Ojemda access in UAE: the EDE pediatric named-patient pathway

How families in the United Arab Emirates access Ojemda (tovorafenib) for relapsed or refractory pediatric low-grade glioma with a BRAF fusion, rearrangement, or V600 mutation, an FDA-approved targeted therapy not yet locally registered.

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Quick orientation

Ojemda is the brand name for tovorafenib, a brain-penetrant type II RAF inhibitor developed by Day One Biopharmaceuticals specifically for pediatric central nervous system disease. The US FDA 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, BRAF rearrangement, or BRAF V600 mutation, who have received at least one prior line of systemic therapy. The label is pediatric-specific. As of this review date, Ojemda is not on the United Arab Emirates federal drug register. A UAE-licensed pediatric neuro-oncologist who wants to prescribe it for a specific child files an unregistered-medicine import permit through the Emirates Drug Establishment (EDE). This page is written for families navigating that process. Reserved for you.

Why pediatric patients in the UAE need Ojemda via a named-patient pathway

Pediatric low-grade glioma is rare in absolute terms. National payer systems and formularies move slowly on orphan pediatric oncology launches, and most jurisdictions outside the United States and the European Union have no national registration for tovorafenib. The European Commission granted Ojemda conditional marketing authorisation in 2026 following a CHMP positive opinion on 27 February 2026; Ipsen holds the European commercialisation rights. UK MHRA, PMDA Japan, Health Canada, Australia TGA, and most Middle East regulators had not granted national marketing authorisation as of this review date. There is no UAE EDE/MOHAP local registration on file. Families in the UAE cannot fill an Ojemda prescription locally because the product is not registered, not stocked, and not on any reimbursement list.

The clinical reason a family reaches for Ojemda is precise. Ojemda is the first systemic therapy approved by the FDA for pediatric LGG with BRAF rearrangements, including the common KIAA1549-BRAF fusion that drives a substantial share of pediatric low-grade glioma cases. The alternative for these children is off-label use of adult RAF or MEK inhibitors not designed or labelled for pediatric pLGG, chemotherapy regimens with established pediatric toxicity profiles, or watchful waiting. Where a BRAF fusion, rearrangement, or V600 mutation has been confirmed by approved molecular testing and the child has progressed on prior systemic therapy, Ojemda is on-label and on-mechanism in a way that local alternatives are not.

The EDE named-patient pathway for Ojemda

The federal pathway is the unregistered-medicine import permit. The Ministry of Health and Prevention (MOHAP) historically administered the framework, and from 29 December 2025 the Emirates Drug Establishment took over 44 core services under Federal Decree-Law No. 38 of 2024, including marketing authorisations, import and export permits, pharmacovigilance oversight, and personal-use import permits. EDE filings flow through ede.gov.ae. The framework allows hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable.

For an Ojemda submission, the clinical justification letter has a specific shape because the indication is molecularly defined. The letter typically opens with the confirmed pLGG histopathology, the tumour location, the date of initial diagnosis, and the patient's age and weight. It then documents the companion diagnostic testing that established the BRAF status. FoundationOne CDx is the FDA-approved companion diagnostic for Ojemda; other validated next-generation sequencing assays used at the treating institution may also be cited where appropriate. The specific BRAF alteration is named (KIAA1549-BRAF fusion, a different BRAF rearrangement, or BRAF V600 mutation). This molecular result is the gate to candidacy and must be present in the package.

The letter then documents prior systemic therapy. Ojemda is approved for patients who have received at least one prior line. The treating pediatric neuro-oncologist records each prior agent (chemotherapy regimen, MEK inhibitor where used, prior RAF inhibitor where applicable for V600-mutant patients), the dose, the duration, the response, the progression event, and the rationale for moving to a pan-RAF inhibitor at this point. Where the molecular profile is a BRAF fusion or rearrangement, the letter notes that dabrafenib plus trametinib is not the on-label option in the same way it is for V600-mutant disease, and Ojemda's type II RAF mechanism is designed to address the dimer-dependent signaling that BRAF fusions drive.

The dosing plan in the letter follows the FDA label: 380 mg per square metre of body surface area, orally once weekly, with or without food, until disease progression or unacceptable toxicity, with a maximum recommended dose of 600 mg once weekly. The pediatric dose tables in the label translate BSA bands into either tablet count (100 mg tablets) or oral suspension volume (25 mg/mL reconstituted). For the youngest children in the approved age band (down to 6 months), the oral suspension is the practical workhorse. The letter records the selected presentation, the planned monitoring schedule, the caregiver counselling plan for suspension reconstitution and storage, and the photosensitivity counselling that is standard for type II RAF inhibitors.

The standard EDE application set follows. The pediatric neuro-oncologist's UAE medical licence verification is filed (MOHAP, DHA, DOH, or Sharjah Health Authority depending on practice location), at consultant grade given the complexity of the indication. The patient identifier is included anonymised where the EDE submission allows; pediatric cases sometimes include the parent's identifier as the responsible party. Full product details: brand name Ojemda, generic name tovorafenib, manufacturer Day One Biopharmaceuticals, Inc., strength (100 mg tablet or 25 mg/mL oral suspension), pack size, quantity requested, intended treatment duration. The destination dispensing facility name, licence number, and pharmacy in charge are listed, with a chain-of-custody plan describing how the medicine moves from US specialty pharmacy (Biologics by McKesson or Onco360, the two named Day One specialty pharmacy partners) through the UAE importer to the dispensing pharmacy. Approval timelines for routine cases are typically 5 to 15 business days.

Where Ojemda gets dispensed in the UAE

Ojemda's tablet presentation is room-temperature stable. The reconstituted oral suspension is refrigerated under the package insert conditions. The product is not a biologic, is not cold-chain in the classic 2 to 8 degrees Celsius infusion sense, and does not require frozen shipping. Logistically this places Ojemda in a forgiving band relative to monoclonal antibody and cell therapy cases. Dispensing requires a UAE-licensed facility with pediatric oncology capability and a pharmaceutical establishment licence, or a relationship with a specialty importer.

The UAE institutions with established pediatric oncology services and prior named-patient import experience include Sheikh Khalifa Medical City (SEHA network, JCI-accredited with cardiology, oncology, and pediatric subspecialty services), Tawam Hospital in Al Ain (the national referral centre for oncology with a cancer centre of excellence developed with the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center), Cleveland Clinic Abu Dhabi, and American Hospital Dubai. These centres handle named-patient imports for pediatric cases routinely. For pediatric neuro-oncology specifically, the case is typically co-managed across pediatric neuro-oncology, pediatric neurosurgery, and pediatric radiation oncology services. For families resident in the Northern Emirates without a local pediatric oncology service, the case routes to a Dubai or Abu Dhabi centre where the treating pediatric neuro-oncologist holds privileges.

Real cost picture for Ojemda in the UAE

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 published in 2024. List-price reference is in the range of roughly USD 33,000 to USD 35,000 per 28-day cycle, or annualised list of approximately USD 440,000, before any patient-assistance, payer rebate, or discount adjustment. Day One's patient access program, EveryDay Support From Day One, provides US-domestic benefits investigation and copay support for commercially insured US patients; these mechanisms do not extend to international named-patient cases.

For named-patient orders to the UAE, the patient-facing picture has three layers: US specialty pharmacy acquisition cost from the named Day One specialty pharmacy channel, international logistics (USD 400 to 800 per shipment for ambient tablets to the UAE; refrigerated handling adds modestly when the suspension presentation is shipped), and regulatory documentation plus Reserve Meds coordination. The UAE dirham is pegged to the US dollar at approximately 3.67 AED to 1 USD, so a 28-day Ojemda cycle at WAC translates to roughly AED 124,500 for the drug itself, before logistics and coordination. Daman National Health Insurance (operator of the Thiqa programme for UAE nationals), GIG Gulf, Sukoon Insurance, ADNIC, and Orient Insurance assess pediatric oncology named-patient imports case by case. Cash-pay is the default posture; insurer reimbursement is filed by the family or the hospital after the fact.

Typical timeline for Ojemda in the UAE

End-to-end, a first Ojemda case in the UAE typically completes in three to six weeks from intake to first dose. The EDE permit runs 5 to 15 business days for routine cases. Reserve Meds confirms eligibility within 24 to 48 hours of intake and aligns US specialty pharmacy sourcing in parallel. Because Ojemda is once-weekly oral, the international shipping leg is two to four business days under standard pharmaceutical air freight (tablet) or controlled refrigerated handling (suspension). UAE customs clearance under the import permit typically takes one to three business days. Repeat fills compress the timeline materially. The once-weekly dosing

cadence is a meaningful pediatric adherence advantage: it collapses the adherence problem into a single anchored day per week, which is materially easier to sustain across school weeks, travel, and inter-current illness than a daily oral oncolytic would be.

What your physician needs to provide

The treating UAE-licensed pediatric neuro-oncologist provides the clinical anchor. The clinical justification letter typically sets out the confirmed pLGG diagnosis with histopathology and tumour location, the patient's age and weight, the BRAF molecular result with the companion diagnostic used (FoundationOne CDx is the FDA-approved companion diagnostic for Ojemda; other validated NGS assays are noted where they were used), and the prior systemic therapy history with response, progression, and reason for switch. The letter sets out the weight-based dosing plan referencing the BSA tables in the label, the selected presentation (100 mg tablet or 25 mg/mL oral suspension), and the planned monitoring schedule.

Monitoring per the FDA label includes liver function tests, complete blood counts, serum creatine phosphokinase, and dermatologic assessments. Pediatric-specific monitoring of growth and pubertal development is recommended given the duration of therapy and the patient age band. Photosensitivity counselling and sun protection are standard. Caregiver counselling for suspension reconstitution and refrigerated storage is part of the onboarding for the youngest patients. The letter documents the caregiver consent flow appropriate for the patient's age and the family structure.

The licence verification, the dispensing facility licence, and the chain-of-custody plan complete the package. Reserve Meds supplies the dispensing-facility and chain-of-custody templates so the pediatric neuro-oncologist's time stays on clinical content.

Common questions about Ojemda in the UAE

Will Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, or Orient cover Ojemda? Each insurer assesses pediatric oncology named-patient imports case by case. Some reimburse fully when the medicine is on their formulary even if not stocked, some reimburse a percentage subject to copay, and several require pre-authorisation. Thiqa, administered by Daman for UAE nationals in Abu Dhabi, has the broadest specialty coverage. We do not promise coverage from any insurer.

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 is the gate to candidacy. FoundationOne CDx is the FDA-approved companion diagnostic for Ojemda; other validated next-generation sequencing assays performed at the treating institution may also support the case. The pathology report with the BRAF result is part of the EDE submission.

Why Ojemda rather than 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 are. Ojemda's type II RAF mechanism is designed to address the dimer-dependent signaling that BRAF fusions drive. For BRAF V600-mutant pediatric LGG, dabrafenib plus trametinib is the FDA-approved alternative with a pediatric indication; the treating pediatric neuro-oncologist owns the choice between mechanisms.

Can the medicine be given at home? Yes, in the sense that Ojemda is oral once-weekly therapy administered by the caregiver at home after dispensing from a UAE-licensed pharmacy.

The dispensing leg requires a UAE-licensed facility; direct international delivery without a licensed UAE dispensing facility in the chain is not the model.

What is the safety profile we should expect? 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. The treating pediatric neuro-oncologist reviews the full label with the family before initiation.

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 physician 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 neuro-oncologist, we do not replace the Emirates Drug Establishment or your emirate-level licensing authority, and we do not replace the dispensing pharmacy. We orchestrate the US specialty pharmacy sourcing through the named Day One specialty pharmacy channel (Biologics by McKesson or Onco360), the regulatory documentation kit your physician needs, the international logistics, and a single named coordinator throughout the case. Pediatric onboarding includes caregiver consent flow, suspension preparation counselling for the youngest patients, and direct routing to the treating pediatric neuro-oncology team rather than to a patient address. No prior closed Reserve Meds Ojemda case is on file at this review date. Standard NPP coordination applies, with pediatric-specific intake handling.

Next step

If your child's treating pediatric neuro-oncologist has confirmed Ojemda as the next clinical step and BRAF testing has identified a fusion, rearrangement, or V600 mutation, the waitlist is the first action. Reserve Meds responds within 24 to 48 hours with eligibility confirmation and a documentation kit your physician can use. Reserved for you.

This guide is informational, not medical or legal advice. The named-patient framework requires a UAE-licensed pediatric neuro-oncologist's clinical judgment. Reserve Meds is the coordinator, not the prescriber.

Related

- Ojemda drug overview
- Ojemda in Saudi Arabia
- United Arab Emirates: the EDE named-patient pathway

- All access pathways

Sources

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- Ojemda US Prescribing Information; FDA Drug Trials Snapshots
- Kilburn LB et al., FIREFLY-1 trial publication, Nature Medicine 2023
- EMA Ojemda EPAR; CHMP positive opinion 27 February 2026
- Emirates Drug Establishment portal, Issue of Permit to Import Medicines for Personal Use

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 ›

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