



# Joenja in India

The CDSCO named-patient coordination pathway — indicative 2026

RARE DISEASE · APDS IMMUNODEFICIENCY

## The clinical situation

Joenja (leniolisib) is the first therapy specifically indicated for Activated PI3K-delta Syndrome (APDS), a selective PI3K-delta inhibitor taken as a twice-daily oral tablet. Manufactured by Pharming Group. APDS is a rare primary immunodeficiency driven by gain-of-function variants in PIK3CD (APDS1) or PIK3R1 (APDS2), causing recurrent infections, lymphoproliferation, and lymphoma predisposition. Eligibility is genetically gated and requires immunology oversight for infection surveillance, imaging, and immunoglobulin-replacement coordination.

### The pathway, 5 steps

- 1 Consultation & clinical rationale.** Clinical immunologist confirms APDS with PIK3CD/PIK3R1 genetic report, clinical phenotype documentation, baseline infection and lymphoproliferation history.
- 2 Treatment-centre identification.** Tertiary immunology centre with primary-immunodeficiency experience confirmed as treating site.
- 3 CDSCO named-patient / personal-import application.** Physician or hospital pharmacy files rationale, genetic report, patient reference, and chain-of-custody plan.
- 4 US-side sourcing & logistics.** Reserve Meds coordinates product through our US-licensed DSCSA-compliant specialty wholesale partner.
- 5 Arrival & dispensing.** Hospital pharmacy releases supply; immunology team schedules infection, imaging, and immunoglobulin-replacement surveillance.

### Indicative economics

**Reference US cash-pay range:** USD 550,000–650,000 per year (drug-only reference; Reserve Meds provides a transparent delivered quote at intake).

### Indicative first-dose timing

**7–14 days** from a complete CDSCO application to first dispensation, once cohort intake opens. Indicative — not guaranteed.

## Reserve Meds's role

**Sourcing.** US-licensed specialty wholesale partner, DSCSA chain-of-custody. **Documentation.** Regulatory package for your physician and CDSCO review, keyed to PIK3CD/PIK3R1 genetic diagnosis. **Logistics.** Chain-of-custody shipment on monthly-refill cadence. **Concierge case lead.** Single case lead supporting multi-patient families across immediate and extended relatives. **We are a coordinator** — not the prescriber, not the dispensing pharmacy. All clinical decisions remain with your treating immunologist.

**COMPOSITE EXAMPLE · PRE-LAUNCH WAITLIST**

**Join the Joenja × India first-cohort waitlist.** *Our concierge reaches out as we open intake.*

[reservemed.com/access-guides/joenja-india.html](https://reservemed.com/access-guides/joenja-india.html)



SCAN TO JOIN

**Reserve Meds** · US-based concierge for cross-border specialty medicine. We are a coordinator; we are not the prescriber and not the dispensing pharmacy. All clinical decisions remain with the treating physician. Not medical advice.

*Reserve Meds is in pre-launch. Service availability is limited to our first cohort; all timelines published are indicative, not guarantees. Composite case examples only.*

**reservemed.com** · [hello@reservemed.com](mailto:hello@reservemed.com) · WhatsApp concierge: +1 516 528 3120 · Reviewed 2026-04-23 by Reserve Meds clinical & regulatory team