Medical benefit drug policies are a source for WyoBlue Advantage medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 06/05/2025

Anktiva® (nogapendekin alfa inbakicept-pmln)

HCPCS: J9028

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved indication
   b. FDA approved age
   c. Prescribed by or in consultation with an oncologist or urologist
   d. Must be Bacillus Calmette-Guérin (BCG) unresponsive defined as:
      i. Persistent or recurrent CIS within 12 months of receiving adequate BCG defined as
         1. At least five of six instillations of an initial BCG induction course plus either
            a) At least two of three instillations of maintenance therapy
            OR
            b) At least two of six instillations of a second induction course
      ii. Recurrent high-grade Ta/T1 disease within 6 months of completion of adequate BCG defined as
         1. At least five of six instillations of an initial BCG induction course plus either
            a) At least two of three instillations of maintenance therapy
            OR
            b) At least two of six instillations of a second induction course
      iii. T1 high-grade disease at the first evaluation following an induction BCG course alone defined as
         1. At least five of six doses of an initial induction course
   e. All visible papillary tumors must be resected and those with persistent T1 disease on transurethral resection of bladder tumor (TURBT) should undergo an additional re-TURBT within 14 to 60 days prior to beginning Anktiva
   f. ECOG performance score less than 2
   g. Must not have concomitant upper tract urothelial carcinoma or urothelial carcinoma within the prostatic urethra
   h. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in WyoBlue Advantage's utilization management medical drug list

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing

b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
c. Renewal Criteria: Until disease persistence after second induction, disease recurrence or progression, unacceptable toxicity up to a maximum of 37 months of therapy

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Bladder cancer is one of the more common forms of cancer. Approximately 75% - 80% of newly diagnosed bladder cancers are classified as NMIBC – a type of cancer that has grown through the lining of the bladder but hasn't yet invaded the muscle layer. This type of cancer is associated with high rates of recurrence (between 30 to 80%) and the risk of progression to invasive and metastatic disease.

- Treatment and care of patients with high-risk NMIBC, including those with CIS, often involves removing the tumor followed by BCG bladder instillation therapy to reduce the risk of recurrence. Few effective treatment options exist for patients who develop BCG-unresponsive disease. The failure to achieve a complete response, or the disappearance of all signs of cancer as seen on cystoscopy, biopsied tissue, and urine, is associated with an increased risk of death or a disease-worsening event.

- Anktiva is an interleukin-15 (IL-15) receptor agonist indicated with 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.

- The 2025 National Comprehensive Cancer Network Bladder Cancer Treatment Guidelines recommend TURBT for staging followed by a single dose of intravesicular mitomycin or gemcitabine as the first step in treatment. Following the tumor evaluation, if the tumor is considered high-grade, BCG is the preferred adjuvant therapy and intravesicular mitomycin or gemcitabine provide additional options to those who aren't candidates for BCG therapy. BCG is typically given weekly for 6 weeks at induction followed by maintenance of 3 weekly instillations at month 3, 6, 12, 18, 24, 30, and 36. Two 6-week BCG induction courses should be completed before the patient is considered non-responsive to the therapy. If patients have had recurrence or are considered non-responsive to BCG therapy, cystectomy, Keytruda®, or Adstiladrin® are currently recommended as second-line therapies.

- Safety and efficacy were evaluated in QUILT-3.032 trial, a single-arm, multicenter trial in 77 adults with BCG-unresponsive, high-risk, NMIBC with CIS with or without Ta/T1 papillary disease following transurethral resection. BCG-unresponsive high-risk NMIBC was defined as persistent or recurrent CIS within 12 months of receiving adequate BCG therapy, recurrent high-grade Ta/T1 disease within 6 months of completion of adequate BCG therapy, or T1 high-grade disease at the first evaluation following an induction BCG course alone. Adequate BCG was defined as the administration 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. If patients experienced failure of BCG therapy during induction, they must have gotten at least 5 of six doses of the initial induction course. Patients were excluded from the trial if they had an ECOG score greater than 2 or had concomitant upper tract urothelial carcinoma or urothelial carcinoma within the prostatic urethra. All visible papillary tumors were resected and those with persistent T1 disease on TURBT should undergo an additional re-TURBT prior to beginning therapy. Patients received 400 mcg Anktiva with BCG weekly for 6 consecutive weeks during the induction treatment period and then once a week every 3 weeks at 4, 7, 10, 13, and 19 months for patients with no or low grade disease. Patients with persistent CIS or high grade Ta disease at 3 months were eligible to receive a second induction course.

Patients with ongoing complete response at 25 months were eligible to receive additional instillations once a week every 3 weeks at months 25, 31, and 37. Overall, 62% of subjects experienced a complete response rate with 58% having a response lasting for at least a year and 40% for at least two years.

References:

1. Anktiva [prescribing information]. Culver City, CA: Altor BioScience, LLC; April 2024.
2. Clinicaltrials.gov. A multicenter clinical trial of intravesical Bacillus Calmette-Guerin (BCG) in combination with ALT-803 (N-803) in patients with BCG unresponsive high grade non-muscle invasive bladder cancer (NCT03022825). Available at: https://classic.clinicaltrials.gov/ct2/show/NCT03022825. Accessed on April 23, 2024.
3. National Comprehensive Cancer Network. Baldder cancer (Version 7.2024). 2025 February 28. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed on March 21, 2025.

Policy History		
#	Date	Change Description
1.0	Initial Effective Date: 01/01/2026	New policy

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*