Ojemda access in Pakistan

The first FDA-approved systemic therapy for pediatric BRAF-altered low-grade glioma, dosed once weekly, reached through the Drug Regulatory Authority of Pakistan Special Permission pathway.

Quick orientation

Ojemda (tovorafenib) is a brain-penetrant, highly selective type II pan-RAF inhibitor developed by Day One Biopharmaceuticals for pediatric central nervous system disease. The US FDA granted accelerated approval on April 23, 2024 for patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (pLGG) harboring a BRAF fusion or rearrangement, or a BRAF V600 mutation, who have received at least one prior line of systemic therapy. This was 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. For Pakistani families whose child has been diagnosed by a pediatric neuro-oncology team and has the molecular alteration confirmed, Ojemda is not yet registered with DRAP and is reached lawfully through the Drug Regulatory Authority of Pakistan Special Permission for Personal Use Import (the NOC), filed through the OIES portal. Reserve Meds coordinates the US specialty pharmacy sourcing, the pediatric documentation kit, and the international logistics with a single coordinator who speaks with caregivers in English and Urdu. Reserved for you.

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

Pediatric low-grade glioma is rare in absolute terms, and international payer systems and national formularies move slowly on orphan pediatric oncology launches. Outside the US, the European Commission has granted conditional marketing authorisation for Ojemda following the CHMP positive opinion of February 27, 2026; most other jurisdictions including DRAP have not yet granted national marketing authorisation. The structural pattern in Pakistan is the third pattern of access gap: the drug is not registered locally at all, the manufacturer has not filed for DRAP registration, and the Pakistani patient population is small relative to the registration cost. Pakistani families cannot fill an Ojemda prescription locally because the product is not registered, not stocked, and not on any local reimbursement list.

The alternatives are limited. For BRAF V600-mutant pediatric LGG specifically, dabrafenib plus trametinib is an FDA-approved alternative with a pediatric indication; for BRAF fusion or rearrangement pLGG (most commonly KIAA1549-BRAF), Ojemda was the first FDA-approved systemic therapy and the clearest on-label option. The alternative paths are off-label use of adult RAF or MEK inhibitors not designed or labeled for pediatric pLGG, chemotherapy regimens with established pediatric toxicity profiles, or watchful waiting. Day One's "EveryDay Support From Day One" patient access program is US-domestic and does not extend to international named-patient cases.

The DRAP named-patient pathway for Ojemda

DRAP regulates the import of unregistered medicines through the QA&LT Division's Import and Export Section. For unregistered medicines required by a specific named patient, DRAP issues a

Special Permission, also referred to as the No Objection Certificate (NOC) for Personal Use Import. Applications are filed through the Online Import and Export System (OIES). For pediatric oncology cases, institutional filings by the dispensing hospital's import pharmacy are the standard pattern.

The application package for an Ojemda case typically includes the clinical justification letter from the treating pediatric neuro-oncologist on hospital letterhead, the oncologist's PMDC licence verification, the patient identifier (B-Form for minors is the standard identifier in place of the CNIC for pediatric patients, along with the parent or legal guardian's CNIC), product details (Ojemda brand name, tovorafenib INN, manufacturer of record Day One Biopharmaceuticals Inc., the 100 mg immediate-release tablet and the oral suspension reconstituted to 25 mg/mL, requested quantity by body surface area band), the destination dispensing facility licence including pediatric oncology service capability, a US specialty pharmacy letter confirming sourcing through one of Day One's named partners (Biologics by McKesson or Onco360) under DSCSA-compliant chain-of-custody, and a chain-of-custody plan from the US source through international shipment to the dispensing facility.

The clinical-justification angle specific to Ojemda is the molecular confirmation. The letter typically documents the pediatric low-grade glioma diagnosis with imaging and pathology basis, the BRAF molecular alteration (BRAF fusion or rearrangement, most commonly KIAA1549-BRAF, or BRAF V600 mutation) confirmed via FoundationOne CDx (the FDA-approved companion diagnostic) or another validated next-generation sequencing assay in clinical use, the at-least-one-prior-line systemic therapy with named regimen and the documented progression or refractoriness, and the clinical rationale for a type II RAF inhibitor designed for pediatric CNS disease. The dosing plan reflects the FDA label: 380 mg per square meter of body surface area, administered orally once weekly, with or without food, until disease progression or unacceptable toxicity, with a maximum recommended dose of 600 mg orally once weekly. The pediatric dose tables in the label translate BSA bands into either tablet count or suspension volume.

Routine DRAP personal-use cases typically clear in four to eight weeks from a complete submission. Pediatric oncology cases involving novel mechanisms and companion diagnostic confirmation can extend to ten to sixteen weeks. Reserve Meds plans on the longer end. DRAP reserves discretion and Reserve Meds does not promise timelines.

Where Ojemda gets dispensed in Pakistan

Ojemda is a small-molecule oral therapy with two presentations: a room-temperature 100 mg tablet and a refrigerated reconstituted oral suspension (25 mg/mL). The tablet ships under ambient conditions and the suspension is dispensed for the youngest patients in the approved age band where tablet swallowing is not realistic; the suspension requires caregiver-side preparation per the package insert with discard timing for unused reconstituted product. There is no infusion administration and no REMS program.

The Pakistani institutions that handle DRAP named-patient imports as an established workflow and have pediatric neuro-oncology infrastructure include Aga Khan University Hospital pediatric oncology in Karachi, Shaukat Khanum Memorial Cancer Hospital and Research Centre pediatric oncology in Lahore, the Indus Hospital and Health Network pediatrics in Karachi, and the Children's Hospital and Institute of Child Health in Lahore (a major pediatric tertiary center with pediatric oncology, hematology, and rare disease capability). Per the country module, these centers handle named-patient imports for children routinely, and the B-Form is used in place of the CNIC for the patient identifier. SKMCH&RC's pediatric oncology service is a strong fit for many Ojemda cases given the institution's established cold-chain and oncology infrastructure.

For families whose pediatric neuro-oncologist is at a smaller institution, the practical route is to coordinate with one of the above centers as the dispensing facility while the treating physician retains clinical oversight, with the medicine routed to the treating team rather than to a home address.

Real cost picture for Ojemda in Pakistan

Reserve Meds quotes Pakistani cases in USD and accepts USD wire transfers from any USD-accessible source. The transparent cost build for an Ojemda case has three line items.

First, the underlying US drug cost. The 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, which puts list-price reference in the range of roughly USD 33,000 to USD 35,000 per 28-day cycle, or annualised list of roughly USD 440,000, before any patient-assistance or discount adjustment. Pediatric oncology pricing of this magnitude reflects orphan-tier economics and accelerated approval positioning. Second, international logistics from a US specialty pharmacy to a Karachi, Lahore, or Islamabad pediatric oncology dispensing facility, typically USD 300 to USD 600 per shipment given the mixed tablet and refrigerated-suspension presentation (cold-chain handling adds to the ambient tablet shipping cost). Third, regulatory documentation handling at the Pakistani end and the Reserve Meds concierge fee, itemised on the firm quote.

Currency context. The Pakistani Rupee traded near PKR 278 to 280 per USD in early May 2026, with annual CPI inflation at 10.9 percent in April 2026. Quoting in USD protects the family from PKR volatility, and many Pakistani families fund pediatric specialty care by pooling resources across overseas relatives. On the insurer side, Jubilee, Adamjee, EFU, and State Life assess pediatric named-patient imports on a case-by-case basis; specialty imports of FDA-approved-but-not-locally-registered orphan pediatric oncology drugs are typically outside formulary. Sehat Sahulat's Rs. 1,000,000 per family per year ceiling does not stretch to cover an extended Ojemda course. The default operating posture is cash-pay, often coordinated with NGO or hospital-affiliated financial support where the dispensing institution offers it (SKMCH&RC's institutional model includes patient assistance for many pediatric cases).

Typical timeline for Ojemda in Pakistan

End to end, a routine Ojemda case at a tertiary pediatric oncology center with established DRAP personal-import workflow typically clears in six to twelve weeks from intake to first dose in the patient's hand. The DRAP OIES review takes four to eight weeks for routine pediatric cases or up to ten to sixteen weeks where the molecular confirmation requires verification, the US specialty pharmacy intake through Biologics by McKesson or Onco360 adds five to ten business days, and international air freight plus FBR Customs clearance at Karachi, Lahore, or Islamabad adds three to five days. The once-weekly oral dosing schedule is a meaningful pediatric advantage. A weekly dose collapses the adherence problem into a single anchored day per week, which is materially easier to sustain across the multi-month international treatment course than a daily oral oncolytic. After the first authorised import, refill cadence is monthly or every 90 days, with continuity of supply prioritised because median duration of response in FIREFLY-1 was reported at 16.6 months and individual courses may run considerably longer.

What your physician needs to provide

The cornerstone document is the clinical justification letter, original and stamped on hospital letterhead, signed by the treating pediatric neuro-oncologist under their active PMDC licence. For Ojemda, the letter typically covers the pediatric low-grade glioma diagnosis with imaging and pathology basis, the BRAF molecular alteration (BRAF fusion or rearrangement, most commonly KIAA1549-BRAF, or BRAF V600 mutation) confirmed via FoundationOne CDx or another validated NGS assay, the prior systemic therapy line with named regimen and documented progression or refractoriness, and the clinical rationale for a type II pan-RAF inhibitor designed to address the dimer-dependent signaling that BRAF fusions drive. The dosing plan is stated (380 mg per square meter of body surface area orally once weekly with or without food, with a maximum of 600 mg once weekly), with the BSA-to-tablet-count or BSA-to-suspension-volume reference to the FDA label's pediatric dose tables.

The monitoring plan covers the FDA label's safety profile: liver function tests, complete blood counts, serum creatine phosphokinase, and dermatologic assessments on a recurring cadence, plus pediatric-specific monitoring of growth and pubertal development given the multi-month duration of therapy and the patient age band. Photosensitivity counseling and sun protection are standard for a RAF inhibitor class effect that includes hair color changes, rash, dry skin, and dermatitis acneiform. The pediatric caregiver workflow for the suspension presentation is documented: reconstitution per the package insert, refrigerated storage, discard timing for unused reconstituted product, and the dosing day-of-week anchor. Children's Hospital and Institute of Child Health Lahore, SKMCH&RC pediatric oncology, AKUH pediatric oncology, and Indus Hospital pediatrics have signing authority on Pakistan Personal Use Import applications.

Common questions about Ojemda in Pakistan

Will Jubilee, Adamjee, EFU, or State Life cover Ojemda for our child?
Coverage of named-patient imports for unregistered orphan pediatric oncology drugs is uncommon across Pakistani health plans. Some insurers assess case-by-case where the pediatric BRAF-altered low-grade glioma diagnosis is fully documented. Reserve Meds supplies the documentation needed. The default is cash-pay, often coordinated with institutional patient assistance at the dispensing center.

How does Sehat Sahulat interact with this?
The Rs. 1,000,000 per family per year ceiling does not stretch to cover an extended Ojemda course. Families who qualify can still use Sehat Sahulat for hospitalisation, imaging, supportive care, and procedures while Ojemda procurement runs cash-pay in parallel at the pediatric oncology dispensing center.

Is BRAF testing required before starting?
Yes. The FDA indication is for patients whose tumor harbors 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 clinical use) is the gate to candidacy and is documented in the DRAP application.

Why Ojemda 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, and Ojemda was the first FDA-approved systemic

therapy specifically for the BRAF fusion or rearrangement pLGG population. The decision rests with your pediatric neuro-oncologist.

What about the once-weekly schedule?
Tovorafenib is dosed once weekly with weight-based titration to body surface area. The once-weekly cadence is a meaningful pediatric adherence advantage. Daily oral oncology agents impose significant caregiver burden across school weeks, travel, and inter-current illness; a weekly dose collapses the adherence problem into a single anchored day per week, which is materially easier to sustain across the multi-month courses that pLGG patients require.

What are the most common side effects?
The FDA label identifies the most common adverse reactions in the FIREFLY-1 population as hair color 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. Your pediatric neuro-oncologist reviews the full label with the family before initiating therapy.

How long will my child stay on Ojemda?
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 neuro-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 pediatric neuro-oncologist, we do not replace DRAP, we do not replace your dispensing pediatric oncology institution. For an Ojemda case in Pakistan, we orchestrate the US specialty pharmacy procurement through Day One's named partners (Biologics by McKesson or Onco360) with full DSCSA-compliant chain-of-custody documentation, prepare the pediatric documentation kit your treating neuro-oncologist needs for the DRAP Special Permission filing through the OIES portal (including the molecular alteration confirmation and the BSA-based dosing plan), coordinate international shipping that handles the room-temperature tablet plus refrigerated suspension presentation under continuous handling controls into Karachi, Lahore, or Islamabad, and stay with the case through monthly or 90-day refills under a single named coordinator who can speak with caregivers in English and Urdu. Pediatric-specific intake includes caregiver consent flow and suspension preparation counseling for the youngest patients. No prior Reserve Meds Ojemda case in Pakistan is on file at this date; standard NPP coordination applies. Clinical decisions remain with your pediatric neuro-oncologist. Regulatory authority remains DRAP. Dispensing remains with the licensed Pakistani institution and routes through the treating team, not to the patient's home address.

Next step

If your family is exploring Ojemda for a child six months of age or older whose pediatric neuro-oncologist has documented relapsed or refractory pediatric low-grade glioma with a confirmed BRAF fusion, rearrangement, or V600 mutation and at least one prior line of systemic therapy, the next step is to join the waitlist. We will confirm eligibility and case fit within 24 to 48 hours, send a documentation kit to your treating pediatric neuro-oncologist in English with Urdu-

language caregiver-facing summaries where requested, and align with your dispensing pediatric oncology institution on the OIES filing.

Reserved for you.

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- Ojemda in Saudi Arabia
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Review & oversight. Content on this page is reviewed by Reserve Meds's clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. Review methodology ›

Last medically reviewed: 2026-05-12.