Xtandi access in Pakistan

How patients in Pakistan access Xtandi (enzalutamide) across the prostate cancer continuum through the DRAP Special Permission Personal Use Import pathway, framed as the primary access channel where local generic enzalutamide is limited.

1. Quick orientation

Xtandi is an oral once-daily androgen receptor pathway inhibitor used as backbone therapy across the prostate cancer continuum. It is FDA-approved across four disease states: metastatic castration-resistant prostate cancer (mCRPC), non-metastatic castration-resistant prostate cancer (nmCRPC), metastatic castration-sensitive prostate cancer (mCSPC), and most recently (November 2023) non-metastatic castration-sensitive prostate cancer (nmCSPC) with high-risk biochemical recurrence. It is manufactured by Astellas Pharma US, Inc. and co-promoted in the United States with Pfizer. Pakistan has limited availability of US-labeled Xtandi and limited generic enzalutamide depth in the local market, which is why Reserve Meds frames the DRAP Special Permission Personal Use Import pathway as a primary access channel for cash-pay-capable patients whose treating oncologist is prescribing the FDA-supported regimen. Clinical decisions remain with your treating oncologist or uro-oncologist. Reserved for you.

2. Why Pakistan patients need Xtandi through the named-patient pathway

Three patterns drive Pakistani prostate cancer patients toward the cross-border channel for Xtandi. First, indication lag: the newest FDA approval (nmCSPC with high-risk biochemical recurrence, November 2023) is not uniformly reflected in non-United States labels yet, so patients whose oncologists want Xtandi at this earlier disease state may find that the local product label still restricts use to mCRPC or mCSPC. Second, limited local generic enzalutamide availability: Pakistan's specialty oncology shelf for ARPI agents is thinner than the GCC or large EU markets, and even where local registration exists, formulary inclusion and on-shelf stocking are inconsistent. Third, sourcing assurance: sophisticated cash-pay patients increasingly prefer United States-sourced product through a documented DSCSA-compliant chain of custody over locally available alternatives where counterfeit risk or supply transparency is a concern.

The DRAP Special Permission Personal Use Import framework is the documented lawful route for the structural-gap and indication-lag cases. Reserve Meds operates inside that framework as the United States-side coordinator while a PMDC-licensed oncologist or urologist at AKUH, Shaukat Khanum, PKLI, Liaquat National, Shifa International, or CMH holds the clinical relationship. Insurance coverage through Adamjee, Jubilee, EFU, State Life, IGI, or Pak-Qatar Family Takaful is unlikely to apply to a cross-border procurement; the realistic default is cash-pay.

3. The DRAP Special Permission pathway for Xtandi

DRAP regulates the import of medicines through the Quality Assurance and Laboratory Testing Division's Import and Export Section. For unregistered medicines, or registered medicines that are not available in the required form, DRAP issues a Special Permission, also called the No Objection Certificate (NOC) for Personal Use Import. Applications are filed through DRAP's Online Import and Export System (OIES). For Xtandi, the cell-specific clinical-justification angle is the disease-state and prior-line documentation, since Xtandi is used across four FDA-approved prostate cancer states and the destination prescriber must specify which state and which prior therapies have been attempted.

The application package typically includes the treating oncologist's clinical justification letter setting out the prostate cancer diagnosis (Gleason score and clinical stage at diagnosis, current disease state, current PSA trajectory, imaging characterization where relevant for mCRPC or mCSPC), the planned disease-state-specific use of Xtandi (mCRPC, nmCRPC, mCSPC, or nmCSPC with high-risk biochemical recurrence per the November 2023 FDA approval), prior-line history (docetaxel exposure if any, prior ARPI exposure if any, surgical or medical castration status), the GnRH agonist

(typically leuprolide) used as backbone in castration-sensitive disease or the medical castration plan in castration-resistant disease, the dosing plan (160 mg once daily as 4 x 40 mg capsules, 4 x 40 mg tablets, or 2 x 80 mg tablets), and the duration estimate for the supply window. The PMDC license verification of the treating physician is attached. The patient identifier is the CNIC.

Product details include the brand name (Xtandi), the generic name (enzalutamide), the manufacturer (Astellas Pharma US, Inc., co-promoted with Pfizer), strengths (40 mg soft gelatin capsules; 40 mg and 80 mg film-coated tablets), the room-temperature storage profile, and the projected three to six month supply quantity. A manufacturer or authorized distributor letter confirms the product is genuine and sourced through the legitimate United States DSCSA-compliant chain. The dispensing facility's institutional license accompanies the package. Routine personal-use applications typically clear in four to eight weeks from a complete submission; well-documented prostate cancer cases run on the shorter end because the diagnostic framework is widely understood.

4. Where Xtandi gets dispensed in Pakistan

Xtandi dispensing in Pakistan concentrates at the tertiary oncology and urology services across the Karachi, Lahore, and Islamabad centers. Shaukat Khanum Memorial Cancer Hospital and Research Centre in Lahore is the natural oncology home and operates outpatient and inpatient pharmacy services with established import-permission experience. Aga Khan University Hospital in Karachi has an established Department of Oncology and uro-oncology service with a 24/7 institutional pharmacy. Pakistan Kidney and Liver Institute (PKLI) in Lahore has urology and uro-oncology services. Liaquat National Hospital in Karachi has a large adult oncology service. Indus Hospital and Health Network in Karachi handles tertiary referrals. Shifa International Hospital in Islamabad serves the federal capital region. The Combined Military Hospitals network at CMH Rawalpindi and CMH Lahore treats military families and civilian referrals through its uro-oncology capacity.

Because Xtandi is a room-temperature oral capsule or tablet with no cold-chain requirement, the dispensing facility constraint is the institutional license and the import-pharmacy workflow. Outpatient dispensing after the institutional receipt is the normal pattern for chronic ARPI therapy.

5. Real cost picture for Xtandi in Pakistan

The United States wholesale acquisition cost for Xtandi as of 2024 and 2025 disclosures 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. Astellas published a WAC of USD 14,332.47 per 120-capsule package in a May 2024 Pfizer co-prescriber disclosure, with subsequent 2025 disclosures trending toward the USD 15,000 mark. A 12-month course at WAC totals roughly USD 165,000 to USD 180,000 before any logistics, coordination, or country-specific markups. WAC does not reflect manufacturer rebates or negotiated payer pricing, and United States patients with insurance frequently pay materially less than WAC; international patients on the cross-border channel do not benefit from those United States-only programs.

For a Pakistan patient, the cost stack is the United States acquisition cost for the projected supply window plus international air freight (typically USD 400 to USD 800 for a room-temperature oral product) plus the Reserve Meds coordination fee. The Pakistani Rupee has been volatile, trading in the 278 to 280 PKR per USD range in May 2026, with April 2026 CPI inflation at 10.9 percent. Reserve Meds quotes in USD and accepts wire transfers from any USD-accessible source, which lets families consolidate funds across overseas relatives. Sehat Sahulat's Rs. 1,000,000 annual ceiling typically does not stretch to cover a year of Xtandi, though Sehat Sahulat can still cover hospitalization, supportive care, and procedures alongside the Xtandi supply procured separately.

6. Typical timeline for Xtandi in Pakistan

Routine DRAP Personal Use Import applications clear in four to eight weeks from a complete submission. Reserve Meds plans on the longer end of this range for first cases and tightens as the documentation pattern is established. Because Xtandi is a room-temperature oral product with no cold-chain requirement, the physical logistics leg adds two to four days for

international air freight plus FBR Customs clearance at Karachi seaport or Karachi, Lahore, or Islamabad airports. The realistic end-to-end estimate from intake to dispensing is six to ten weeks for the first cycle, with subsequent refill cycles compressing to a faster cadence. Treatment is continuous daily dosing until disease progression or unacceptable toxicity; median treatment duration in the pivotal trials ranged from approximately 14 to 35 months depending on the disease state and trial arm, with longer durations seen in earlier-stage indications. Reserve Meds plans the relationship as a multi-cycle coordination.

7. What your physician needs to provide

The clinical justification letter, signed by a PMDC-licensed medical oncologist or urologist, is the cornerstone of the application. For Xtandi, the letter sets out the prostate cancer diagnosis (Gleason score, clinical stage at diagnosis, current disease state), the prior-line history (docetaxel exposure if any, prior ARPI exposure if any), the current PSA trajectory and imaging characterization where relevant, the planned disease-state-specific Xtandi use (mCRPC, nmCRPC, mCSPC, or nmCSPC with high-risk biochemical recurrence), the GnRH agonist or surgical castration status, and the dosing plan (160 mg once daily). Dose modifications apply if a Grade 3 or higher adverse reaction or intolerable side effect emerges; the label permits dose reduction to 120 mg or 80 mg daily, with dose interruption for up to one week. Treatment with strong CYP2C8 inhibitors should be avoided; if unavoidable, the Xtandi dose is reduced to 80 mg daily. Strong CYP3A4 inducers (such as rifampin or phenytoin) reduce enzalutamide exposure and should be avoided where possible.

The monitoring plan attached to the application typically describes regular blood pressure monitoring, assessment for new neurologic symptoms (seizure, posterior reversible encephalopathy syndrome) with low threshold for evaluation, periodic liver function tests, and fall and fracture risk assessment particularly in older patients and those with osteoporosis history. The label directs permanent discontinuation in patients who develop a seizure during treatment. Drug-drug interaction screening with the patient's full medication list is part of onboarding, with CYP3A4 inducers and strong CYP2C8 inhibitors as the highest-yield flags. Adverse events are reported through the DRAP Pharmacovigilance Centre.

8. Common questions about Xtandi in Pakistan

Why does my oncologist want Xtandi rather than locally available enzalutamide? Pakistan has limited generic enzalutamide availability and limited US-labeled Xtandi on the local shelf, particularly for the newest FDA indications (nmCSPC with high-risk biochemical recurrence). Sourcing assurance and DSCSA-compliant United States supply are reasons sophisticated cash-pay patients prefer the cross-border route. The clinical choice belongs to your treating physician.

Will Adamjee, Jubilee, EFU, or State Life cover Xtandi? Coverage for named-patient imports of unregistered or recently FDA-expanded indications is uncommon across Pakistani health plans. Jubilee General's Personal HealthCare and Adamjee Health Insurance cover in-hospital chemotherapy and radiotherapy in their formularies, but specialty imports of ARPI agents are typically outside formulary. Reserve Meds supplies the documentation an insurer needs to assess the claim. The realistic default is cash-pay.

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, diarrhea, and hypertension. Falls and fractures occur at increased frequency versus placebo. Seizure is the most clinically distinctive risk: seizure occurred in roughly 0.6 percent of Xtandi-treated patients across eight randomized trials, and at higher rates in patients with predisposing factors. Posterior reversible encephalopathy syndrome (PRES) has been reported. Hypersensitivity reactions, including angioedema, are listed in the label.

Is there an alternative ARPI? Within the ARPI class, abiraterone acetate (Zytiga, plus 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. Within castration-sensitive disease, darolutamide has a lower CNS penetration profile that some clinicians weight for patients with seizure history or CNS comorbidities. The choice between agents is a clinical decision Reserve Meds does not influence.

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 and the trial arm.

How does diaspora-pooled funding work for Xtandi refills? Pakistan's diaspora pattern is well-established, with major remittance corridors from Saudi Arabia, the UAE, the United Kingdom, the United States, and Canada. Many prostate cancer families fund chronic ARPI supply by pooling resources across overseas relatives. Reserve Meds quotes in USD and accepts wire transfers from any USD-accessible source.

9. Where Reserve Meds fits in Xtandi cases

Reserve Meds is a United States-based concierge coordinator. We do not replace your treating oncologist or urologist, we do not replace DRAP, we do not replace your dispensing hospital pharmacy or the in-country importer. What we do for an Xtandi case is orchestrate the United States-side sourcing through a licensed specialty pharmacy channel that can validate prescription chain-of-custody, the regulatory documentation kit for the DRAP Personal Use Import application, the international logistics for a room-temperature oral product through bonded air freight, the FBR Customs coordination at the port of entry, and a single named coordinator who stays with your case across refill cycles. Because Xtandi therapy is continuous and median treatment duration runs to 14 to 35 months depending on disease state, Reserve Meds plans the relationship as a multi-cycle coordination.

Xtandi is one of the higher-volume drug-name inquiries Reserve Meds expects in the prostate cancer category, alongside abiraterone and apalutamide. No prior closed Reserve Meds case experience for Xtandi specifically at this module date; standard NPP coordination applies.

10. Next step

If you or a family member has prostate cancer in any of the four FDA-approved Xtandi disease states (mCRPC, nmCRPC, mCSPC, or nmCSPC with high-risk biochemical recurrence) and your treating oncologist or urologist at Shaukat Khanum, AKUH, PKLI, Liaquat National, Shifa, or CMH is prescribing Xtandi, the next step is to join the Reserve Meds waitlist. We confirm eligibility within 24 to 48 hours and send the documentation kit to your physician and hospital pharmacy.

Reserved for you.