TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Nogapendekin alfa inbakicept-pmln (Anktiva)	**CRITERIA ID:** TX.CC.PHAR.42
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 11/01/2024	**PRODUCT(S):** STAR, STAR Kids, STAR Health, STAR Plus, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 11/1/2024	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for nogapendekin alfa inbakicept-pmln (Anktiva).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
NMIBC - Non-muscle invasive bladder cancer
CIS – Carcinoma in situ
BCG - Bacillus Calmette-Guérin
TURBT - Transurethral resection of bladder tumor

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of nogapendekin alfa inbakicept-pmln (Anktiva); procedure code: C9169

Description/Mechanism of Action:
Nogapendekin alfa inbakicept-pmln (Anktiva) is an interleukin-15 (IL-15) receptor agonist.

FDA Approved Indications:
Nogapendekin alfa inbakicept-pmln (Anktiva) is indicated for the treatment of adult clients with Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

Formulations:
Nogapendekin alfa inbakicept-pmln (Anktiva): Intravesical instillation. Clear to slightly opalescent and colorless to slightly yellow solution supplied as a 400mcg/0.4ml single-dose vials.

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria:

A. Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS):

1. The client is 18 years of age or older.
2. The client has a confirmed diagnosis of NMIBC with CIS with or without papillary tumors.
3. The client's disease is high-risk and BCG-unresponsive, defined as one of the following:
    - Persistent disease following adequate BCG therapy;
    - Disease recurrence after an initial tumor-free state following adequate BCG therapy;
    - T1 disease following a single induction course of BCG.
4. Documentation to support Anktiva is being used in combination with BCG.
5. Documentation that the client has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components).
6. The client does not have any metastatic urothelial carcinoma.

Approval duration: 6 months

II. Continued Therapy

A. Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS):

1. Currently receiving medication via the company benefit or member has previously met initial approval criteria or had received the drug from a previous Medicaid MCO (continuity of coverage).
2. The client continues to have a diagnosis as listed in the initial therapy criteria above and has been treated with Anktiva in the past with no adverse reactions.
3. The client has no signs of unacceptable toxicity (e.g., hematuria, dysuria, or micturition urgency) while on treatment with Anktiva.

Approval duration: 12 months (maximum total approval duration of up to 38 months)

REFERENCES: Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Criteria Document	HHSC requires prior authorization for Anktiva (procedure code C9169) for Medicaid and CHIP, effective for dates of service on or after Nov. 1, 2024.	11/01/2024

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