Akeega access in UAE: the MOHAP and EDE named-patient pathway

How patients in the United Arab Emirates with BRCA-mutated metastatic prostate cancer obtain Akeega (niraparib plus abiraterone acetate) through the federal unregistered-medicine import permit.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team. Akeega is FDA-approved for BRCA-mutated metastatic castration-resistant prostate cancer and BRCA2-mutated metastatic castration-sensitive prostate cancer; it is not registered in the UAE as of this review date. UAE patients access it through the federal named-patient framework after companion-diagnostic BRCA testing.

Quick orientation for UAE patients

Akeega is a fixed-dose oral combination of niraparib (a PARP inhibitor) and abiraterone acetate (a CYP17 androgen-biosynthesis inhibitor), the first dual-action tablet of its kind for prostate cancer. The U.S. Food and Drug Administration approved Akeega on 11 August 2023 in combination with prednisone for BRCA-mutated metastatic castration-resistant prostate cancer (mCRPC), as determined by an FDA-approved companion diagnostic such as FoundationOne CDx. A December 2025 FDA action extended the label to BRCA2-mutated metastatic castration-sensitive prostate cancer (mCSPC). Akeega is not registered in the UAE, so a local pharmacy cannot stock it. The federal named-patient framework, administered through MOHAP and (from 29 December 2025) the Emirates Drug Establishment, is the route for UAE patients who have completed BRCA testing and whose treating oncologist has set Akeega as the next step. Reserved for you.

Why patients in the UAE need Akeega via the named-patient pathway

Akeega is a textbook UAE named-patient case for three reasons. First, the product is not on the UAE federal register. Janssen has not pursued UAE marketing authorisation for Akeega specifically, and the local oncology supply chain stocks niraparib (Zejula) and abiraterone (Zytiga and generics) only as separate molecules, not as the fixed-dose combination tablet. Second, the indication is gated by BRCA1 or BRCA2 mutation confirmation. UAE patients who arrive at the Akeega prescription decision have typically already completed BRCA testing through a tertiary cancer center locally or through a US or EU reference lab, and the operational question becomes how to procure the medicine, not whether to test.

Third, the combination tablet simplifies daily life relative to running niraparib and abiraterone as two separate prescriptions on two separate adherence schedules. UAE patients managing other prostate-cancer therapy elements (ongoing androgen deprivation therapy, prednisone, supportive medicines) prefer one combination tablet. The MOHAP and EDE framework recognizes FDA approval as a reference-authority basis, and the European Commission also extended the EU Akeega label to BRCA1/2-mutated mCSPC in March 2026, strengthening the regulatory footing.

The MOHAP and EDE named-patient pathway for Akeega

The federal unregistered-medicine import permit, administered through the EDE portal at ede.gov.ae from 29 December 2025 under Federal Decree-Law No. 38 of 2024, is the legal mechanism. For Akeega specifically, the cell-level clinical-justification angle is the BRCA companion-diagnostic result plus the prior-line oncology context.

A complete application typically includes:

- A clinical justification letter from the treating medical oncologist. The letter names the histologic diagnosis (metastatic prostate adenocarcinoma), the disease state (castration-resistant or castration-sensitive), the BRCA1 or BRCA2 mutation status with the companion diagnostic name (FoundationOne CDx or equivalent FDA-approved companion diagnostic), the lab and report date, and the prior-line context (treatment history, ongoing androgen deprivation therapy, prior chemotherapy if any).
- The treating physician's emirate-specific medical license verification (MOHAP for the Northern Emirates, DHA for Dubai, DOH for Abu Dhabi, or Sharjah Health Authority for Sharjah).
- An anonymized patient identifier with age and weight.
- Full product detail: brand name Akeega, generic name niraparib plus abiraterone acetate, the strength configuration required to deliver the 200 mg niraparib plus 1,000 mg abiraterone daily dose, manufacturer Janssen Biotech (a Johnson and Johnson company), quantity calculated against the continuous once-daily dose, and intended treatment duration (continuous until progression or unacceptable toxicity).
- The destination dispensing facility name, pharmaceutical establishment license number, and pharmacy in charge.
- A chain-of-custody plan describing US-to-UAE transit. Akeega ships ambient (20 to 25 degrees Celsius, excursions to 15 to 30 degrees Celsius), so no cold-chain is required, but tamper-evident manufacturer packaging must be preserved and ambient temperature logging through summer transit is good practice. Customs documentation should explicitly name BRCA-mutated prostate cancer as the indication so customs reviewers do not mischaracterize the shipment as a generic specialty oral.

Approval timelines for routine oncology cases generally fall within the 5 to 15 business days window. Complex first-of-molecule reviews can extend to 4 to 6 weeks. Akeega is a small molecule with no REMS, no controlled-substance status, and no special handling, which simplifies the file.

Where Akeega gets dispensed in the UAE

The institutional set that handles Akeega imports overlaps with the UAE adult oncology specialty hospital network. Cleveland Clinic Abu Dhabi, on Al Maryah Island, runs adult oncology and complex hematology and oncology with ASHP-accredited pharmacy services. Sheikh Khalifa Medical City in Abu Dhabi on the SEHA network handles oncology with in-house import pharmacy. Tawam Hospital in Al Ain, the SEHA national referral center for oncology developed with Johns Hopkins, handles hematology, radiation oncology, and palliative care alongside adult oncology. American Hospital Dubai (Mayo Clinic Care Network member) has surgical and

medical oncology depth. King's College Hospital London Dubai has breast and urologic oncology service lines that often coordinate genitourinary cases. Mediclinic City Hospital in Dubai Healthcare City has urologic oncology and oncology service lines. NMC Healthcare flagship sites have oncology service lines and import pharmacy infrastructure.

For patients based in the Northern Emirates, the standard pattern is to route the case through a Dubai or Abu Dhabi oncology center where the treating oncologist holds joint privileges, or to file through a specialty importer who delivers under chain-of-custody to the prescribing hospital's outpatient pharmacy.

Real cost picture for Akeega in the UAE

The US wholesale acquisition cost for Akeega is approximately USD 19,193.60 for a 60-tablet bottle of the 100 mg niraparib plus 500 mg abiraterone acetate strength, per 2024 Drugs.com pricing references. The daily dose requires two tablets of that strength (or one of an equivalent combined-strength configuration) to deliver 200 mg niraparib plus 1,000 mg abiraterone acetate. Patient-month cost in the US specialty channel therefore runs USD 19,000 to 20,000 per 30-day supply at WAC, before any discounts.

At the UAE dirham peg of approximately 3.67 AED to 1 USD, monthly drug cost lands at roughly AED 70,000 to 73,500 at US WAC reference. Canadian list-price equivalents calculated by CADTH placed the 28-day cost near CAD 8,283, meaningfully below the US WAC, which is one of several sourcing levers Reserve Meds evaluates per firm quote. International logistics for an ambient oral oncology product typically runs USD 400 to 800 (AED 1,500 to 3,000) per shipment. EDE permit handling fees are nominal relative to drug cost. Reserve Meds' concierge fee is itemized separately on every firm quote. UAE insurance treatment varies; Daman (Thiqa), GIG Gulf, Sukoon, ADNIC, and Orient assess oncology named-patient imports case by case. Cash-pay is the default posture with self-reimbursement where coverage applies.

Typical timeline for Akeega in the UAE

The full arc for a routine BRCA-confirmed mCRPC or mCSPC case looks like this. Day 0 to Day 2: Reserve Meds confirms eligibility, the treating oncologist completes the clinical justification with BRCA report attached, and the hospital pharmacy or specialty importer prepares the EDE filing. Day 3 to Day 12: the EDE permit application sits in review under the 5 to 15 business day routine window. Day 12 to Day 16: permit issued, Reserve Meds aligns US-side release with the UAE importer, ambient shipment moves with temperature logging. Day 16 to Day 20: UAE customs clears the shipment, the medicine arrives at the hospital pharmacy, the indication is verified against the import permit so customs does not mischaracterize, final verification completes, and the patient receives the bottle. First-of-molecule complex review can add 2 to 4 weeks. Refill cycles run on a monthly cadence given continuous daily dosing, and routine refills typically clear faster once the institutional precedent exists.

What your physician needs to provide

The clinical justification letter is the core deliverable. For Akeega, the letter typically covers: histologic diagnosis (metastatic prostate adenocarcinoma), disease state (mCRPC or mCSPC), BRCA1 or BRCA2 mutation status with companion-diagnostic name (FoundationOne CDx or equivalent FDA-approved companion diagnostic), the testing lab and report date, the prior-line context, current androgen deprivation therapy regimen (continued in parallel unless the patient

has undergone bilateral orchiectomy), and the rationale for selecting Akeega over olaparib plus abiraterone or talazoparib plus enzalutamide.

The dosing plan documents the FDA-approved regimen: 200 mg niraparib plus 1,000 mg abiraterone acetate orally once daily on an empty stomach, with no food for at least one hour before or two hours after each dose, plus prednisone 10 mg orally once daily, continued until radiographic progression or unacceptable toxicity. The monitoring plan covers complete blood count weekly for the first month then monthly (because PARP-class hematologic toxicity is the principal acute concern), blood pressure, liver function tests, serum potassium at baseline and at regular intervals, cortisol monitoring if adrenal insufficiency is suspected (abiraterone contributes adrenocortical insufficiency under stress conditions), and long-term vigilance for myelodysplastic syndrome and acute myeloid leukemia. The FDA label describes the MDS and AML risk as a warning following reports including fatal cases with niraparib and other PARP inhibitors, and this is a watchpoint the prescribing oncologist tracks across the treatment arc.

Common questions about Akeega in the UAE

Will Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, or Orient cover Akeega?
Each insurer assesses oncology named-patient imports case by case. Pre-authorisation is typically required. Thiqa has the broadest specialty oncology coverage for UAE nationals in Abu Dhabi. We supply documentation that lets the insurer assess; the claim is yours or your hospital's to file.

Do I need to repeat BRCA testing if I tested in the US or EU?
No, where the report is from an FDA-approved companion diagnostic such as FoundationOne CDx, or an equivalent recognised by the FDA. The treating UAE oncologist incorporates that report into the clinical justification.

Will my MOHAP, DHA, or DOH-licensed oncologist's letter be sufficient?
Yes. Any UAE-licensed medical oncologist practicing in good standing in the emirate of the dispensing facility has signing authority. Genitourinary specialists at the named centers handle these applications routinely.

What is the MDS and AML risk and how is it monitored?
Myelodysplastic syndrome and acute myeloid leukemia have been reported with niraparib and other PARP inhibitors, including fatal cases. This risk is described in the FDA label as a warning. Monitoring is via the same complete blood count cadence used for hematologic toxicity (weekly for the first month, then monthly), with persistent unexplained cytopenias triggering further hematology workup. The treating oncologist sets the threshold for additional investigation.

Why Akeega versus olaparib plus abiraterone (Lynparza plus Zytiga) or talazoparib plus enzalutamide (Talzenna plus Xtandi)?
Each combination has a distinct FDA label and a distinct evidence base. Reserve Meds does not recommend one over another. The treating oncologist makes that selection based on patient-specific factors.

What about the food restriction?
The 200 mg niraparib plus 1,000 mg abiraterone acetate combination must be taken on an empty stomach: no food for at least one hour before or two hours after each dose. This is because abiraterone exposure increases significantly when taken with food and the increase is associated with toxicity. Patient education on the empty-stomach rule is part of the standard dispensing process at the hospital pharmacy.

Where Reserve Meds fits in Akeega cases

Reserve Meds has no prior case experience on Akeega at the date of this page. Standard NPP coordination applies. What we add to a UAE BRCA-mutated prostate cancer case is structured US specialty-pharmacy sourcing through Onco360 or another authorised limited-distribution partner, a documentation kit your treating oncologist can pass through to the hospital pharmacy filing the EDE permit (with BRCA companion-diagnostic report attached for customs clarity), ambient logistics with temperature logging into the destination emirate, and a single named coordinator (Arabic available) through the case. We do not handle BRCA testing, do not select between Akeega and the alternative PARP-plus-androgen-axis combinations, and do not prescribe.

Next step

Add your case to the Reserve Meds Akeega-in-UAE waitlist. We confirm eligibility within 24 to 48 hours and send the documentation kit to your treating oncologist.

Reserved for you.

This guide is informational, not medical or legal advice. The named-patient framework requires a licensed UAE physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber. Sources cited: FDA Akeega approval (August 11, 2023) and mCSPC extension (December 12, 2025); UAE country module 2026-05-11; Drugs.com Akeega pricing reference; CADTH Reimbursement Recommendation.