

Anktiva

Saudi Arabia · access guide

Anktiva access in Saudi Arabia: the SFDA 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. Saudi Arabia patients use the Saudi Food and Drug Authority 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 Saudi Arabia with a single named coordinator carrying the case end-to-end.

Why Saudi patients need Anktiva through the named-patient pathway

Saudi Arabia 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: Bupa Arabia, Tawuniya, MEDGULF, GIG Saudi, Walaa, and the Council of Health Insurance (CHI) framework 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 Saudi-licensed physician's clinical decision with US-sourced, FDA-labelled product for a specific identified patient.

The SFDA named-patient pathway for Anktiva

The Saudi Food and Drug Authority (SFDA) administers the Special Access Programme under Article 5 of the Drug Law, accepting personal-use and named-patient import requests through its sfda.gov.sa portal and the SFDA Ghad digital platform. Applications are filed by the prescribing physician or by a licensed pharmaceutical establishment holding the patient's authorisation. 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 Saudi physician's licensure with the Saudi Commission for Health Specialties (SCFHS) 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 7 to 21 business days for routine cases, with sovereign-tied pathways (Royal Court Medical Care, Ministry of Health Higher Committee for Treatment Abroad) running in parallel where the patient qualifies. The SFDA retains discretion on timing, and we do not promise specific durations.

Where Anktiva gets dispensed in Saudi Arabia

A focused group of Saudi Arabia 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 King Faisal Specialist Hospital and Research Centre (Riyadh and Jeddah campuses), King Abdulaziz Medical City under the Ministry of National Guard Health Affairs (NGHA), Prince Sultan Military Medical City, King Fahad Medical City in Riyadh, King Abdulaziz University Hospital in Jeddah, Dr. Sulaiman Al Habib Medical Group, and Saudi German Hospitals.

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 SFDA 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 Saudi Arabia

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 Saudi riyal is pegged to the US dollar at approximately 3.75 SAR to 1 USD. On that basis, the drug cost alone is materially significant before logistics, the SFDA 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 Saudi Arabia typically runs in the low to mid four-figure USD range depending on origin, urgency, and packaging requirements. On the insurance side, Bupa Arabia, Tawuniya, MEDGULF, GIG Saudi, Walaa, and the Council of Health Insurance (CHI) framework 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 Saudi Arabia

SFDA routine processing is typically 7 to 21 business days for routine cases, with sovereign-tied pathways (Royal Court Medical Care, Ministry of Health Higher Committee for Treatment Abroad) running in parallel where the patient qualifies 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 SFDA retains discretion on timing, and shipping windows depend on lane and packaging.

What your Saudi physician needs to provide

For a Saudi-licensed specialist prescribing Anktiva through the SFDA 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 the Saudi Commission for Health Specialties (SCFHS), 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 Saudi Arabia

Will Bupa Arabia or other major Saudi 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 Saudi Arabia? 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 SFDA 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 Saudi Arabia 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 SFDA 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 SFDA 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 Saudi specialist, we do not replace the SFDA, 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 Saudi Arabia, 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.

Reserve Meds

reserved for you.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

reservemeds.com · hello@reservemeds.com