Xtandi access in UAE through the MOHAP and EDE named-patient pathway

How UAE prostate cancer patients source US-labeled Xtandi (enzalutamide) when the local label, the local formulary, or the local supply chain does not match the prescribed indication. What the application looks like and where Reserve Meds fits.

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Quick orientation

Xtandi is the brand name for enzalutamide, an oral small-molecule androgen receptor pathway inhibitor (ARPI) developed by Medivation and Astellas Pharma and co-promoted in the US by Astellas and Pfizer. Xtandi was first approved by the FDA on 31 August 2012 and has expanded across the prostate cancer continuum, with FDA approvals in metastatic castration-resistant prostate cancer (mCRPC, chemo-pretreated 2012, chemo-naive 2014), non-metastatic castration-resistant prostate cancer (nmCRPC, 2018), metastatic castration-sensitive prostate cancer (mCSPC, 2019), and non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (16 November 2023). Xtandi is registered in the UAE through Astellas's regional affiliate. UAE patients still reach for US-sourced Xtandi through the named-patient pathway for three specific reasons. Reserve Meds coordinates the US-side sourcing and the documentation kit your oncologist needs. Reserved for you.

Why UAE patients need US-sourced Xtandi through the named-patient pathway

Xtandi is registered in the UAE, which is unusual for a Reserve Meds named-patient candidate. The country-module pattern that applies most directly here is the second pattern: registered for a different indication. The newest FDA approval (nmCSPC with high-risk biochemical recurrence, November 2023) is not uniformly reflected in non-US labels, and a UAE patient whose oncologist is prescribing Xtandi at this earlier disease state may find that the local label still restricts use to mCRPC or mCSPC. The first pattern (registered but not stocked) also applies in some cases when a particular hospital pharmacy or community-pharmacy network does not have a given dose strength or pack size on hand.

Two additional drivers cluster with these: formulary exclusion (UAE private insurance plans and the Daman or Thiqa formulary may exclude or restrict Xtandi, particularly for the newest indications, and patients unwilling to wait through an appeal cycle reach for the named-patient route) and sourcing assurance (sophisticated cash-pay patients sometimes prefer US-labelled product through a documented chain of custody over locally available stock from less transparent supply lines). The EDE unregistered-medicine import permit is the documented pathway when any of these three drivers apply.

The MOHAP and EDE named-patient pathway for Xtandi

The federal pathway is the unregistered-medicine import permit, filed through the EDE portal at ede.gov.ae since 29 December 2025. The framework allows hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority and a clinically equivalent locally registered alternative is not suitable. Where the local-label gap is the driver, the application leans on this last clause: the FDA-approved indication that the treating oncologist is prescribing for is not part of the locally registered label, so the locally available stock is not the clinical equivalent.

For Xtandi specifically, the clinical-justification angle that anchors the application is indication-state documentation. The application is strongest when the treating oncologist's letter sets out (1) the precise prostate cancer disease state (nmCRPC, mCRPC, mCSPC, or nmCSPC with high-risk biochemical recurrence), (2) the staging and biomarker evidence (PSA trajectory, PSA doubling time for nmCSPC with high-risk BCR, imaging including PSMA PET where used, and bone or visceral metastasis status), (3) the FDA-approved indication that supports the prescription, (4) whether the patient is castration-sensitive or castration-resistant and how castration is maintained (medical castration with a GnRH agonist such as

leuprolide, or prior bilateral orchiectomy), and (5) the rationale for US-labelled product rather than the locally registered presentation.

A complete package typically includes:

- Clinical justification letter from the treating oncologist with the staging and biomarker evidence attached
- Treating oncologist's UAE medical license verification (MOHAP, DHA, DOH, or Sharjah Health Authority)
- Patient identifier (anonymised reference where the EDE submission allows)
- Product details: Xtandi 40 mg soft gelatin capsules or 40 mg and 80 mg film-coated tablets; 160 mg daily dose; manufacturer Astellas Pharma US, Inc. with Pfizer Inc. as US co-promotion partner; quantity requested per refill cycle (typically one 120-capsule bottle per 30 days) and intended treatment duration
- Destination dispensing facility name, license number, and pharmacy in charge
- Chain-of-custody plan from the US specialty pharmacy through the importer to the UAE dispensing pharmacy

Approval timelines for routine cases are typically 5 to 15 business days. Xtandi has been moving through cross-border channels for over a decade and the molecule is familiar to the EDE reviewers; first-import cases at a UAE oncology center that has not previously cleared US-labelled Xtandi for that patient may extend toward 4 weeks.

Where Xtandi gets dispensed in the UAE

Xtandi is a room-temperature oral capsule or tablet with no cold-chain requirement, no reconstitution, and no infusion infrastructure. The capability that matters is an outpatient oncology service that can prescribe and monitor across the four FDA-approved disease states, with urology and radiation oncology integration where relevant. The UAE institutions with this profile and established import pharmacy workflow are:

- **Cleveland Clinic Abu Dhabi** (M42 group, Al Maryah Island). Adult oncology service line including genitourinary oncology, ASHP-accredited pharmacy services.
- **Tawam Hospital, Al Ain** (SEHA network). National referral center for oncology with hematology, radiation oncology, and palliative care services; cancer center of excellence developed in collaboration with the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center.
- **Sheikh Khalifa Medical City (SKMC), Abu Dhabi** (SEHA network, managed by the Cleveland Clinic). JCI-accredited with oncology subspecialty services.

- **American Hospital Dubai** (Mayo Clinic Care Network member). Oncology and surgical oncology services.
- **King's College Hospital London Dubai**. UK-affiliated private hospital with oncology depth.
- **Mediclinic City Hospital, Dubai Healthcare City**. Multispecialty private hospital with urologic oncology service line, directly relevant for prostate cancer cases.
- **NMC Healthcare** flagship sites in Abu Dhabi, Dubai, Sharjah, and Al Ain. Large private network with oncology service lines.

Outpatient pharmacy dispensing is appropriate; Xtandi is dispensed bottle by bottle on the standard monthly refill cadence. Direct-to-home delivery without a licensed dispensing facility in the chain is not the model.

Real cost picture for Xtandi in the UAE

US wholesale acquisition cost for Xtandi is approximately USD 13,650 to USD 15,005 per 120-capsule 40 mg bottle, which represents one month of therapy at the standard 160 mg daily dose. The Astellas WAC disclosure of approximately USD 14,332 per 120-capsule package in May 2024, with subsequent 2025 disclosures trending toward USD 15,000, anchors the range. At the pegged rate of approximately 3.67 AED to 1 USD, that translates to approximately AED 50,100 to AED 55,100 per month for the drug. A 12-month course at WAC totals roughly USD 165,000 to USD 180,000 (approximately AED 605,000 to AED 661,000) before any logistics, coordination, or country-specific markups.

WAC does not reflect rebates, manufacturer discounts, or negotiated payer pricing, and US patients with insurance frequently pay materially less than WAC. For cross-border NPP routing the relevant economic anchor is unsubsidized list-equivalent pricing, since Astellas Pharma Support Solutions copay support and the US patient assistance program do not extend internationally. International logistics for a room-temperature oral capsule typically runs USD 400 to USD 800 (approximately AED 1,500 to AED 2,900) per refill. UAE customs and EDE permit fees are nominal relative to the drug cost. The Reserve Meds concierge fee is itemised separately on every firm quote. UAE insurer coverage (Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, Orient) is assessed case by case; coverage outcomes are more variable for the newest FDA indication (nmCSPC with high-risk BCR) than for the more-established mCRPC and mCSPC indications.

Typical timeline for Xtandi in the UAE

Xtandi is room-temperature stable in capsule or tablet format, which removes cold-chain handoffs. The modality-adjusted typical end-to-end timeline for a first import is 3 to 5 weeks: 5 to 15 business days for routine EDE permit review (Xtandi is a familiar molecule for

reviewers and processing typically runs at the faster end of the range), 5 to 7 days for US-side specialty pharmacy procurement (Xtandi moves through Optum, CVS Specialty, Accredo, and similar specialty pharmacies in the Astellas network), and 2 to 4 days for ambient air freight and UAE customs clearance. Repeat monthly refills for an established patient typically run 2 to 3 weeks because the EDE dossier and US-side procurement path are already in place.

What your physician needs to provide

The treating oncologist's clinical justification letter is the cornerstone of the EDE package. For Xtandi specifically, the letter typically addresses:

- **Mechanism and FDA indication.** Enzalutamide is an oral androgen receptor pathway inhibitor approved by the FDA across nmCRPC, mCRPC, mCSPC, and nmCSPC with high-risk biochemical recurrence. The letter identifies the specific disease state for this patient.
- **Staging and biomarker evidence.** PSA trajectory; for nmCSPC with high-risk BCR, the PSA doubling time threshold the FDA label references; imaging summary including PSMA PET where used; bone scan and CT or MRI for metastasis status.
- **Castration status and backbone.** Castration-sensitive or castration-resistant designation; in castration-sensitive disease, the GnRH agonist (typically leuprolide) or prior bilateral orchiectomy; in castration-resistant disease, the maintenance of medical castration alongside Xtandi.
- **Dosing plan.** 160 mg orally once daily, taken as four 40 mg capsules, four 40 mg tablets, or two 80 mg tablets, with or without food. Continuous administration until disease progression or unacceptable toxicity. Permitted dose reductions to 120 mg or 80 mg daily and dose interruption for up to one week for Grade 3 or higher adverse reactions. Strong CYP3A4 inducer avoidance; if a strong CYP2C8 inhibitor is unavoidable, dose reduction to 80 mg daily.
- **Monitoring plan.** Blood pressure monitoring; new neurologic-symptom surveillance with low threshold for evaluation (seizure occurred in roughly 0.6 percent of treated patients across eight randomised trials; PRES has been reported); periodic liver function tests; fall and fracture risk assessment particularly in older patients; permanent discontinuation in patients who develop a seizure during treatment per the label.
- **Indication-gap rationale where relevant.** If the prescription is for an FDA-approved indication that the locally registered Xtandi label does not yet include, the letter sets out why a clinically equivalent locally available alternative is not suitable.
- **Physician license.** Verification of MOHAP, DHA, DOH, or Sharjah Health Authority licensing in active standing, matching the emirate of the dispensing facility.

Common questions about Xtandi in the UAE

Will Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, or Orient cover this?

Each insurer assesses coverage case by case. Coverage is more established for the older indications (mCRPC and mCSPC) and more variable for the newest FDA indication (nmCSPC with high-risk BCR, November 2023). Where the local Xtandi label has been included on an insurer's formulary, named-patient imports of US-labelled product sit in a separate category and frequently require pre-authorisation. We do not promise coverage. We supply the documentation set that lets your insurer assess the case; the claim sits with you or your hospital.

Will my DHA-licensed or DOH-licensed medical oncologist's letter be sufficient?

Yes. Any UAE-licensed physician practicing in good standing in the emirate of the dispensing facility has signing authority. For prostate cancer the EDE expects a medical oncologist or genitourinary oncologist; urology with prostate cancer subspecialty is also recognised. The credential is institutional rather than a separate EDE registration.

Why source US-labelled Xtandi when local Xtandi is registered?

Three drivers, applied case by case. First, indication lag where the local label has not yet caught up to the newest FDA approval. Second, formulary exclusion or sourcing constraints at the specific institution or insurer. Third, sourcing assurance preference for US-labelled product through a documented chain of custody.

Is there a competitor or alternative within the ARPI class?

Within the ARPI class, abiraterone acetate with prednisone, apalutamide (Erleada), and darolutamide (Nubeqa) are the most directly substitutable agents. Class selection depends on disease state, comorbidities, CNS exposure considerations, and drug-drug interaction profile. Reserve Meds does not influence this clinical choice.

What is the safety profile?

The most common adverse reactions across the prostate cancer indications include fatigue, back pain, hot flush, constipation, arthralgia, decreased appetite, diarrhoea, and

hypertension. Falls and fractures occur at increased frequency versus placebo. Seizure is the most clinically distinctive risk and PRES has been reported. Hypersensitivity reactions including angioedema are listed in the label.

What is the typical course duration?

Continuous daily dosing until disease progression or unacceptable toxicity. There is no fixed-duration regimen. Median treatment duration in the pivotal trials ranged from approximately 14 to 35 months depending on the disease state.

Where Reserve Meds fits in Xtandi cases

Reserve Meds is a US-based concierge coordinator. We do not replace your oncologist, the EDE, or your dispensing pharmacy. For Xtandi specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty pharmacy in the Astellas distribution network, prepare the documentation kit your UAE oncologist needs to file the EDE permit (with the indication-state framework, the staging and biomarker template, and the drug-drug interaction screening template for GnRH agonist co-administration and bone-targeted therapy considerations), align the ambient air-freight shipment plan with the UAE importer, and assign a single named coordinator who carries the patient through the first cycle and the recurring monthly refills. Xtandi is one of the higher-volume drug-name inquiries we expect in the prostate cancer category, alongside abiraterone and apalutamide. No prior Reserve Meds closed-case experience for Xtandi as of this page date; standard NPP coordination applies.

Next step

If your UAE oncologist has identified Xtandi as the right next step and any of the three named-patient drivers apply to your case, add it to our waitlist. We will confirm eligibility within 24 to 48 hours and send the documentation kit to your physician.

Add my Xtandi UAE case to the waitlist

Reserved for you.

Review and oversight. Content on this page is reviewed by Reserve Meds's clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. Review methodology ›

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