

## Aldurazyme

Bahrain · access guide

# Aldurazyme (laronidase) for a Bahraini family: what the pathway looks like in 2026

By Reserve Meds clinical & regulatory team. Last reviewed 2026-05-20.

Bahraini families looking into Aldurazyme for a child with mucopolysaccharidosis type I, MPS I, are in a workable position. The therapy has a long track record in the region. The Bahrain National Health Regulatory Authority (NHRA) operates a mature pharmaceutical regulatory framework. Salmaniya Medical Complex and Bahrain Defence Force Hospital handle the initial workup and the ongoing surveillance. For severe Hurler patients needing HSCT, cross-border BMT-centre referrals to KFSHRC Riyadh, to Saudi German Hospital networks, or to international centres of excellence are operationally familiar to the Bahraini medical community.

This page is meant to be the first honest read you get on Aldurazyme in Bahrain, written by the team that would coordinate around your child's case if you decided you wanted operational support on the workup, the MoH treatment-abroad documentation (if applicable), the cross-border logistics, or the long-term cost picture.

We will be specific about MPS I, what the workup decides, the regulatory pathway, the cost in BHD and US dollars, the cross-border infusion patterns, and where Reserve Meds adds value.

## What MPS I actually is, in plain terms

MPS I is a lysosomal storage disorder caused by deficiency of the enzyme alpha-L-iduronidase (IDUA). The deficiency leads to progressive accumulation of dermatan sulfate and heparan sulfate in lysosomes across the body. Presentation spans a clinical spectrum: severe Hurler with infant-onset multisystemic disease and progressive cognitive decline, intermediate Hurler-Scheie with somatic features but preserved cognition, and attenuated Scheie often diagnosed in adolescence or adulthood.

Aldurazyme is recombinant alpha-L-iduronidase, administered as a weekly intravenous infusion at 0.58 mg/kg over 3 to 4 hours. The therapy is disease-modifying for non-CNS manifestations. It does not cross the blood-brain barrier and does not address the cognitive decline of severe Hurler.

For severe Hurler infants, the standard of care is hematopoietic stem cell transplantation, HSCT, ideally before age 2 to 2.5. Aldurazyme is used as a bridge to HSCT and often as an adjunct afterwards. For Hurler-Scheie and Scheie patients, ERT alone is typically the long-term answer.

## The workup that decides eligibility

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The workup has five components: urinary GAG screen, alpha-L-iduronidase enzyme activity assay (the definitive enzymatic confirmation), IDUA gene sequencing for severity classification, baseline organ assessments (echocardiogram, FVC, sleep study, ophthalmology, ENT, hepatomegaly, joint range of motion, 6-minute walk test), and severity classification by the metabolic specialist.

In Bahrain, the workup typically begins at: - **Salmaniya Medical Complex (SMC)**, the public-sector tertiary. Paediatric service with rare-disease support. - **Bahrain Defence Force Hospital**, paediatric services with subspecialty access. - **King Hamad University Hospital**, the major teaching hospital, paediatric services with rare-disease genetics support. - **Bahrain Specialist Hospital** and **Royal Bahrain Hospital** for private-sector workup.

For IDUA sequencing and confirmatory enzyme assays, samples are typically sent to a regional reference laboratory. The clinical rationale letter from the treating paediatrician documents the diagnosis, the severity classification, the recommended treatment plan, and the long-term monitoring schedule.

## The Bahrain regulatory pathway and the cross-border infusion picture in 2026

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NHRA is the Bahrain regulatory authority for medicines. Aldurazyme has a long regional track record; [VERIFY: current NHRA registration status of Aldurazyme 2026]. Where formal registration is in place, standard prescription and import procurement applies; where not, the named-patient mechanism is workable.

The infusion picture in Bahrain itself is workable for the weekly ERT delivery. Salmaniya Medical Complex and the Bahrain Defence Force Hospital have paediatric infusion infrastructure and anaphylaxis-management capability suitable for the weekly Aldurazyme schedule. For uncomplicated Hurler-Scheie or Scheie patients on a stable weekly infusion routine, in-country delivery is the operationally simplest pattern.

For severe Hurler patients needing HSCT, the cross-border pattern is more common. The realistic destinations: - **King Faisal Specialist Hospital and Research Centre (KFSHRC) Riyadh**. Deep paediatric BMT and metabolic-disease infrastructure. The natural cross-border destination for many Bahraini severe Hurler families. - **UAE qualified centres**. Cleveland Clinic Abu Dhabi, Tawam Hospital Al Ain (for the metabolic surveillance long term), SKMC, SSMC. - **International BMT centres of excellence** in the US or Europe for families preferring international referral.

For severe Hurler patients, the typical pattern is: in-Bahrain diagnostic workup at SMC, KHUH, or BDF Hospital → MoH treatment-abroad application (Bahraini nationals) → cross-border HSCT evaluation at KFSHRC Riyadh or a UAE BMT centre → HSCT performed at the cross-border centre → return to Bahrain for ongoing Aldurazyme adjunct infusions and surveillance.

## The cost conversation, in the form a Bahraini family needs

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Aldurazyme is one of the most expensive enzyme replacement therapies on the market, and because it is administered weekly for life, the lifetime cost is what matters most.

The 2026 indicative annual list price is roughly USD 200,000 to USD 500,000 per year, or approximately BHD 75,000 to BHD 188,000 per year, depending on your child's weight (0.58 mg/kg weekly). Over a multi-decade course for an attenuated Scheie patient, the cumulative drug cost can sit between USD 5 million and USD 15 million, before supportive-care costs.

For Bahraini nationals, the MoH treatment-abroad programme has at times funded eligible cross-border specialty therapies including rare-disease ERTs. Application runs through your treating consultant and the MoH treatment-abroad office. Reserve Meds can support documentation at no charge. For in-country Aldurazyme delivery at SMC or BDF Hospital, the public-system financial framing differs from cash-pay.

For expatriate residents and self-pay families, the standard cash-pay pattern applies. We separate every line: drug per infusion, infusion-suite charges, pre-medication, monitoring labs, our coordination fee. Nothing is bundled. We do not put a markup on the manufacturer's drug price.

Private insurance coverage in Bahrain (AXA Gulf, Bahrain National Insurance, GIG Bahrain, others) for rare-disease ERTs is handled on case-by-case prior authorisation.

## **The weekly infusion reality**

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Aldurazyme is a weekly intravenous infusion of approximately 3 to 4 hours including the slow titration period. Pre-medication with an antihistamine (with or without an antipyretic) is given about 60 minutes before each infusion. For long-term patients, a central venous access device is often placed.

Infusion-associated reactions are common particularly during the first months; the infusion suite must have anaphylaxis-management capability on site.

For a Bahraini family, weekly clinic time becomes a permanent calendar feature. The infusion centre becomes a known place, and the nursing team becomes part of the family network.

## **Monitoring on therapy**

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The MPS I surveillance schedule on long-term Aldurazyme: urinary GAG every 3 to 6 months, anti-laronidase antibody titre at intervals, annual 6-minute walk test, FVC, echocardiogram, ECG, ophthalmology, ENT, audiology, sleep study as indicated, orthopaedic and physiotherapy reviews, hepatosplenomegaly assessment. SMC, BDF Hospital, and KHUH coordinate the multidisciplinary surveillance in-country; for some families, the multidisciplinary surveillance is coordinated with cross-border specialist input.

## **When Aldurazyme is not the right answer, or not the only answer**

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For severe Hurler infants, ERT alone does not address the cognitive trajectory. HSCT is the standard intervention, ideally before age 2 to 2.5, and the cross-border BMT-centre pattern is the most common Bahraini path. Aldurazyme functions as a bridge before transplant and an adjunct afterwards.

For severe Hurler patients diagnosed late, after the cognitive window for HSCT benefit has closed, the honest conversation is about palliating somatic progression with ERT.

For attenuated Scheie adults, the management is closer to chronic-disease management of a multisystemic condition.

Emerging AAV-based gene therapy programmes for MPS I are in clinical trials internationally but are not yet approved.

## What Reserve Meds does for a Bahraini family

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**For Bahraini nationals applying for MoH treatment-abroad funding:** documentation support, second-opinion clinical reviews from international centres, coordination of cross-border referral logistics, and case management around the destination centre stay. We do not process the MoH application directly. That runs through your treating consultant and the MoH treatment-abroad office. We provide the documentation packet that increases approval likelihood.

**For expatriate residents in Bahrain paying cash:** standard Reserve Meds scope. Regulatory documentation, sourcing from manufacturer's authorised distribution under DSCSA chain of custody, cold-chain logistics (2-8 degrees Celsius, do not freeze), qualified-centre liaison, named case-lead coordination.

**For families on in-country Aldurazyme delivery at SMC or BDF Hospital:** sourcing and documentation concierge layer rather than full cross-border coordination. We can support the chain-of-custody documentation and the insurance prior-authorisation packet.

**For families considering cross-border HSCT for severe Hurler:** coordination of the BMT-centre referral (KFSHRC Riyadh, UAE centres, international) alongside the in-Bahrain Aldurazyme bridge therapy.

Reserve Meds is not your child's prescriber. We do not practise medicine. We do not manufacture Aldurazyme. We do not own or operate any infusion centre. Clinical decisions stay with your treating team.

We work cash-pay (where applicable). Our coordination fee is disclosed in writing.

## A note for families weighing this

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For Muslim families thinking through the religious-ethical dimension, Aldurazyme is recombinant, produced in CHO cell culture, not derived from animal tissue or human plasma. The Islamic bioethics consensus on life- and function-preserving therapies is broadly permissive across both Sunni and Shia schools. Families typically consult with their religious advisors before committing.

For Bahraini families with affected relatives or carrier history in the extended family, the carrier-testing conversation for siblings and cousins is a separate but important thread.

## What to do if you want to start

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The first concrete step is a call with our case-lead so we can confirm the diagnostic stage your child is at and whether the right next move is the workup, the ERT initiation, the cross-border HSCT pathway evaluation, or a combination.

If your child has been diagnosed with MPS I but you have not yet made the severity classification decision, reach out anyway: we will help you get the workup completed at SMC, BDF Hospital, or KHUH before the treatment-plan conversation.

Most families reach us first on WhatsApp, which is the medium we hold open during Bahrain business hours (Sunday-Thursday) and on weekends for active cases.

Start your child's case on the portal, or open a WhatsApp conversation with the case-lead and we will take it from there.

### ***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.

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### **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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