**Briumvi**

Saudi Arabia · access guide

# How to access Briumvi for relapsing multiple sclerosis from Saudi Arabia: 2026 pathway via Saudi neurology and infusion supply

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

Saudi Arabia operates one of the largest adult multiple sclerosis (MS) populations in the wider region and has invested substantially in neurology infrastructure over the past two decades. King Faisal Specialist Hospital and Research Centre (KFSHRC) Riyadh and Jeddah, King Abdulaziz Medical City (KAMC) Riyadh, King Fahd Medical City (KFMC), King Khalid Hospital, the Ministry of National Guard Health Affairs hospitals across Riyadh, Jeddah, Dammam, and Al-Ahsa, and the Dr Sulaiman Al Habib network in Riyadh and Jeddah all run adult MS services through dedicated MS clinics, neurology infusion suites, and multidisciplinary disease-modifying therapy programmes. Briumvi (ublituximab-xiiy), TG Therapeutics' glycoengineered anti-CD20 monoclonal antibody, was approved by the FDA in December 2022 and by the EMA in May 2023 as the third anti-CD20 biologic for relapsing MS (joining Ocrevus and Kesimpta). For a Saudi-resident adult with relapsing-remitting MS, active secondary-progressive MS, or clinically isolated syndrome on MRI evidence, the operational question in 2026 is no longer whether anti-CD20 therapy is reachable: it is whether Briumvi, Ocrevus, or Kesimpta is the right fit, where the infusion is delivered, what funding pathway applies, and how a years-long twice-yearly infusion routine fits into the patient's work and family life.

This page explains how the pathway works in 2026 for a Saudi-resident adult patient: who qualifies, where the prescribing neurologist conversation happens, how the loading regimen and maintenance infusions are coordinated, what the realistic cost band looks like in SAR for cash-pay scenarios, what to monitor (infusion reactions, infection risk, hepatitis B reactivation, JC virus, immunoglobulin levels), and how the years-long treatment plan fits into a Saudi patient's life.

## Why Briumvi, and why now

Briumvi is ublituximab-xiiy, a glycoengineered humanised IgG1 monoclonal antibody that binds CD20 on B-lymphocytes and depletes them through antibody-dependent cellular cytotoxicity (ADCC), complement-dependent cytotoxicity, and direct B-cell apoptosis. The glycoengineering (low-fucose Fc) makes Briumvi a more potent ADCC trigger than prior anti-CD20 agents, allowing a smaller maintenance dose (450 mg vs Ocrevus 600 mg) and a substantially shorter infusion time (approximately 1 hour maintenance vs Ocrevus 3 to 4 hours).

The FDA approved Briumvi in December 2022 for relapsing forms of MS: relapsing-remitting MS (RRMS), active secondary-progressive MS (SPMS), and clinically isolated syndrome (CIS). The pivotal trials, ULTIMATE I and ULTIMATE II (Steinman L et al., NEJM 2022), randomised approximately 1,100 patients to Briumvi versus teriflunomide 14 mg oral daily and showed a 49 to 59 percent reduction in annualised relapse rate with significant reduction in MRI new and enhancing lesion burden.

For a Saudi patient who has either tried one or more moderate-efficacy DMTs without adequate disease control or who wants to start with a high-efficacy option from the outset, Briumvi is the operational pathway to a twice-yearly anti-CD20 infusion. The conversation about whether to start with Briumvi versus Ocrevus versus Kesimpta versus continuing on an oral DMT (teriflunomide, dimethyl fumarate, fingolimod) is the central clinical decision. This page is the operational layer underneath that conversation.

## What Briumvi is, in plain language

Briumvi is an intravenous infusion administered in a hospital or clinic infusion suite. It is not self-administered. There is no home-dosing route.

Loading regimen (first two doses): - **Day 1**: 150 mg IV infusion over approximately 4 hours including premedication, infusion, and observation. - **Day 15**: 450 mg IV infusion over approximately 1 hour (total visit ~3 hours with premedication and observation).

Maintenance regimen from Week 24 onwards: - **Week 24, then every 24 weeks (twice yearly) indefinitely**: 450 mg IV infusion over approximately 1 hour (total visit ~2 to 3 hours).

Premedication before each infusion typically includes a corticosteroid (methylprednisolone 100 mg IV or equivalent), an antihistamine (diphenhydramine 25 to 50 mg IV or oral), and an antipyretic (acetaminophen / paracetamol 650 mg oral). Premedication reduces infusion-reaction incidence and severity.

Briumvi is taken for as long as it controls relapse burden and disability accumulation. There is no fixed stop point in the FDA label. The stopping conversation is a neurology decision informed by serum immunoglobulin levels, infection history, and individual disease trajectory.

## Eligibility at a Saudi neurology service

For Saudi-resident patients, neurology services apply the FDA and EMA criteria with local funding adaptation:

1. Confirmed diagnosis of relapsing MS by a neurologist applying the 2017 McDonald criteria. 2. Recent MRI brain and spine within 3 months of initiation. 3. Active disease evidence: clinical relapse within the past 12 to 24 months, new or enhancing MRI lesions, or continued disability accumulation on prior therapy. 4. Trial and inadequate response or intolerance of prior disease-modifying therapy is the most common Saudi funding threshold for the first anti-CD20 agent. Some scenarios approve anti-CD20 as first-line for highly active disease at diagnosis. 5. Pre-treatment screening: HBsAg, anti-HBcore (HBV screening), JC virus serology, HIV, tuberculosis screening (IGRA or chest film per local practice). 6. Serum quantitative immunoglobulins (baseline IgG, IgM, IgA). 7. Vaccination status reviewed; inactivated vaccines administered at least 2 weeks before first infusion. Live vaccines contraindicated during treatment. 8. Pregnancy planning discussion for women of childbearing potential. Contraception during treatment and for 6 months after last infusion.

A Saudi patient should arrive at the Briumvi conversation with the most recent MRI report, written MS disease history from the treating neurologist, prior DMT history with response durations and reasons for switch, baseline laboratory work, and the funding pre-authorisation documentation that the neurologist's office or hospital administration initiates.

## The Saudi prescribing and supply picture, plainly

Briumvi Saudi Food and Drug Authority (SFDA) registration status is verified at intake. As of mid-2026 Briumvi is either registered or in late-cycle review with the SFDA; named-patient supply via the regulatory affairs office of the prescribing centre remains a parallel pathway during any registration transition window. The dual NPP/domestic framing applies: for a registered indication and stocked product, supply runs through standard distributor channels; for an unstocked or registration-pending scenario, named-patient compassionate-use supply runs through the prescribing centre's regulatory office under SFDA authorisation.

The pathway is:

1. **Prescribing neurologist with MS expertise**: any SCFHS-licensed Saudi neurologist treating MS, ideally with multiple sclerosis as a primary clinical focus. MS-specialised neurology programmes run at KFSHRC Riyadh and Jeddah, KAMC Riyadh, King Fahd Medical City Riyadh, King Faisal Specialist Hospital Jeddah, the Ministry of National Guard Health Affairs hospitals, and the Dr Sulaiman Al Habib network. The Saudi MS Society maintains a national MS programme that connects patients with established centres. 2. **Infusion centre logistics**: Briumvi is administered in a neurology day-infusion suite. The major Saudi tertiary centres run neurology infusion programmes that also handle Ocrevus, natalizumab (Tysabri), and IVIG. 3. **Pharmacy dispensing**: hospital pharmacy supplies the vials to the infusion centre. No community-pharmacy retail dispensing pathway. 4. **Funding pre-authorisation**: For Saudi nationals, the Ministry of Health hospital network funds anti-CD20 MS therapy on documented eligibility through the hospital pharmacy and therapeutics committee. KFSHRC, KAMC, and KFMC have established processes. CCHI-regulated commercial insurance for residents handles Briumvi on a case-by-case basis. Bupa Arabia, Tawuniya, MedGulf, and the major commercial insurers require similar documentation requirements as Daman in the UAE. 5. **Pre-treatment workup completion**: HBV, JC virus, immunoglobulins, HIV, TB, vaccination update completed before first infusion. 6. **Ongoing monitoring**: neurology follow-up every 3 to 6 months. MRI annually or per neurology judgement. Quarterly serum IgG monitoring. Symptom-based infection screening at each follow-up.

## The 2026 pathway, step by step

Week 0 to 2: Reserve Meds builds the documentation pack with the treating neurologist's office. We collect the MS disease history, prior DMT history, current MRI, baseline labs, vaccination history, and funding card or insurance details. The neurologist's office initiates funding pre-authorisation and orders pre-treatment screening if not complete.

Week 2 to 6: Funding pre-authorisation review. MoH pathway for Saudi nationals typically processes within 2 to 4 weeks for established MS centres. Commercial insurance for residents takes 2 to 4 weeks. In parallel, pre-treatment screening results return.

Week 6 to 8: First infusion (Day 1, 150 mg) at the prescribing centre's infusion suite. Full-day appointment.

Week 8 to 10: Second infusion (Day 15, 450 mg). Approximately 3 hours total visit.

Week 8 to 32: Patient returns to baseline neurology follow-up cadence. No infusion visits.

Week 32 (Week 24 from first infusion in the FDA schedule): First maintenance infusion at 450 mg.

Week 56, 80, 104, and onward: Maintenance infusions every 24 weeks (twice yearly).

Annual MRI brain and spine. Quarterly serum IgG monitoring. Neurology clinical follow-up every 3 to 6 months.

## Cost expectation in SAR

US list price (WAC) for Briumvi is approximately USD 59,000 per 450 mg infusion. MENA pharmacy pricing for biologics typically lands lower at the wholesale level; the cash-pay band in Saudi tertiary centres sits in the USD 45,000 to 55,000 per 450 mg vial range.

Year 1 total cost of therapy: - US list equivalent: approximately USD 137,000 to 140,000. - MENA cash-pay band: approximately USD 105,000 to 130,000. - At 2026 indicative cross rates: SAR 395,000 to 490,000 cash-pay for Year 1.

Year 2 and beyond steady state (two maintenance infusions per year): - US list equivalent: approximately USD 117,000 to 120,000. - MENA cash-pay band: approximately USD 90,000 to 110,000. - SAR equivalent: SAR 340,000 to 415,000 per year cash-pay.

For Saudi nationals the MoH-funded MS therapy pathway covers anti-CD20 treatment on documented eligibility through the established tertiary centres. CCHI-regulated commercial insurance for residents reduces out-of-pocket exposure substantially. Cash-pay exposure is the worst-case scenario for uninsured residents.

The conversation about long-term cost matters because Briumvi is a years-long commitment. A 10-year treatment course is not unusual for a patient who maintains response.

## What to monitor

The notable adverse-event signals for Briumvi are infusion reactions, infections, hepatitis B reactivation, JC virus reactivation, and hypogammaglobulinaemia.

**Infusion reactions** are common (~48 percent in ULTIMATE), occur predominantly with Day 1, and are mostly mild to moderate (chills, headache, fever, throat irritation, fatigue). Premedication reduces incidence and severity. Severe reactions are rare but managed by infusion-suite staff.

**Infection risk**. Upper respiratory tract infections, urinary tract infections, herpes infections, and respiratory infections at increased frequency. Patients counselled to report fever, persistent cough, or unusual symptoms promptly.

**Hepatitis B virus (HBV) reactivation**. Pre-treatment HBsAg and anti-HBcore screening mandatory. Patients with chronic HBV need hepatology coordination and antiviral prophylaxis. Patients with resolved HBV need frank reactivation-risk discussion.

**Progressive multifocal leukoencephalopathy (PML)**. JC virus serology at baseline establishes risk. Any new neurological symptom during treatment warrants prompt neurology re-evaluation with MRI.

**Hypogammaglobulinaemia**. Quarterly IgG monitoring during treatment. IgG below 4 g/L warrants re-assessment.

**Vaccinations**. Inactivated vaccines (annual flu, COVID-19, pneumococcal) at least 2 weeks before first infusion. Live vaccines contraindicated during treatment and for 6 months after. Hajj or travel requiring yellow fever vaccination needs planning.

## Religious, ethical, and family-logistics framing

Briumvi is a recombinant humanised IgG1 monoclonal antibody produced in mammalian cell culture. No donor element, no human tissue source, no foreign genetic content. The classical analogy to vaccines and other injectable biologics holds in MENA Islamic medical ethics, where biologics are generally treated as permissive with the standard expectation that the patient and family decide in consultation with the treating physician.

The twice-yearly infusion cadence is the practical advantage for many Saudi patients. A working adult plans two clinic days per year. Family caregivers plan ride-and-return logistics for two days. There is no daily pill, no weekly self-injection, no monthly clinic visit beyond standard neurology follow-up.

The pre-treatment workup (HBV, JC virus, immunoglobulins, vaccinations) is one-off at initiation plus the ongoing quarterly IgG check. Reserve Meds explains the workup at intake; this is standard for any anti-CD20 agent.

Pregnancy planning is the conversation that lands hardest for younger Saudi patients. Contraception during treatment and for 6 months after last infusion. For a patient or couple actively planning family, the conversation centres on whether to defer pregnancy, time conception in the 6-month window between maintenance doses, or use an alternative DMT during the family-building years. This is an initiation conversation, not a post-first-infusion one.

## When Briumvi is not the right call

For a Saudi patient whose MS is well controlled on a moderate-efficacy oral agent, whose disease is primary-progressive (Briumvi not indicated; ocrelizumab is the anti-CD20 with PPMS approval), where serum immunoglobulin levels are already low at baseline, where active or chronic untreated hepatitis B precludes immunosuppression without hepatology co-management, or where pregnancy is imminent and DMT washout is not an option:

- **Ocrevus (ocrelizumab)**: the other major IV anti-CD20 for MS. Similar efficacy, longer infusion (3 to 4 hours maintenance). PPMS approval is unique. - **Kesimpta (ofatumumab)**: subcutaneous monthly anti-CD20. Self-administered at home. Different operational profile. - **Off-label rituximab**: used in some MENA centres for MS. Off-label in MS. The on-label agents (Briumvi, Ocrevus) are the regulatory primary path. - **Natalizumab (Tysabri)**: non-anti-CD20 high-efficacy option. JC virus serology determines suitability. - **High-efficacy oral agents**: cladribine, siponimod (SPMS), ozanimod (RRMS). - **Moderate-efficacy oral agents**: teriflunomide, dimethyl fumarate, fingolimod.

Reserve Meds does not promote one anti-CD20 MS therapy over another. The choice between Briumvi, Ocrevus, Kesimpta, or off-label rituximab is made with your treating neurologist based on infusion logistics, prior exposure, immunoglobulin levels, infection history, and patient preference.

## What Reserve Meds does on this case

We are a US-based concierge coordinator. We are not the prescriber and not the dispensing pharmacy. On a Saudi Briumvi case we build the documentation pack with the treating neurologist's office, run the funding pre-authorisation conversation alongside the clinical pre-authorisation conversation, coordinate the pre-treatment workup (HBV, JC virus, immunoglobulins, vaccinations) with the prescribing centre's laboratory, organise the infusion-suite scheduling for the loading regimen and the first maintenance infusion, and stay with the case through the first 18 months of dosing with handoff to the local neurologist. Clinical decisions remain with your treating neurologist.

## Frequently asked patient questions

**How is Briumvi different from Ocrevus?** Glycoengineered for stronger immune-cell recruitment, smaller maintenance dose, shorter infusion (~1 hour vs Ocrevus 3 to 4 hours). Similar efficacy. Infusion logistics drive most choices.

**Will I need to stop my current MS medication?** Most prior DMTs require washout. The neurologist plans the timing.

**How long do I take Briumvi for?** For as long as it controls your MS. There is no fixed stop point.

**Can I get pregnant on Briumvi?** Contraception during treatment and for 6 months after last infusion.

**What about vaccines?** Inactivated vaccines at least 2 weeks before first infusion. Live vaccines off-limits during treatment and for 6 months after.

**What does the infusion day look like?** Day 1: about 4 hours. Day 15: about 3 hours. Maintenance: about 2 to 3 hours. Day-procedure, no overnight.

### *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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