

October 24, 2024

PRIOR AUTHORIZATION CRITERIA FOR ANKTIVA EFFECTIVE NOV. 1, 2024

BACKGROUND

On Oct. 1, 2024, Anktiva became a benefit of Medicaid and CHIP. HHSC requires prior authorization for Anktiva (procedure code C9169) for Medicaid and CHIP, effective for dates of service on or after Nov. 1, 2024.

KEY DETAILS

Anktiva (Nogapendekin Alfa Inbakicept-pmln) is an interleukin-15 (IL-15) receptor agonist indicated to treat adult clients with Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

HHSC requires prior authorization for Anktiva (Nogapendekin Alfa Inbakicept-pmln). Initial therapy for Anktiva may be approved for a 6-month duration if all the following criteria are met:

- The client is 18 years or older.
- The client has a confirmed diagnosis of NMIBC with CIS with or without papillary tumors.
- The client's disease is high-risk and BCG-unresponsive, defined as persistent disease following adequate BCG therapy, disease recurrence after an initial tumor-free state following adequate BCG therapy, or T1 disease following a single induction course of BCG.
- Nogapendekin alfa inbakicept-pmln (Anktiva) is used in combination with BCG.
- The client has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components).
- The client does not have any metastatic urothelial carcinoma.

Requests for Renewal or Continuation of Therapy

For renewal or continuation of therapy of nogapendekin alfa inbakicept-pmln (Anktiva), the client must meet the following requirements:

- The client continues to have a diagnosis as listed in the initial therapy criteria above and has been treated with nogapendekin alfa inbakicept-pmln (Anktiva) in the past with no adverse reactions.
- The client has no signs of unacceptable toxicity (e.g., hematuria, dysuria, or micturition urgency) while on treatment with nogapendekin alfa inbakicept-pmln (Anktiva).

ADDITIONAL INFORMATION

Refer to the [Outpatient Drug Services Handbook Chapter](#) of the Texas Medicaid Provider Procedure Manual for more details on the clinical policy and prior authorization requirements.

HHSC approved this updated clinical prior authorization for use by MCOs, and will implement criteria for fee-for-service Medicaid on Nov. 1, 2024. MCOs do not need to wait for publication in the TMPPM before implementation. MCOs may choose to implement the updated requirements but shall not make them more restrictive.