Anktiva

United Arab Emirates · access guide

Anktiva access in UAE: the EDE named-patient pathway

Last reviewed 2026-05-16 by Reserve Meds clinical and regulatory team.

Quick orientation

Anktiva (nogapendekin alfa inbakicept-pmln) is IL-15 receptor agonist (IL-15 superagonist complex) approved by the US FDA in April 2024 for BCG-unresponsive non-muscle-invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumours in adult patients, in combination with BCG. The drug is manufactured by ImmunityBio. UAE patients use the Emirates Drug Establishment named-patient pathway when the locally registered indication, the stocked presentation, or the available payer coverage does not match what the prescribing physician has written. Reserve Meds coordinates the US-side sourcing through a DSCSA-compliant specialty channel, builds the documentation packet your physician needs to file, and orchestrates the logistics into UAE with a single named coordinator carrying the case end-to-end.

Why UAE patients need Anktiva through the named-patient pathway

UAE operates a developed pharmaceutical regulatory environment, and Anktiva may be on the local register, may be in commercial review, or may be entirely absent depending on the stage of ImmunityBio's regional rollout. Several patterns drive cross-border requests. First, indication lag: newer indications, particularly the April 2024 FDA approval timeline, often reach local registration 12 to 36 months later. Second, biomarker-defined eligibility: BCG-unresponsive disease status (the trial entry criterion); no separate companion diagnostic can be the diagnostic gate, and where the relevant testing infrastructure is still maturing locally, families coordinate the workup before or in parallel with sourcing. Third, payer coverage: Daman, Thiqa, GIG Gulf (formerly AXA Gulf), Sukoon (formerly Oman Insurance Company), ADNIC, and Orient each assess specialty therapies case by case, and step-therapy criteria can fail even where the drug is registered. Fourth, stocking gaps: the local agent may not carry every presentation or dose strength reliably, and named-patient import is the operational mechanism that bridges to the exact label the prescriber has written. In each pattern, the named-patient pathway is the legal mechanism that connects a UAE-licensed physician's clinical decision with US-sourced, FDA-labelled product for a specific identified patient.

The EDE named-patient pathway for Anktiva

As of 29 December 2025, under Federal Decree-Law No. 38 of 2024, the Emirates Drug Establishment (EDE) assumed 44 core services from MOHAP including marketing authorisations and personal-use import permits. Filings now route through the EDE portal at ede.gov.ae. The framework permits hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and either a clinically equivalent locally registered alternative is not suitable, or the patient's clinical profile does not match the locally approved label.

A complete application for Anktiva typically includes a clinical justification letter from the treating physician documenting the patient's diagnosis (BCG-unresponsive non-muscle-invasive bladder cancer with carcinoma in situ), severity assessment, prior systemic therapy history, any relevant biomarker results (BCG-unresponsive disease status (the trial entry criterion); no separate companion diagnostic), and a clinical rationale for selecting Anktiva over locally available alternatives. The UAE physician's licensure with MOHAP, DHA, DOH, or Sharjah Health Authority, depending on practice location is verified through the application. The packet also specifies the dispensing facility name and license number, the pharmacy in charge of the facility, full product details (brand name, generic name, manufacturer, strength, dosage form, pack size, quantity, intended treatment duration), and a chain-of-custody plan describing how the medicine will move from the US manufacturer through the importer to the dispensing pharmacy.

For Anktiva specifically, the clinical justification typically frames the case around Anktiva is the first IL-15 superagonist in oncology; the cross-border route addresses bladder cancer patients where the local register has not caught up to the April 2024 approval and where radical cystectomy is undesired. Approval timelines are typically 5 to 15 business days for routine cases, 4 to 6 weeks for complex first-of-kind requests. The EDE retains discretion on timing, and we do not promise specific durations.

Where Anktiva gets dispensed in UAE

A focused group of UAE institutions handle named-patient specialty-medicine imports as established workflow, with in-house import pharmacy capabilities and physicians experienced with the application set. For Anktiva specifically, the dispensing facility must accommodate the administration profile: tertiary urology with intravesical instillation programme; outpatient cystoscopy-based instillation in clinic; close follow-up cystoscopy and urine cytology surveillance. Tertiary centres that meet this profile include Cleveland Clinic Abu Dhabi on Al Maryah Island (an M42 group hospital), Sheikh Khalifa Medical City in Abu Dhabi (a SEHA-network 586-bed JCI-accredited hospital), Tawam Hospital in Al Ain (a SEHA-network referral centre), Burjeel Medical City Abu Dhabi, American Hospital Dubai (a Mayo Clinic Care Network member), King's College Hospital London Dubai, Mediclinic City Hospital in Dubai Healthcare City, and the larger NMC Healthcare sites across the emirates.

For physicians at smaller hospitals without internal import infrastructure, the common pattern is to route through a licensed pharmaceutical establishment that holds the import licence and files the EDE application on the prescribing physician's behalf. The medicine then moves under chain-of-custody documentation into the prescribing hospital's outpatient pharmacy for administration.

Real cost picture for Anktiva in UAE

US WAC for Anktiva is approximately USD 28,000 per dose, which translates to an annual WAC in the range of approximately USD 300,000 per induction-and-maintenance year for the standard regimen at the labelled dose. The UAE dirham is pegged to the US dollar at approximately 3.67 AED to 1 USD. On that basis, the drug cost alone is materially significant before logistics, the EDE permit fees (which are nominal relative to drug cost), the destination dispensing hospital's administration fees, and Reserve Meds' concierge fee (which is itemised separately on every firm quote).

International cold-chain or ambient logistics into UAE typically runs in the low to mid four-figure USD range depending on origin, urgency, and packaging requirements. On the insurance side, Daman, Thiqa, GIG Gulf (formerly AXA Gulf), Sukoon (formerly Oman Insurance Company), ADNIC, and Orient each assess named-patient imports case by case. Some reimburse fully when the medicine is on their formulary even if not stocked, some reimburse a percentage subject to copay, and many require pre-authorisation with documented step-therapy failure. We do not promise coverage from any payer. US manufacturer patient assistance programmes do not extend internationally; cross-border patients pay cash or rely on local payer coverage where available.

Clinical evidence and where Anktiva sits in the treatment landscape

QUILT-3.032 (NCT03022825) phase 2/3 trial demonstrated a complete response rate of 71 percent in BCG-unresponsive CIS at 12 months with durable responses. The drug acts as IL-15 receptor agonist (IL-15 superagonist complex), and the dosing schedule is intravesical instillation in combination with BCG; induction phase weekly for 6 weeks, then maintenance schedules per protocol.

Within the treatment landscape, Anktiva sits alongside radical cystectomy (the historical alternative for BCG-unresponsive disease), pembrolizumab intravenous immunotherapy (also FDA-approved for BCG-unresponsive CIS), nadofaragene firadenovec (Adstiladrin) intravesical gene therapy, and clinical-trial options. The choice between targeted therapies in this space depends on the patient's full clinical profile, prior therapy exposure, biomarker status, comorbidities, and the prescriber's judgment. Reserve Meds coordinates whichever therapy the physician has selected; we do not steer prescribing.

Safety surveillance for Anktiva centres on dysuria, haematuria, urinary frequency and urgency (the local intravesical effect), urinary tract infection, fatigue, and rare systemic IL-15 effects. The dispensing facility and the prescribing physician retain clinical responsibility for monitoring and adverse-event management; Reserve Meds does not provide medical care.

Typical timeline for Anktiva in UAE

EDE routine processing is typically 5 to 15 business days for routine cases, 4 to 6 weeks for complex first-of-kind requests from a complete filing. End-to-end, most cases complete within 4 to 8 weeks from first complete documentation, with first-of-kind cases and complex biomarker-dependent workups potentially extending further. Where the administration setting is tertiary urology with intravesical instillation programme, hospital scheduling and infusion-chair availability are additional sequencing factors that families plan around. We do not promise specific durations; the EDE retains discretion on timing, and shipping windows depend on lane and packaging.

What your UAE physician needs to provide

For a UAE-licensed specialist prescribing Anktiva through the EDE pathway, the clinical justification letter is the cornerstone of the application. The letter typically documents the patient's diagnosis (BCG-unresponsive non-muscle-invasive bladder cancer with carcinoma in situ), the relevant biomarker work (BCG-unresponsive disease status (the trial entry criterion); no separate companion diagnostic), prior systemic therapy history, the FDA-approved indication being invoked, and the clinical rationale for Anktiva as the appropriate next step.

The letter also specifies the exact dosing plan per the FDA-approved label: intravesical instillation in combination with BCG; induction phase weekly for 6 weeks, then maintenance schedules per protocol. The monitoring plan references dysuria, haematuria, urinary frequency and urgency (the local intravesical effect), urinary tract infection, fatigue, and rare systemic IL-15 effects. The treating physician's licence number with MOHAP, DHA, DOH, or Sharjah Health Authority, depending on practice location, the dispensing facility license number, and the pharmacy in charge of dispensing complete the package. Where biomarker testing requires reference-lab coordination, the physician documents the assay used and the report; Reserve Meds can route this through a US-side reference laboratory where the regional pathway is unavailable.

Common questions about Anktiva in UAE

Will Daman or other major UAE insurers cover Anktiva? Each insurer assesses named-patient imports case by case. Some reimburse fully when Anktiva is on their formulary even if not currently stocked; others assess based on step-therapy criteria and biomarker documentation. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you, your physician, or your hospital. We do not promise coverage from any payer.

Is Anktiva registered locally in UAE? Local registration status changes as ImmunityBio pursues regional rollout; even where the drug is registered, the specific indication, presentation, or dosing strength your prescriber has written may not align with what is currently stocked. The EDE named-patient pathway exists precisely to bridge these gaps for individually identified patients.

What about competitor therapies? The treatment landscape includes radical cystectomy (the historical alternative for BCG-unresponsive disease), pembrolizumab intravenous immunotherapy (also FDA-approved for BCG-unresponsive CIS), nadofaragene firadenovec (Adstiladrin) intravesical gene therapy, and clinical-trial options. The choice depends on the patient's full clinical profile and prescriber judgment. Reserve Meds coordinates whichever medicine the physician has prescribed; we do not steer prescribing decisions and we do not have a financial relationship with any specific manufacturer.

How is the cold chain or storage managed? Anktiva ships in validated packaging with continuous temperature logging through the lane where cold-chain handling applies. The handoff ends at the dispensing pharmacy; home storage instructions, where the patient takes the medicine home for self-administration, are part of the patient onboarding kit.

Do US manufacturer patient assistance programmes (such as ImmunityBio co-pay or PAP programmes) extend to UAE patients? No. US-resident patient assistance programmes are limited to US-resident patients with US prescription coverage by programme design. Cross-border patients pay cash for the drug and the coordination fee, with local payer reimbursement assessed separately.

Can the case be resupplied year over year if the patient responds? Yes. Reserve Meds maintains the case file and re-files EDE permits at the relevant intervals (or coordinates with the dispensing hospital's pharmacy if they hold the permit). Patients on long-term therapy typically settle into a quarterly or biannual resupply cadence after the first cycle.

What is the administration setting? Tertiary urology with intravesical instillation programme; outpatient cystoscopy-based instillation in clinic; close follow-up cystoscopy and urine cytology surveillance.

My physician is at a smaller hospital without an internal import pharmacy. Can the case still proceed? Yes. The common pattern is to route through a Dubai, Riyadh, Mumbai, Cairo, Karachi, or other regional licensed pharmaceutical establishment that holds the import licence and files the EDE application on the prescribing physician's behalf. The medicine moves into the prescribing hospital's outpatient pharmacy under chain-of-custody documentation.

Where Reserve Meds fits in Anktiva cases

Reserve Meds is a US-based concierge coordinator. We do not replace your UAE specialist, we do not replace the EDE, and we do not replace your dispensing pharmacy. For Anktiva specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty channel, build the documentation packet your physician submits, coordinate logistics into UAE, and assign a single named coordinator through the case. The pharmacist-of-record review, prescription validation, biomarker confirmation, and physician sign-off are the recurring operational fundamentals for this drug.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

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