

Brineura

Oman · access guide

How to access Brineura from Oman, the cross-border treatment pathway, 2026

By Reserve Meds, Clinical and regulatory team. Last reviewed 2026-05-13.

An Oman patient with neuronal ceroid lipofuscinosis type 2 (CLN2 disease, late-infantile Batten disease) to slow the loss of ambulation may receive a recommendation for Brineura (cerliponase alfa) from their treating paediatric neurologist with neurosurgical support. Brineura is FDA-approved in the United States and manufactured by BioMarin Pharmaceutical. It is a recombinant tripeptidyl peptidase 1 enzyme replacement therapy delivered by intracerebroventricular infusion. This is important: Brineura is not a ready-to-ship pharmacy medicine. It is delivered as a specialty procedure at a certified treatment site. That makes the cross-border pathway materially different from a conventional named-patient drug import.

This guide explains how the pathway works, what documentation your specialist needs, indicative cost and timing, and where Reserve Meds fits in.

The clinical situation

Brineura is a recombinant tripeptidyl peptidase 1 enzyme replacement therapy delivered by intracerebroventricular infusion. Mechanism: a recombinant proenzyme of human tripeptidyl peptidase 1 that, after activation, cleaves N-terminal tripeptides from substrates accumulating in CLN2. Dosing: 300 mg by intracerebroventricular infusion every two weeks via a surgically placed reservoir, per FDA labeling. Baseline workup per FDA labeling includes neurosurgical evaluation for reservoir placement, baseline CLN2 clinical rating, neurodevelopmental assessment, and cardiac evaluation. The FDA boxed warning covers reservoir-related complications, infusion-associated cardiovascular events, and hypersensitivity. Other important warnings include reservoir-related complications including infection and device failure, infusion-related cardiovascular events with bradycardia and hypotension, and hypersensitivity reactions. Your specialist and the US treatment center will discuss the risk-benefit profile, the requirement for a certified site, and the practical logistics before initiating therapy.

How does this work across borders?

Because Brineura is administered as intracerebroventricular infusion via implanted reservoir at a certified site under specific facility protocols, the standard cross-border access pathway is patient travel to a US certified center, not import of the product into Oman. DGPADC does support named-patient drug imports, but intracerebroventricular ERT products are practically delivered via patient travel to a certified treatment facility under that facility's protocol.

Reserve Meds can help coordinate the referral arc to a US certified center, help your specialist assemble the referral package, and coordinate the family logistics around the multi-week stay. We do not perform the procedure, we do not manufacture the product, and we do not provide the infusion. Those are functions of the US treatment center under its FDA authorisation.

How the pathway works, step by step

1. **Consultation with your treating specialist in Oman.** The recommendation is clinical, based on diagnosis, prior workup, and fitness for the regimen.
2. **Referral package to a US certified center.** Pathology, imaging, prior-therapy summary, organ function panel, and infectious disease screening are assembled into a referral package.
3. **US center evaluation.** The US center reviews the package, accepts the referral (or asks for additional workup), and schedules the procedure.
4. **Patient travel.** The patient travels to the US center. Reserve Meds coordinates travel, accommodations, and caregiver presence where required.
5. **Procedure and recovery.** The certified center delivers Brineura under its FDA-authorized protocol with appropriate monitoring.
6. **Post-procedure follow-up.** The patient transitions to ongoing follow-up coordinated between the US center and Oman specialist.

What documentation your specialist needs

Your specialist will typically need to assemble:

- A clinical summary letter confirming diagnosis, prior workup, and Brineura as the recommended next step
- Pathology and imaging reports relevant to the indication
- Organ function panel and other baseline labs aligned with FDA labeling
- Confirmation that the patient has a designated caregiver who can accompany them for the duration of US treatment
- A monitoring plan covering neurosurgical readiness, reservoir maintenance plan, and CLN2 clinical rating baseline

Reserve Meds provides a referral kit that bundles what US certified centers expect to see in a complete referral package for intracerebroventricular ERT cases.

Typical costs and indicative timing

Reserve Meds gives you a transparent reference range and an itemised quote at intake. As an illustrative composite case, the US cash-pay reference range for a typical month of every-2-week infusions of Brineura sits in an indicative 2026 band of approximately USD 75,000 to 110,000. The treatment center facility and physician fees, baseline workup, complication management, and post-procedure follow-up add substantially more. Travel, accommodations, caregiver presence, and the multi-week stay are additional. Reserve Meds itemises each component in the delivered quote at intake.

Indicative timing from referral acceptance to the first procedure is typically 6 to 10 weeks (includes neurosurgical reservoir placement scheduling): time for the US center to review and schedule, plus patient travel logistics. Maintenance dosing then runs on the FDA-labeled schedule.

Service availability is limited to our first cohort. All timelines are indicative, not guarantees. These cases require additional clinical and logistical vetting given the complexity and cost profile.

Where Reserve Meds fits in

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Brineura specifically, we provide:

- **Referral coordination.** We work with your Oman specialist to identify candidate US certified centers and route the referral package.
- **Documentation.** Referral package assembly aligned with US center intake requirements.
- **Travel and logistics.** Coordination of patient and caregiver travel, accommodation near the treatment center, and the multi-week stay.
- **Concierge case lead.** A named point of contact for the family across the full case arc.

Reserve Meds coordination fee for this pathway.

A flat concierge fee of **USD 15,000 to 35,000** per case, scaled to the complexity of the pre-trip, in-US, and post-trip coordination required. The fee covers candidate US-certified center selection, referral package assembly and routing, pre-trip clinical workup and records transmission, financial-clearance coordination with the receiving center, visa and travel logistics for the patient and caregiver, in-US transport and translator support where needed, and post-trip clinical follow-up coordination back to the treating hematologist for 6 to 12 months.

The fee is paid directly to Reserve Meds. The CAR-T product cost, the US treatment-center charges, and any third-party travel and accommodation expenses are paid by the patient or family directly to the relevant counterparty. Reserve Meds does not mark up the center or the manufacturer, and Reserve Meds does not receive a referral fee from the center for the first patient cohort.

An itemised quote is issued at intake. Cash-pay only. No insurance billed.

We are a coordinator. We are not the prescriber, not a US treatment center, not the manufacturer, and not an oncology or rare disease provider. The US treatment center is the clinical entity under its FDA authorisation. Reserve Meds operates on cash-pay only and does not bill insurance.

Frequently asked

Is this legal? Yes. Patient travel to a US-certified treatment center is a long-established pathway used by international patients across many specialty programs. Reserve Meds operates as the coordination layer, not the clinical provider.

Can I receive Brineura locally? If a local certified program exists and your physician concludes it is appropriate for your case, that is typically the simpler pathway. Reserve Meds is most useful when the local option is not available, not stocked, or your case requires a US specialist evaluation.

Will my private health insurance cover this? Cash-pay is the default posture. Some Oman private insurers (Daman, AXA, Mednet-administered plans) reimburse named-patient imports on a case-by-case basis when the documentation package is strong. We supply documentation for your submission but do not process insurance claims.

What if I cannot travel to the US? Then cross-border Brineura access via this pathway is not feasible, and your specialist should explore other locally available options. Reserve Meds will tell you that directly rather than charge for a service that cannot deliver.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

Reserve Meds

reserved for you.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

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