



Vyondys 53 in India

The CDSCO named-patient coordination pathway — indicative 2026

RARE DISEASE · DMD EXON 53 SKIPPING

The clinical situation

Vyondys 53 (golodirsén) is a phosphorodiamidate morpholino oligomer (PMO) antisense oligonucleotide that restores partial dystrophin production in Duchenne muscular dystrophy patients amenable to exon 53 skipping (~8% of DMD). Manufactured by Sarepta Therapeutics. Administered by weekly weight-based IV infusion, indefinitely. Eligibility is strictly genotype-gated, requires paediatric neurology oversight, a day-infusion facility, and ongoing monitoring including renal function, cardiac assessment, and motor scales (NSAA, 6MWT).

The pathway, 5 steps

- 1 Consultation & clinical rationale.** Paediatric neurologist confirms DMD diagnosis, exon-53-skip-amenable genotype, baseline NSAA, 6MWT, cardiac and renal assessments.
- 2 Treatment-centre identification.** Indian tertiary hospital with paediatric neurology and infusion-day-unit capacity confirmed as administering site.
- 3 CDSCO named-patient / personal-import application.** Physician or hospital pharmacy files clinical rationale, genotyping 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 (Sarepta authorised channel).
- 5 Arrival & first infusion.** Hospital pharmacy receives Vyondys 53; paediatric neurology team administers weekly IV infusion and manages rolling refills.

Indicative economics

Reference US cash-pay range: USD 300,000–1,000,000+ per year weight-dependent (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 exon-53-skip-amenable genotype. **Logistics.** Chain-of-custody shipment to administering hospital pharmacy on weekly-refill cadence. **Concierge case lead.** Named point of contact managing long-term refills and weight-based dose adjustments as the child grows. **We are a coordinator** — not the prescriber, not the dispensing pharmacy. All clinical decisions remain with your treating paediatric neurologist.

COMPOSITE EXAMPLE · PRE-LAUNCH WAITLIST

Join the Vyondys 53 × India first-cohort waitlist. *Our concierge reaches out as we open intake.*

reservemed.com/access-guides/vyondys-53-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.

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