Mayzent access in Bahrain

How Bahraini families pursue siponimod, the S1P receptor modulator approved for active secondary progressive multiple sclerosis, via the NHRA named-patient pathway.

Last reviewed 2026-05-12 by Reserve Meds clinical & regulatory team. This page combines the Bahrain country research module with the Mayzent drug module to describe the path families actually walk.

Quick orientation

Mayzent (siponimod) is an oral sphingosine 1-phosphate (S1P) receptor modulator approved by the US Food and Drug Administration in March 2019 for relapsing forms of multiple sclerosis, with the labeled indication that specifically includes active secondary progressive multiple sclerosis (SPMS). The manufacturer is approximately Novartis. Siponimod is one of a small number of disease-modifying therapies with evidence specifically in the active SPMS population, where treatment options have historically been narrower than in relapsing-remitting MS. For a Bahraini family weighing this option, the practical question is whether the molecule is registered locally, whether the registered version is in stock, and if not, how the NHRA named-patient pathway delivers it. Reserved for you.

Why this drug is hard to source in Bahrain

The Kingdom of Bahrain is the smallest GCC market by population (approximately 1.7 million residents) and one of the most regulator-mature relative to its size. The National Health Regulatory Authority (NHRA) frequently moves earlier than its regional peers on advanced therapy approvals (Bahrain was an early Casgevy approver in 2024). The recurrent pattern, though, is small market with fast regulator and limited stocking depth. Even where Mayzent has a path to local supply, the volume of confirmed active SPMS patients in Bahrain in any given quarter is small enough that hospital pharmacies do not always keep it on the shelf.

Bahraini patients with active SPMS therefore encounter one of three gaps. Some find that Mayzent is registered by the NHRA but their hospital pharmacy does not have it stocked at the moment they need to initiate. Some find that an alternative S1P modulator is on the local register but their neurologist judges siponimod the right molecule for the patient's specific MS phenotype, given that siponimod's pivotal EXPAND trial evidence base is specifically in active SPMS. Some find that the molecule is not registered locally at all, requiring a named-patient import. The NHRA named-patient pathway exists to close the gap in each case.

The active SPMS indication is also part of why this case can feel urgent. SPMS is a progressive phenotype, and treatment that targets active inflammation in this phase is time-sensitive. Bahraini neurology services at Salmaniya Medical Complex, Bahrain Defence Force Hospital, and King Hamad University Hospital have the clinical capability to manage siponimod therapy, but the supply pathway frequently sits ahead of clinical readiness.

The NHRA named-patient pathway

The pathway for a Bahraini-licensed neurologist to obtain a medicine that is not registered or not stocked locally is the unregistered-medicine import permit, administered through the NHRA's Pharmaceutical Product Regulation directorate. 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 (typically the US FDA, EMA, MHRA, PMDA Japan, Health Canada, or the SFDA in Saudi Arabia) and a clinically suitable locally registered alternative is not available. Compassionate-use provisions cover serious or progressive illness where no alternative treatment is suitable.

A complete NHRA application for a Mayzent case typically includes the clinical justification letter from the treating neurologist (MS diagnosis with documented progression to active SPMS, EDSS score, MRI evidence of active inflammation, prior disease-modifying therapy history, CYP2C9 genotype where required for dosing, and the case for siponimod specifically), the treating physician's NHRA license verification, an anonymised patient identifier, full product details for siponimod (brand name Mayzent, manufacturer approximately Novartis, strength 0.25 mg or 2 mg tablets, pack size, quantity requested, intended treatment duration), the destination dispensing facility name with NHRA pharmacy license number and pharmacy in charge, the chain-of-custody plan, and documentation of the FDA approval as the reference-authority anchor.

Approval timelines for routine cases are 7 to 21 business days. Complex first-of-kind submissions extend to 4 to 6 weeks. Urgent neurology cases with documented progressive disease can receive expedited review at the NHRA's discretion. The NHRA frequently compresses its review window when the SFDA, EDE, or another GCC authority has already registered the molecule, and Mayzent has registration footprints across multiple reference jurisdictions.

Real costs in BHD and USD

The Bahraini dinar is pegged to the US dollar at approximately 1 BHD to 2.65 USD, and the peg has held since 1980. Mayzent's US wholesale acquisition cost for a typical 30-day supply at the 2 mg maintenance dose is approximately USD 9,000 to 10,000 per month, which translates to approximately BHD 3,400 to 3,770. Annual drug cost at maintenance dosing is therefore approximately USD 108,000 to 120,000, or approximately BHD 41,000 to 45,000.

The starter-titration pack (used to gradually escalate from 0.25 mg to the 2 mg target dose over the first week of therapy) is a separate billed item. Mayzent dosing in CYP2C9*3 carriers is reduced to 1 mg maintenance, which lowers monthly cost proportionally; the CYP2C9 genotype test is mandatory before initiation under the FDA label.

All-in delivered cost for a Bahraini patient pursuing Mayzent cross-border is the drug cost plus international logistics (approximately USD 400 to 1,500, or approximately BHD 150 to 565, per shipment), NHRA permit fees (nominal), customs handling at Bahrain International Airport, regulatory documentation handling, and the Reserve Meds concierge fee. Each fee line is itemised separately on the firm quote.

Insurance treatment of Mayzent in Bahrain varies by carrier. Sehati handles specialty neurology medicines case by case, with pre-authorisation the norm. Expatriate residents covered by employer or private insurance (Bahrain Kuwait Insurance / gig Bahrain, Solidarity Bahrain, Bahrain National Insurance, Medgulf, Bupa Arabia cross-border) each assess named-patient MS therapy individually. Reserve Meds supplies the documentation set that lets the insurer assess the case. We do not promise coverage from any insurer.

Timing - what to expect

The NHRA permit itself is not the long pole. Routine NHRA submissions process in 7 to 21 business days; complex first-of-kind submissions extend to 4 to 6 weeks. The full Mayzent pathway from referral to first dose typically runs 4 to 10 weeks end to end. The CYP2C9 genotype test sits at the front of the pathway and the result is required before the prescription is written; turnaround for the test at Bahraini reference laboratories is typically 5 to 10 business days. The titration pack and first month's supply are then sourced, shipped, customs-cleared, and dispensed.

Active SPMS treatment is an ongoing commitment, not a one-time event. After the first dispense, the renewal cycle establishes a steadier rhythm. Reserve Meds frames the case as an ongoing relationship with the treating neurologist and the dispensing pharmacy, with the first cycle as the slowest and subsequent cycles faster as the documentation foundation is already in place.

What your physician needs

The clinical justification letter for a Mayzent NHRA submission carries the weight of the application. The treating neurologist's letter typically addresses the patient's MS diagnosis with year of onset, the documented transition to a secondary progressive phenotype, current disability burden expressed as the Expanded Disability Status Scale (EDSS) score, MRI evidence of active inflammation (gadolinium-enhancing lesions or new T2 lesions on follow-up imaging), prior disease-modifying therapy history (interferons, glatiramer

acetate, dimethyl fumarate, teriflunomide, fingolimod, ocrelizumab, ofatumumab, natalizumab, cladribine where applicable, and the outcomes), the case for siponimod specifically given its active-SPMS evidence base, and the planned monitoring schedule (liver function tests, lymphocyte counts, ophthalmologic examination for macular edema, cardiology assessment for the first-dose bradycardia consideration).

Three documents sit alongside the letter. The CYP2C9 genotype result is mandatory before initiation under the FDA label. Patients homozygous for CYP2C9*3 should not receive Mayzent; CYP2C9*1/*3 and *2/*3 carriers receive a reduced 1 mg maintenance dose. The cardiology clearance for first-dose monitoring (the FDA label specifies first-dose monitoring in patients with certain cardiac conditions) is documented. The vaccination status check for varicella zoster (the FDA label requires VZV antibody status or vaccination before initiation) is documented. The treating physician's NHRA license must be in active standing.

Salmaniya Medical Complex and the Bahrain specialty-dispensing network

Bahrain's geography (a small island with short transit times between facilities) means the dispensing network is more compact than in larger GCC markets, and most named-patient neurology cases flow through a handful of tertiary centers. Salmaniya Medical Complex (SMC) in Manama is the kingdom's largest public tertiary hospital, operated by the Ministry of Health with approximately 1,200 beds and a full-spectrum neurology service. SMC is the default referral center for complex public-sector neurology and the single largest dispensing site in the country for specialty medicines.

Bahrain Defence Force Hospital (BDF Royal Medical Services) in Riffa offers multispecialty tertiary services with a strong reputation for handling complex cases. The military supply chain and royal patronage give BDF operational latitude on advanced therapies that the public sector sometimes lacks. King Hamad University Hospital (KHUH) in Busaiteen is a 312-bed teaching hospital affiliated with the Royal College of Surgeons in Ireland - Medical University of Bahrain, with a growing neurology and cell-therapy program.

On the private side, Royal Bahrain Hospital and Bahrain Specialist Hospital in Manama, Al Hilal Hospital in Muharraq, and American Mission Hospital (the oldest private hospital in the Gulf, founded 1903) all hold specialty practice and can host named-patient dispensing through their internal pharmacy infrastructure or through a Bahraini specialty importer. For physicians at smaller facilities without internal import infrastructure, the typical pattern is to route through a Bahraini specialty importer holding an NHRA pharmaceutical establishment license, or to refer the case into one of the tertiary centers above where the institutional pharmacy files on the prescribing physician's behalf.

Pharmacovigilance and cold-chain

Mayzent is an oral medication and is shipped ambient. Cold-chain handling is not required for siponimod tablets, which simplifies the logistics relative to biologics or gene therapies. The chain-of-custody documentation is still maintained from the US manufacturer through the importer to the dispensing pharmacy, and customs clearance at Bahrain International Airport flows through the NHRA permit framework.

Pharmacovigilance reporting obligations sit with the treating physician and the dispensing facility. Serious adverse drug reactions (those leading to hospitalisation, persistent disability, or a life-threatening condition) typically require NHRA reporting within 7 calendar days; other significant adverse events fall within 15 to 30 day windows. For Mayzent specifically, the monitoring agenda includes liver function (transaminase elevations are a known class effect), lymphocyte count (S1P modulators cause a sustained lymphocyte reduction), macular edema screening (ophthalmologic examination at baseline and 3 to 4 months after initiation), and infection surveillance (particularly varicella zoster and progressive multifocal leukoencephalopathy in the broader S1P modulator class).

Common questions about Mayzent in Bahrain

Will Sehati or my private insurance cover this? Sehati and private insurers assess named-patient MS therapy case by case. Pre-authorisation is the norm. Reserve Meds supplies the documentation set that lets your insurer assess the case. We do not promise coverage from any insurer.

Will my NHRA-licensed neurologist's letter be sufficient? Yes. Any Bahraini-licensed neurologist practicing in good standing has signing authority on the clinical justification letter. The NHRA license is national, not jurisdiction-specific within the kingdom, simplifying the documentation set relative to neighboring markets.

Is Mayzent a controlled substance? No. Mayzent is not a DEA scheduled substance. The federal narcotics framework does not apply. NHRA's standard pharmaceutical import documentation governs.

Why Mayzent and not an alternative S1P modulator? Mayzent (siponimod) has FDA-label evidence specifically in active secondary progressive MS, anchored on the EXPAND pivotal trial. Other S1P modulators (fingolimod, ozanimod, ponesimod) have labels weighted toward relapsing-remitting MS. The clinical choice rests with the treating neurologist. Reserve Meds does not steer the clinical decision.

What about the CYP2C9 genotype test? The test is mandatory before initiation under the FDA label. Bahraini reference laboratories at Salmaniya Medical Complex, BDF Hospital, and the major private hospital pathology departments offer the test. Turnaround is typically 5 to

10 business days. Patients homozygous for CYP2C9*3 should not receive Mayzent; CYP2C9*1/*3 and *2/*3 carriers receive a reduced 1 mg maintenance dose.

Where Reserve Meds fits in Mayzent cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating neurologist, the NHRA, the dispensing pharmacy, or the institutional clinical team. For a Mayzent case specifically, our work is identifying the FDA-approved product source, supplying the documentation set to your neurologist for the NHRA submission, coordinating the US-side release and shipment to the named Bahraini importer, and holding a single named coordinator through the case from first inquiry to dispense. We do not select the dispensing facility on the patient's behalf. We do not file pharmacovigilance reports on the physician's behalf. We do not promise insurance coverage from any carrier. Reserved for you.

Next step

If a treating neurologist in Bahrain is weighing Mayzent for a family member with active secondary progressive MS, the waitlist is the first step. We respond within 24 to 48 hours with an eligibility confirmation and a documentation kit for the physician.

Reserved for you.

Related

- Mayzent clinical resource
- Mekinist in Bahrain
- Bahrain country page
- Multiple sclerosis condition page

Sources

1. FDA approval, Mayzent (siponimod), Novartis, NDA approval March 2019 for relapsing forms of multiple sclerosis including active secondary progressive disease.
2. Bahrain National Health Regulatory Authority (NHRA), Pharmaceutical Product Regulation directorate, unregistered-medicine import permit framework.
3. Central Bank of Bahrain, USD-BHD peg at 1 BHD = 2.65 USD (established 1980).

Review and oversight. Content on this page is reviewed by the Reserve Meds 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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