Reference number(s)
6476-A

SPECIALTY GUIDELINE MANAGEMENT

ANKTIVA (nogapendekin alfa inbakicept-pmln)

POLICY

I. 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 Indication
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 are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Bladder Cancer
Authorization of 6 months may be granted for treatment of bladder cancer when all of the following criteria are met:
1. The member has non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors
2. The disease is Bacillus Calmette-Guerin (BCG)-unresponsive
3. The requested medication will be used in combination with Bacillus Calmette-Guerin (BCG)
4. The member will receive maintenance doses at months 4, 7, 10, 13 and 19 after induction therapy.

III. CONTINUATION OF THERAPY

Authorization of 12 months [for a total of 24 maintenance doses (37 months of treatment)] may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease recurrence or progression while on the current regimen.

IV. REFERENCES

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