# Akeega access in India: the CDSCO Rule 36 named-patient pathway

How families in India legally obtain Akeega (niraparib + abiraterone acetate fixed-dose oral combination) for BRCA-mutated metastatic prostate cancer from US-source supply through CDSCO personal importation, with BRCA confirmation and PARP-class monitoring built into the case plan.

*Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.*

## Quick orientation

Akeega is a Janssen fixed-dose combination oral tablet containing niraparib (a poly(ADP-ribose) polymerase, or PARP, inhibitor) and abiraterone acetate (a CYP17 inhibitor that blocks androgen biosynthesis), the first dual-action tablet of its kind for prostate cancer. The US Food and Drug Administration approved Akeega on 11 August 2023 in combination with prednisone for BRCA-mutated metastatic castration-resistant prostate cancer (mCRPC), with a December 2025 label extension to BRCA2-mutated metastatic castration-sensitive prostate cancer (mCSPC). BRCA testing through an FDA-approved companion diagnostic (such as FoundationOne CDx) is mandatory before initiation. Akeega is not registered with the CDSCO as of this review. Indian patients with confirmed BRCA-mutated metastatic prostate cancer reach Akeega through the Central Drugs Standard Control Organization (CDSCO) personal importation framework under Rule 36 of the Drugs and Cosmetics Rules 1945, with the Form 12A application and Form 12B permit issued by the office of the Drugs Controller General of India (DCGI). Reserve Meds coordinates the US-side limited-distribution specialty pharmacy sourcing, ambient-temperature pharmaceutical logistics, and the documentation kit your treating oncologist needs to file.

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## Why patients in India need Akeega via the named-patient pathway

India has a large and rising prostate cancer caseload concentrated at the National Cancer Grid centres, including Tata Memorial Centre Mumbai (the anchor institution), AIIMS New Delhi, Christian Medical College Vellore, Apollo Hospitals (Chennai flagship, Delhi, Bangalore, Hyderabad, Kolkata), Kokilaben Dhirubhai Ambani Hospital Mumbai, Fortis Memorial Research Institute Gurgaon, Medanta The Medicity Gurgaon, and MGM Healthcare Chennai. BRCA mutation testing access in India has improved meaningfully over the last several years, with germline and somatic testing now available through tertiary cancer genetics services at Tata Memorial Centre and at major private oncology centres, and with specialty diagnostic laboratories offering FoundationOne CDx and equivalent comprehensive genomic profiling panels for tumours. For the subset of patients who have completed BRCA testing and have a confirmed deleterious or suspected deleterious BRCA1 or BRCA2 mutation, the FDA-approved PARP-plus-androgen-axis combinations become clinically actionable.

Akeega is not on the CDSCO register. The separate components are available in India in different forms: abiraterone acetate is available locally as Zytiga and as multiple Indian generics, while

niraparib is available locally as Zejula through the importing routes that Janssen and partners use for the ovarian cancer indication. Running the components separately on two prescriptions is medically feasible but operationally heavier on the patient and the family, particularly when the patient is managing prednisone, ongoing androgen deprivation therapy (such as a GnRH analogue), and the adherence schedule across distinct dispensing pipelines. The fixed-dose tablet is the preferred procurement route when patients and oncologists prefer adherence simplicity, and Rule 36 is the legal vehicle for the unregistered fixed-dose product.

India's NPRD 2021 INR 50 lakh financial-assistance ceiling under the Rashtriya Arogya Nidhi umbrella scheme is structured around rare-disease one-time treatments and does not extend to oncology drug supply. Cash-pay, often through diaspora-funded structures, is the working financial posture for Akeega cases. Diaspora-funded care, where an adult child working overseas pays the invoice for a parent under care at Tata Memorial Centre or Apollo Chennai, is a common configuration that the Rule 36 framework accommodates when the named patient is the Indian resident.

## The CDSCO Rule 36 named-patient pathway for Akeega

The legal foundation for personal import of an unregistered medicine into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits the import of a small quantity of a drug, whose import would otherwise be prohibited under Section 10 of the Drugs and Cosmetics Act 1940, for the exclusive personal use of a named patient. Form 12A is the application for the permit. Form 12B is the permit itself, issued by the office of the DCGI at FDA Bhawan, Kotla Road, New Delhi, or by designated CDSCO Port Offices. The application is accompanied by a prescription from a Registered Medical Practitioner (RMP) showing the RMP's National Medical Commission (NMC) registration number and the quantity required for treatment. The quantity of any single drug imported is capped at one hundred average doses per application.

For Akeega specifically, the clinical-justification angle in a Form 12A application is the BRCA-confirmation requirement that is the gating clinical criterion in the FDA label. The strongest applications consistently include a treating oncologist's confirmed diagnosis of metastatic prostate cancer (with castration status documented to distinguish mCRPC from mCSPC, given the two separate FDA-approved indications); the BRCA mutation result from an FDA-recognized companion diagnostic or equivalent comprehensive genomic profiling panel, with the testing laboratory named (FoundationOne CDx is the FDA-approved companion diagnostic; tumour somatic or germline panels at Tata Memorial Centre or other tertiary cancer genetics services with appropriate clinical reporting are also documented); the documented prior therapies tried and failed where the patient is on the mCRPC pathway; the proposed daily dose (200 mg niraparib plus 1,000 mg abiraterone acetate orally once daily on an empty stomach, with prednisone 10 mg once daily, and ongoing androgen deprivation therapy continued unless the patient has undergone bilateral orchiectomy); and the PARP-class monitoring plan covering complete blood count weekly for the first month then monthly during treatment, blood pressure, liver function tests, serum potassium, and long-term vigilance for myelodysplastic syndrome and acute myeloid leukemia.

For institutional Compassionate Use of drugs not approved for marketing in India at all, the parallel pathway is the Compassionate Use application route to the DCGI by a government hospital, a registered medical practitioner, a pharmaceutical company, or the patient. This route applies when the drug is approved by a recognised reference authority (FDA, EMA, MHRA, Health Canada, PMDA) for an unmet medical need. Akeega qualifies under FDA and EMA approval. Government institutions including AIIMS New Delhi and Tata Memorial Centre Mumbai

have established workflow for this pathway in oncology cases. CDSCO's published guidance states Form 12B is typically issued within one to two days for routine applications where documentation is complete. Indian families and hospitals plan for a two to four week window from oncologist decision to first dose, because the bulk of elapsed time runs through upstream documentation assembly (most notably BRCA confirmation if not already complete) and downstream international logistics rather than the regulator's stamp.

## Where Akeega gets dispensed in India

Akeega is an oral solid-dose product. It is stable at controlled room temperature (20 to 25 degrees Celsius), does not require refrigeration, and ships as a standard pharmaceutical commodity in tamper-evident, child-resistant manufacturer packaging. Dispensing capability is therefore broader than for an infusion biologic, but the dispensing facility must hold a valid drug licence covering imported unregistered medicines and must operate an oncology pharmacy desk capable of family training on the on-an-empty-stomach administration requirement (no food for at least one hour before or two hours after each dose, because abiraterone exposure increases significantly with food and that exposure increase is associated with toxicity).

Indian institutions with established medical oncology and prostate cancer programmes plus the import pharmacy infrastructure include Tata Memorial Centre Mumbai (autonomous institution under the Department of Atomic Energy, India's oldest and largest cancer institute, anchor of the National Cancer Grid, with multidisciplinary disease-group model and roughly 60 percent of patients receiving free or highly subsidised care while international and private named-patient imports run in parallel), AIIMS New Delhi (apex public-sector institution), Christian Medical College Vellore (globally recognised for oncology), Apollo Hospitals (Chennai flagship plus Delhi, Bangalore, Hyderabad, Kolkata, with dedicated international patient services and JCI plus NABH accreditation), Kokilaben Dhirubhai Ambani Hospital Mumbai (advanced cancer programmes), MGM Healthcare Chennai, Fortis Memorial Research Institute Gurgaon, and Manipal Hospitals Bangalore.

For patients identified at smaller oncology services without an in-house import pharmacy desk, the practical pattern is to route the case to one of the centres above, or to work through a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that handles the Form 12A filing and the chain-of-custody documentation. Reserve Meds aligns with the importer on US-side sourcing and with the treating oncologist on clinical documentation. Multi-city and cross-border families (the patient in Hyderabad, the oncologist at Tata Memorial Mumbai, an adult child in Bengaluru handling logistics, and a son in Dubai or London paying the invoice) are common, and Reserve Meds' single-coordinator model is built for that pattern.

## Real cost picture for Akeega in India

Costs sit in Indian rupees with the rupee floating against the US dollar. In May 2026 the USD/INR rate is in the 94 to 95 range. Pricing in this section is expressed in USD for portability; the actual invoice converts at the prevailing rate on the day of the transaction.

Per published US pricing references (Drugs.com), 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. The daily dose requires two tablets of that strength (or an equivalent combined-strength configuration) to deliver 200 mg niraparib plus 1,000 mg abiraterone acetate. Patient-month cost in the US specialty channel is therefore in the order of USD 19,000 to 20,000 per 30-day supply at WAC, before any discounts. The CADTH

reimbursement recommendation placed Canadian list-price equivalents at approximately CAD 8,283 per 28-day supply, meaningfully below US WAC. International payer pricing is highly variable. The Reserve Meds quote line for the medicine is sized to the supply duration agreed at intake.

International ambient-temperature shipping for Akeega is among the more forgiving logistics profiles for an oral oncology product. A 30-day course fits within a small parcel envelope, which simplifies customs declaration and last-mile delivery. Logistics surcharges typically run USD 200 to 500 per shipment depending on city of destination, parcel weight, and whether multiple monthly supplies are consolidated. Tablets must remain in original sealed manufacturer packaging for chain-of-custody and import documentation, and heat-excursion risk during summer transit through northern Indian flight paths is a routing consideration the 3PL plans around. India's Union Budget 2026-27 fully exempted basic customs duty on a set of named cancer drugs and broadened the rare-disease list; the specific HSN code and exemption status of each Akeega shipment is confirmed at the documentation stage. GST on most life-saving medicines is 5 percent.

None of the major Indian private insurers (Star Health and Allied Insurance, HDFC ERGO, ICICI Lombard, Niva Bupa) reimburse a Rule 36 personal import of an unregistered oncology medicine as a standard line item. CGHS provides for life-saving and anti-cancer medicines that are not in the standard formulary to be considered case by case by an Expert Committee under Special DG (DGHS), with stricter constraints on drugs not approved by the DCGI; the family may pursue this evaluation but the operating expectation is cash-pay. Reserve Meds itemises the US-side procurement, the international logistics, and the concierge coordination fee separately on every firm quote so that any reimbursement attempt the family chooses to pursue has clean documentation to work with.

## Typical timeline for Akeega in India

For a routine Indian Akeega case, the CDSCO Form 12B permit window is typically one to two business days from a complete Form 12A filing, per the regulator's published guidance. The ambient-temperature handling class keeps Akeega on standard international transit windows with no cold-chain time pressure. End-to-end, most families plan for two to four weeks from oncologist decision to first dose, with the elapsed time dominated by upstream documentation assembly and downstream logistics rather than the permit stamp.

Where BRCA testing is not yet complete at the time of inquiry, the BRCA result is the rate-limiting upstream step rather than the CDSCO permit. A germline test through a major tertiary cancer genetics service typically returns in two to four weeks; a comprehensive tumour genomic profile through FoundationOne CDx or equivalent typically returns in three to four weeks from sample receipt at the laboratory. Reserve Meds does not coordinate the BRCA testing step itself but flags the dependency at intake so the family understands the sequencing. Because Akeega is dosed daily on a continuous (not cycled) basis until disease progression or unacceptable toxicity, Reserve Meds plans repeat-shipment cadence at case acceptance, with the dose-modification triggers documented (niraparib reduction to 100 mg daily in two steps for hematologic toxicity, abiraterone held rather than reduced).

## What your physician needs to provide

The clinical justification letter is the cornerstone of the Form 12A filing. For Akeega, the strongest letters consistently include: a treating oncologist's confirmed diagnosis of metastatic

prostate cancer with castration status documented (mCRPC under the August 2023 FDA approval or BRCA2-mutated mCSPC under the December 2025 FDA expansion); the BRCA mutation result from FoundationOne CDx or equivalent comprehensive genomic profiling with the testing laboratory named; prior therapies tried and failed where applicable to the mCRPC indication; the proposed daily dose (200 mg niraparib plus 1,000 mg abiraterone acetate orally once daily on an empty stomach, with prednisone 10 mg once daily, and ongoing androgen deprivation therapy continued unless the patient has undergone bilateral orchiectomy); and the monitoring plan covering complete blood count weekly for the first month then monthly, blood pressure, liver function tests, serum potassium at baseline and at regular intervals, cortisol if adrenal insufficiency is suspected under stress, and long-term vigilance for myelodysplastic syndrome and acute myeloid leukemia. The prescribing oncologist's NMC registration number, the dispensing facility's drug licence, and a chain-of-custody plan from the US specialty pharmacy to the Indian dispensing pharmacy complete the file. Import documentation explicitly names BRCA-mutated metastatic prostate cancer as the indication so customs reviewers do not mischaracterize the shipment.

The treating oncologist retains the clinical decision and the Pharmacovigilance Programme of India (PvPI) adverse-event reporting obligation through the Indian Pharmacopoeia Commission for any imported product. Reserve Meds includes the PvPI reference in the physician documentation kit; the reporting obligation itself stays with the prescribing physician.

## Common questions about Akeega in India

### What if BRCA testing has not been done yet?

BRCA confirmation is mandatory before Akeega initiation under the FDA label. Indian patients without prior testing route through tertiary cancer genetics services at Tata Memorial Centre, AIIMS, Christian Medical College Vellore, or major private oncology centres for germline testing, or through FoundationOne CDx or equivalent comprehensive tumour genomic profiling for somatic testing. Reserve Meds flags the dependency at intake but does not coordinate the testing step itself. The first Akeega shipment is sequenced to follow the BRCA result.

### What is the MDS and AML risk we should be aware of?

The FDA label warning on Akeega includes the PARP-class risk of myelodysplastic syndrome and acute myeloid leukemia, including fatal cases reported with niraparib and other PARP inhibitors. Long-term vigilance is required. The most common adverse reactions in the MAGNITUDE trial were anemia, hypertension, fatigue, constipation, nausea, and musculoskeletal pain. Abiraterone contributes hypertension, hypokalemia, fluid retention, and adrenocortical insufficiency under stress. The monitoring schedule is set by the treating oncologist.

### Why the fixed-dose Akeega rather than separate niraparib (Zejula) and abiraterone (Zytiga)?

The fixed-dose tablet simplifies administration and adherence relative to two separately prescribed and separately sourced medicines, particularly while the patient is also managing prednisone and ongoing androgen deprivation therapy. The clinical decision belongs to the treating oncologist. Reserve Meds does not advise on the comparator choice.

### What about the empty-stomach requirement?

The FDA label requires Akeega to be taken on an empty stomach, with 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 that exposure increase is associated with toxicity. Family training at the dispensing pharmacy and follow-up reinforcement by the treating oncology team is the standard practice.

### Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover Akeega?

Each plan handles named-patient imports case by case. None of the major Indian private insurers reimburse a Rule 36 personal import of an unregistered oncology medicine as a standard line item. Reserve Meds provides the itemised documentation that lets the insurer evaluate. Cash-pay is the working posture.

### Does FCRA affect a diaspora-funded Akeega case?

The Foreign Contribution (Regulation) Act 2010 (FCRA), as proposed to be amended by the Foreign Contribution (Regulation) Amendment Bill 2026, regulates foreign donations to Indian organisations and individuals. For a patient family paying for the medicine themselves, including an adult child overseas paying for a parent's treatment, FCRA is generally not engaged. Where a foreign foundation or oncology-focused diaspora group is funding the treatment, FCRA registration of the recipient organisation and the donation route can become relevant. Reserve Meds does not provide FCRA legal advice; we flag the question so it reaches the right adviser early.

## Where Reserve Meds fits in Akeega cases

Reserve Meds is a US-based concierge coordinator. We do not replace your oncologist, do not replace CDSCO or the DCGI, and do not replace the dispensing hospital pharmacy or the licensed specialty importer, and we do not coordinate the BRCA testing step. What we do is orchestrate the US-side specialty pharmacy sourcing through Janssen's limited-distribution network (including authorised partners such as Onco360) once the BRCA result is documented, ambient-temperature pharmaceutical logistics with documented temperature logging through a bonded pharmaceutical 3PL, and the documentation kit your treating oncologist needs for the Form 12A filing. No prior Reserve Meds case experience exists for Akeega as of this review, so standard NPP coordination applies with particular attention to BRCA confirmation as the gating clinical criterion, the empty-stomach administration training at dispensing, the PARP-class monitoring cadence the oncologist holds, and clear indication labelling on customs documentation. A single named coordinator carries the case from intake through continuous daily dosing until progression or unacceptable toxicity.

## Next step

If an Indian patient with BRCA-mutated metastatic prostate cancer has an oncologist considering Akeega, add the case to the waitlist. We will respond within 24 to 48 hours with a documentation kit for your oncologist and an indicative cost range.

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*This guide is informational, not medical or legal advice. The named-patient framework requires a licensed Indian physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.*