Akeega access in Pakistan

How patients in Pakistan reach Akeega (niraparib plus abiraterone acetate) for BRCA-mutated metastatic prostate cancer through the DRAP Special Permission Personal Use Import pathway.

Quick orientation

Akeega is a fixed-dose combination oral tablet containing niraparib (a PARP inhibitor) and abiraterone acetate (a CYP17 androgen-axis inhibitor), the first dual-action tablet of its kind for prostate cancer. The U.S. FDA approved Akeega on August 11, 2023 in combination with prednisone for adult patients with BRCA-mutated metastatic castration-resistant prostate cancer (mCRPC), with a December 2025 label extension to BRCA2-mutated metastatic castration-sensitive prostate cancer. BRCA mutation testing through an FDA-approved companion diagnostic is mandatory before initiation. In Pakistan, Akeega has no DRAP marketing authorization. Patients with BRCA-confirmed advanced prostate cancer reach the combination through the Drug Regulatory Authority of Pakistan's Special Permission for Personal Use Import, typically with BRCA confirmation already in hand from Shaukat Khanum Memorial Cancer Hospital's molecular pathology service or AKUH's tertiary molecular diagnostics. Reserve Meds is the U.S.-side coordinator for that import. The treating medical oncologist remains the prescriber. The dispensing hospital pharmacy remains the dispensing setting. Reserved for you.

Why prostate cancer families in Pakistan need Akeega via NPP

Three structural reasons converge on the DRAP Special Permission pathway for Akeega. First, the combination is not registered with DRAP, so no Pakistani pharmacy can stock or fill it through normal commercial channels. Local niraparib (Zejula) and local abiraterone (Zytiga and generic abiraterone) availability is uneven, and the fixed-dose combination is not in any case the same product. Second, the indication is gated by BRCA testing. BRCA1/2 germline and somatic testing capability in Pakistan is concentrated at Shaukat Khanum Memorial Cancer Hospital and Research Centre's molecular pathology service and AKUH's tertiary molecular diagnostics. Patients with BRCA-confirmed mCRPC or mCSPC arrive at the Akeega prescription decision through a clinical pathway that the local oncology community recognizes, even where the medicine itself is not stocked. Third, the operational case for the fixed-dose tablet is simpler than running niraparib and abiraterone as two separate prescriptions on two separate adherence schedules with two separate procurement chains, particularly in a Pakistani context where the patient may already be managing other prostate cancer therapy elements and where adherence support is a real factor.

Patients across Karachi, Lahore, Islamabad, and the smaller cities all route through the same DRAP framework. The operational difference is whether the patient is treated at one of the major oncology centers with in-house import pharmacy capacity, or partners with a DRAP-licensed importer that handles the regulatory interface on behalf of the treating clinic.

The DRAP Special Permission pathway for Akeega

The Drug Regulatory Authority of Pakistan issues Special Permission for Personal Use Import of unregistered medicines through its Quality Assurance and Laboratory Testing Division, with

applications filed on the Online Import and Export System (OIES) portal. For an Akeega case, the file is built in the patient's name with the CNIC as identifier, against a PMDC-licensed treating medical oncologist, with a clinical justification letter that establishes the case for the unregistered combination tablet.

The application package includes the clinical justification letter from the treating medical oncologist with the prostate cancer diagnosis (Gleason score, PSA at diagnosis and current, stage), the BRCA mutation result with the specific BRCA1 or BRCA2 variant identified, the testing laboratory and date (Shaukat Khanum molecular pathology, AKUH molecular diagnostics, an international reference lab such as FoundationOne CDx, or another DRAP-acceptable lab), prior therapies attempted with outcomes (ADT history, prior chemotherapy if any, prior androgen-receptor-pathway inhibitor if any), the current disease status (radiographic progression, biochemical progression, ECOG performance status), and the rationale for the Akeega combination versus alternatives such as olaparib plus abiraterone or talazoparib plus enzalutamide. It includes PMDC license verification for the prescriber. It includes product details (brand Akeega, INN niraparib plus abiraterone acetate, manufacturer Janssen Biotech as a Johnson and Johnson company, country of origin, presentation as 100 mg niraparib plus 500 mg abiraterone acetate tablets, daily-dose configuration to deliver 200 mg niraparib plus 1,000 mg abiraterone acetate, requested quantity, batch and expiry where available). It includes the destination dispensing facility license, and the chain-of-custody plan from U.S. release through FBR Customs at Karachi or Lahore airport to the receiving Pakistani pharmacy.

For Akeega specifically, three file features deserve attention. The BRCA test result is the gating diagnostic; DRAP reviewers expect to see the laboratory report attached, not just summarized. The clinical letter should reference the FDA-approved companion diagnostic framework explicitly. Second, the file should reference the myelodysplastic syndrome and acute myeloid leukemia (MDS/AML) warning in the FDA label, because reviewers expect a documented monitoring plan covering complete blood count weekly for the first month, then monthly during treatment, and long-term vigilance for MDS and AML. Third, the file should name the supportive medications (prednisone 10 mg daily, ongoing ADT) that the local market typically supplies and that Reserve Meds does not need to source.

Routine cases at established oncology centers typically clear in four to eight weeks from a complete submission. Complex cases involving documentation queries on BRCA confirmation, first-time DRAP filers, or PMDC license issues can extend to ten to sixteen weeks.

Where Akeega gets dispensed in Pakistan

For Akeega, the relevant institutions are the oncology centers with established medical oncology programs, BRCA molecular diagnostic capability or established referral pathways, and DRAP-experienced import pharmacy operations. Shaukat Khanum Memorial Cancer Hospital and Research Centre (SKMCH and RC) in Lahore is Pakistan's flagship cancer hospital with a long history of negotiating directly with multinational manufacturers and accessing medicines through import permissions, and has BRCA molecular pathology capability in-house. Aga Khan University Hospital (AKUH) in Karachi has the Department of Oncology with eighteen full-time faculty across medical, pediatric, radiation, and palliative oncology, tertiary molecular diagnostics, and a 24/7 temperature-controlled pharmacy. The Indus Hospital and Health Network has oncology and hematology capability across Karachi, Lahore, and Hyderabad. Liaquat National Hospital in Karachi adds a further private tertiary oncology option. Shifa International Hospital in Islamabad operates an established import pharmacy workflow for federal-capital-region patients. The

Combined Military Hospitals (CMH) network handles military family oncology cases at CMH Rawalpindi, CMH Lahore, and other major cantonment cities.

Because Akeega ships as a standard pharmaceutical commodity in tamper-evident manufacturer packaging at room temperature, the dispensing-facility list is wider than for cold-chain biologics. The relevant institutional capability is medical oncology care, BRCA result documentation, and DRAP-experienced import pharmacy operation. Patients outside the major metros typically have their case routed through one of the centers above, with last-mile travel handled separately by the patient.

Real cost picture for Akeega in Pakistan

The U.S. 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 published 2024 pricing references. The daily dose requires two tablets of the 100 plus 500 mg strength to deliver 200 mg niraparib plus 1,000 mg abiraterone acetate. Patient-month cost in the U.S. specia