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

How families in India with a child diagnosed with relapsed or refractory BRAF-altered pediatric low-grade glioma legally obtain Ojemda (tovorafenib) from US-source supply, with once-weekly oral dosing built for cross-border maintenance.

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

Quick orientation

Ojemda (tovorafenib) is a brain-penetrant, highly selective type II RAF kinase inhibitor developed by Day One Biopharmaceuticals for pediatric central nervous system disease. The US Food and Drug Administration granted accelerated approval on 23 April 2024 for patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (pLGG) harbouring a BRAF fusion or rearrangement, or a BRAF V600 mutation, who have received at least one prior line of systemic therapy. Ojemda is the first systemic therapy approved by the FDA for pediatric LGG with BRAF rearrangements, including the KIAA1549-BRAF fusion that drives a substantial share of pediatric low-grade glioma cases. There is no public record of Ojemda registration with the Central Drugs Standard Control Organization (CDSCO) as of this review. Indian families reach the medicine through the CDSCO personal importation framework under Rule 36 of the Drugs and Cosmetics Rules 1945, with Form 12A application and Form 12B permit issued by the Drugs Controller General of India (DCGI), or through the institutional Compassionate Use route at hospitals such as AIIMS New Delhi and Tata Memorial Centre Mumbai. Reserve Meds coordinates US closed-network specialty-pharmacy sourcing (Biologics by McKesson and Onco360), international logistics, and the documentation kit your child's pediatric neuro-oncologist needs to file.

Reserved for you.

Why patients in India need Ojemda via the named-patient pathway

Pediatric oncology demand in India is high and clinical capability is significant. Tata Memorial Centre Mumbai runs one of the world's largest pediatric oncology programmes through its ACTREC and Homi Bhabha Children's Hospital arms. AIIMS New Delhi has a high-volume pediatric neuro-oncology unit. Apollo Cancer Centres (Chennai flagship, Delhi, Bangalore, Hyderabad, Kolkata), Christian Medical College (CMC) Vellore, Kokilaben Dhirubhai Ambani Hospital Mumbai, MGM Healthcare Chennai, Manipal Hospitals Bangalore, and Rainbow Children's Hospital Hyderabad have established pediatric oncology workflow. The National Cancer Grid coordinates pediatric oncology standard-of-care across more than 250 institutions. What is missing on local formularies is a BRAF-targeted oral therapy for pediatric low-grade glioma. Carboplatin-vincristine, vinblastine, and other historical chemotherapy regimens are widely available. Adult-labeled BRAF and MEK inhibitors are not on-label for pediatric pLGG. Ojemda is not yet locally registered with CDSCO; personal importation under Rule 36 is the legal route.

The clinical case for reaching across the border is on-label, on-mechanism candidacy. For a child whose tumour carries a BRAF fusion or rearrangement (most commonly KIAA1549-BRAF), the alternatives at the Indian dispensing point are off-label use of adult RAF or MEK inhibitors not designed for pediatric pLGG, chemotherapy regimens with established pediatric toxicity profiles, or watchful waiting. Ojemda is on label in this population. Indian families with a child whose tumour has been molecularly characterised and who has progressed on prior systemic therapy reach for Ojemda precisely because of this mechanism-first match.

The CDSCO Rule 36 named-patient pathway for Ojemda

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 a once-weekly oral oncolytic this comfortably covers a multi-month treatment supply per filing.

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. Pediatric low-grade glioma that has progressed on prior systemic therapy fits the unmet-medical-need framing where on-label, on-mechanism alternatives are not locally available. AIIMS, Tata Memorial Centre, and other public-sector pediatric oncology centres have established Compassionate Use workflow.

For Ojemda specifically, the clinical-justification angle in the Form 12A filing is the molecular confirmation and the prior-line documentation. The strongest applications consistently document: a histologically or radiologically confirmed diagnosis of pediatric low-grade glioma with the WHO grade and location; molecular confirmation of a BRAF fusion or rearrangement (including KIAA1549-BRAF where relevant) or a BRAF V600 mutation, with the testing methodology (FoundationOne CDx is the FDA-approved companion diagnostic; other validated next-generation sequencing assays are in use clinically); documented prior systemic therapy with dates, regimen, response, and reason for discontinuation; the patient's current age (the indication starts at 6 months) and weight with the calculated body surface area for dosing; the proposed dosing plan following the FDA-labeled schedule (380 mg per square metre orally once weekly, with a 600 mg maximum cap; pediatric dose tables in the label translate BSA bands into either tablet count or suspension volume); the presentation chosen (immediate-release 100 mg tablet for older children; reconstituted oral suspension at 25 mg/mL for younger children, with caregiver suspension preparation counselling planned); and the monitoring plan covering liver function tests, complete blood counts, serum creatine phosphokinase, dermatologic assessments, and pediatric-specific growth and pubertal development tracking given the indefinite course. CDSCO's published guidance states Form 12B is typically issued within one to two business days for routine applications where documentation is complete.

Where Ojemda gets dispensed in India

Ojemda is an oral medicine in two presentations: a 100 mg immediate-release tablet stored at room temperature and a 25 mg/mL oral suspension that is refrigerated after reconstitution per the package insert. There is no infusion infrastructure required. The dispensing facility must hold a valid drug licence. The Indian institutions that routinely handle pediatric named-patient oncology imports include Tata Memorial Centre Mumbai (Homi Bhabha Children's Hospital and ACTREC arms), AIIMS New Delhi pediatric neuro-oncology, Apollo Cancer Centres (Chennai flagship, Delhi, Bangalore, Hyderabad, Kolkata, with dedicated international patient services and JCI plus NABH accreditation), CMC Vellore, Kokilaben Dhirubhai Ambani Hospital Mumbai, MGM Healthcare Chennai, Manipal Hospitals Bangalore, Rainbow Children's Hospital Hyderabad, and PGIMER Chandigarh pediatric oncology. Where the treating pediatric oncologist is in a smaller city, the practical pattern is to route through a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore.

For Ojemda, the dispensing model routes the medicine to the treating pediatric neuro-oncology team rather than direct to the family residence. Caregiver counselling on suspension preparation (where the suspension presentation is used), once-weekly dosing day anchoring, photosensitivity and sun-protection guidance, and the discard timing for unused reconstituted product is built into the dispensing handoff.

Real cost picture for Ojemda 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. US wholesale acquisition cost for Ojemda has been reported at approximately USD 33,916 for a 28-day supply across both the 100 mg tablet (16-count) presentation and the 300 mg / 12 mL oral suspension presentation, per Day One regulatory filings published in 2024. This puts list-price reference in the range of roughly USD 33,000 to 35,000 per 28-day cycle, or annualised list of roughly USD 440,000, before any patient assistance, payer rebate, or discount adjustment. At the prevailing USD/INR rate, the published US list price converts to approximately INR 31.9 lakh per 28-day cycle or INR 4.14 crore per year. International shipping for an ambient oral product (tablet presentation) to an Indian destination typically runs USD 200 to 500 per shipment (approximately INR 19,000 to 47,000); the refrigerated suspension presentation, where used, may require a small cold-pack envelope at modestly higher cost.

CDSCO permit fees are nominal. India's Union Budget 2026-27 expanded customs-duty exemption on a set of named cancer medicines; the specific HSN code and exemption status of each Ojemda 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 pediatric oncology drug as a standard line item. CGHS provides for life-saving anti-cancer medicines that are not in the standard formulary to be considered by an Expert Committee under Special DG (DGHS), case by case, with stricter constraints on drugs not approved by DCGI. The National Policy for Rare Diseases 2021 framework provides one-time financial assistance for designated rare-disease conditions through Centres of Excellence, with a ceiling of INR 50 lakh per patient under the Rashtriya Arogya Nidhi umbrella; whether a specific pLGG case fits the NPRD framework is determined at the Centre of Excellence intake stage. The Day One "EveryDay Support From Day One" US patient assistance program is US-only and does not extend to international named-patient orders. Cash-pay is the operating default.

Typical timeline for Ojemda in India

For a routine Indian Ojemda case at an established pediatric neuro-oncology institution, 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. Because Ojemda tablets are room-temperature stable, the international transit window is the favourable ambient-cargo range (typically three to five business days from US specialty pharmacy dispatch to Indian customs clearance, depending on the destination port and the day of week). The refrigerated oral suspension adds modest cold-pack handling but does not require validated 2 to 8 degree Celsius shipping infrastructure. End-to-end, families typically plan for two to four weeks from pediatric oncologist decision to first dispensed cycle, with the bulk of elapsed time sitting in upstream documentation assembly (notably the molecular-testing report) and US closed-network specialty-pharmacy intake at Biologics by McKesson or Onco360. The once-weekly cadence is a meaningful pediatric advantage for cross-border maintenance: a single anchored dosing day per week is materially easier to sustain across school terms, family travel, and inter-current illness than a daily oral oncolytic.

What your physician needs to provide

The clinical justification letter is the cornerstone of the Form 12A filing. For Ojemda, the strongest letters consistently include: a histologically or radiologically confirmed diagnosis of pediatric low-grade glioma with the WHO grade, anatomical location, and any prior surgical history; molecular confirmation of a BRAF fusion or rearrangement (KIAA1549-BRAF or other) or a BRAF V600 mutation, with the testing methodology cited (FoundationOne CDx as the FDA-approved companion diagnostic, or a validated NGS assay); the documented prior systemic therapy sequence with dates, regimens (most commonly carboplatin-vincristine, vinblastine, or other pediatric pLGG regimens), response observed, and reason for discontinuation or unsatisfactory response; the patient's current age (the indication starts at 6 months), weight, and the calculated body surface area used for dose computation; the proposed dosing plan following the FDA-labeled schedule (380 mg per square metre orally once weekly, with the 600 mg maximum cap, until disease progression or unacceptable toxicity); the presentation chosen (immediate-release 100 mg tablet versus reconstituted oral suspension at 25 mg/mL); caregiver counselling acknowledgement for suspension preparation where applicable, photosensitivity and sun protection, and the once-weekly dosing day anchor; the monitoring plan covering LFTs, complete blood counts, serum creatine phosphokinase, dermatologic assessments, and pediatric-specific growth and pubertal development tracking; and the prescribing pediatric oncologist's NMC registration number.

The patient identifier, the dispensing institution's drug licence, and the chain-of-custody plan from the US closed-network specialty pharmacy (Biologics by McKesson or Onco360) to the Indian dispensing pharmacy complete the file. The treating pediatric oncologist retains the clinical decision and the Pharmacovigilance Programme of India (PvPI) adverse-event reporting obligation. Reserve Meds includes the PvPI reference in the documentation kit.

Common questions about Ojemda in India

Is BRAF testing required before starting?

Yes. The FDA indication is for patients whose tumour harbours a BRAF fusion, rearrangement, or V600 mutation. Molecular testing (FoundationOne CDx is the FDA-approved companion diagnostic, with other validated next-generation sequencing assays in use clinically) is the gate to

candidacy. Reserve Meds reviews the molecular report at intake; if testing has not been performed, we flag that to the treating pediatric oncologist as the prerequisite.

What is the safety profile families should be aware of?

The FDA label identifies the most common adverse reactions in the pivotal FIREFLY-1 population as hair colour changes, rash, fatigue, viral infection, vomiting, headache, pyrexia, dry skin, constipation, nausea, dermatitis acneiform, and upper respiratory tract infection. Laboratory abnormalities of note include changes in liver enzymes, increased creatine phosphokinase, and hematologic shifts. Skin and hair effects, including depigmentation and photosensitivity, are characteristic of RAF inhibitors as a class. Sun protection counselling is standard. The treating pediatric oncologist reviews the full label with the family before initiating therapy.

Why this drug versus dabrafenib plus trametinib?

The choice is driven by molecular profile. Patients with BRAF fusion or rearrangement (most commonly KIAA1549-BRAF) are not candidates for dabrafenib plus trametinib in the same way as V600-mutant patients; Ojemda's type II RAF mechanism is designed to address the dimer-dependent signaling that BRAF fusions drive. For V600-mutant pLGG specifically, dabrafenib plus trametinib is an FDA-approved alternative. The treating pediatric oncologist owns the choice.

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

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 pediatric oncology drug as a standard line item. Some plans have considered case-by-case reimbursement for pediatric rare-disease indications. Reserve Meds provides the itemised documentation. Cash-pay is the operating default.

Does the National Policy for Rare Diseases support pediatric oncology cases?

The NPRD 2021 framework provides one-time financial assistance for designated rare-disease conditions through Centres of Excellence (including AIIMS New Delhi), with a ceiling of INR 50 lakh per patient under the Rashtriya Arogya Nidhi umbrella. Whether a specific pLGG case fits the NPRD framework is determined at the Centre of Excellence intake stage based on the rare-disease list and clinical criteria. NPRD assistance is meaningful where it applies but is widely understood by clinicians and families to fall short of the full lifetime cost of many specialty therapies.

What is the typical course duration?

The label specifies continuation until disease progression or unacceptable toxicity. FIREFLY-1 reported median duration of response of 16.6 months as a clinical reference point. Individual treatment course length is determined by the treating pediatric oncologist based on response and tolerability.

Where Reserve Meds fits in Ojemda cases

Reserve Meds is a US-based concierge coordinator. We do not replace your child's pediatric oncologist, do not replace CDSCO or the DCGI, and do not replace the dispensing hospital pharmacy or the licensed specialty importer. What we do is orchestrate US closed-network specialty-pharmacy sourcing through Biologics by McKesson or Onco360 (the two named Ojemda dispensing partners under Day One Biopharmaceuticals) under DSCSA-compliant serialisation,

international logistics (ambient for tablets, cold-pack for suspension), and the documentation kit your pediatric oncologist needs for the Form 12A filing, including the molecular-testing report reference and the BSA-based dosing plan. Pediatric-specific intake handling includes caregiver consent flow, suspension-preparation counselling where applicable, and routing to the treating pediatric neuro-oncology team rather than to the family residence. No prior Reserve Meds closed case experience exists for Ojemda in India as of this review; standard NPP coordination applies with particular attention to caregiver communication around a young child's chronic oncology course.

Next step

If a child in India has been diagnosed with relapsed or refractory pediatric low-grade glioma carrying a BRAF fusion, rearrangement, or V600 mutation and the treating pediatric oncologist is considering Ojemda, add the case to the waitlist. We will respond within 24 to 48 hours with a documentation kit for your pediatric oncologist and an indicative cost range.

Reserved for you.
