties

The requested medication must be prescribed by or in consultation with one of the following:

1. Oncologist
2. Urologist

Criteria for Initial Approval

Bladder Cancer

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

1. Member is 18 years of age and older.
2. Member has non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.
3. The disease is Bacillus Calmette-Guerin (BCG)-unresponsive.
4. The requested medication will be used in combination with Bacillus Calmette-Guerin (BCG).

5. Member has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components).

Continuation of Therapy

Bladder Cancer

Authorization of 12 months may be granted for the treatment of bladder cancer when all of the following criteria are met:

1. Member has a complete response (CR) to therapy defined as a negative result for cystoscopy [with TURBT/biopsies as applicable] and urine cytology.
2. For patients at treatment month 25 or later:
   A. Member is experiencing an ongoing (CR) and will require continued treatment; AND
   B. Member has not received greater than 37 months of therapy (24 doses as maintenance therapy).

Other

Anktiva (nogapendekin alfa inbakicept-pmln) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

For induction: Anktiva is recommended at a dose of 400 mcg administered intravesically with BCG once a week for 6 weeks. A second induction course may be administered if complete response is not achieved at month 3.

For maintenance: After BCG and Anktiva induction therapy, Anktiva is recommended at a dose of 400 mcg administered intravesically with BCG once a week for 3 weeks at months 4, 7, 10, 13 and 19 (for a total of 15 doses). For patients with an ongoing complete response at month 25 and later, maintenance instillations with BCG may be administered once a week for 3 weeks at months 25, 31, and 37 for a maximum of 9 additional instillations.

Note: The recommended duration of treatment is until disease persistence after second induction, disease recurrence or progression, unacceptable toxicity, or a maximum of 37 months.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J9028 – Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram (effective 1/1/25)
- C9169 – Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram (cancelled 1/1/2025)
- J3490 – Unclassified drugs (when specified as [Anktiva] (nogapendekin alfa inbakicept-pmln))
- J3590 – Unclassified biologics (when specified as [Anktiva] (nogapendekin alfa inbakicept-pmln))
- J9999 – not otherwise classified, antineoplastic drugs (when specified as [Anktiva] (nogapendekin alfa inbakicept-pmln))

- C9399 – Unclassified drugs or biologics (when specified as [Anktiva] (nogapendekin alfa inbakicept-pmln))

REFERENCES

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

The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 4.2024). © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org.

The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org.

Chamie K, Chang SS, Kramolowsky E, et al. IL-15 Superagonist NAI in BCG-Unresponsive Non-Muscle-Invasive Bladder Cancer. NEJM Evid. 2023 Jan;2(1):EVIDoa2200167. doi: 10.1056/EVIDoa2200167. Epub 2022 Nov 10. PMID: 38320011.

POLICY HISTORY

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