Uplizna access in the United Arab Emirates: the EDE named-patient pathway

How UAE adults with aquaporin-4 antibody-positive neuromyelitis optica spectrum disorder or generalised myasthenia gravis pursue inebilizumab, the anti-CD19 B-cell-depleting monoclonal antibody, when prior immunotherapy has not delivered durable disease control.

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

Quick orientation

Uplizna (inebilizumab-cdon) is a humanised anti-CD19 monoclonal antibody developed by Viela Bio, acquired by Horizon Therapeutics, and now part of Amgen. The US Food and Drug Administration approved Uplizna in June 2020 for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody-positive, and in April 2025 for generalised myasthenia gravis in adults who are anti-acetylcholine receptor antibody-positive. The dosing schedule is two intravenous infusions of 300 mg given two weeks apart at initiation, then 300 mg every 6 months on maintenance. Inebilizumab targets CD19 rather than CD20, which produces deeper B-cell depletion including the CD19+CD20- plasmablast and short-lived plasma cell populations that drive AQP4 autoantibody production. Reserved for you.

Why UAE patients need Uplizna via a named-patient pathway

Neuromyelitis optica spectrum disorder is a rare but disabling autoimmune disease of the central nervous system, with regional UAE neurology practice typically managing a small but identifiable AQP4-positive cohort. The historical treatment landscape relied on chronic azathioprine, mycophenolate mofetil, and rituximab off-label. Three biologics now hold dedicated FDA approval for AQP4-positive NMOSD: eculizumab (Soliris, terminal complement inhibitor), satralizumab (Enspryng, IL-6 receptor antagonist), and inebilizumab (Uplizna, anti-CD19 B-cell depleter). For generalised myasthenia gravis, the recent

expansion of Uplizna's label adds it to a treatment landscape that includes pyridostigmine, corticosteroids, conventional immunosuppressants, intravenous immunoglobulin, plasma exchange, the neonatal Fc receptor inhibitor efgartigimod (Vyvgart), and rituximab off-label.

Uplizna is not consistently held in UAE federal stock. The case for Uplizna specifically is built when the treating neurologist wants deeper B-cell depletion than rituximab (because of the CD19 versus CD20 mechanism), when the patient has not achieved disease quiescence on prior NMOSD therapy, when the every-6-month maintenance schedule supports adherence, or when the AQP4-positive or AChR-positive antibody profile and the clinical course point to B-cell-directed therapy. The EDE named-patient pathway is the established route.

The EDE / MoHAP named-patient pathway applied to Uplizna

The federal pathway for a UAE-licensed physician to obtain a medicine that is not registered or not stocked locally is the unregistered-medicine import permit, administered through the Emirates Drug Establishment (EDE) at ede.gov.ae. The EDE took over 44 core services from MoHAP under Federal Decree-Law No. 38 of 2024. 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 such as the US FDA and a locally registered alternative is not suitable.

For Uplizna, the clinical justification packet is structured around the autoimmune disease state. For NMOSD, the treating neurologist documents the diagnosis (NMOSD by the 2015 international consensus criteria), the AQP4 antibody status with the laboratory report attached, the relapse history with timing and severity, the prior therapy trail (acute corticosteroid courses for relapses, plasma exchange where indicated, chronic immunotherapy with azathioprine, mycophenolate mofetil, or rituximab including response and reason for switching), and the rationale for CD19-directed B-cell depletion. For generalised myasthenia gravis, the documentation parallels but anchors on AChR antibody status, MG-ADL or QMG scores, and prior immunotherapy history.

A complete EDE application for Uplizna typically includes the neurologist's clinical justification letter, the antibody laboratory report, the treating physician's MoHAP, DHA, DoH, or Sharjah Health Authority licence verification, an anonymised patient identifier, full product details (Uplizna 100 mg/10 mL single-dose vial for intravenous infusion), the destination dispensing infusion facility name with licence number and pharmacy in charge, the cold-chain handling plan, and the patient informed consent. The hepatitis B screening and tuberculosis screening status is documented before the first infusion. Approval timelines for routine cases are 5 to 15 business days. First-of-kind submissions extend to 4 to 6 weeks.

Where Uplizna gets dispensed in the UAE

Uplizna is administered by intravenous infusion over approximately 90 minutes (with premedication for the first two infusions to mitigate infusion reactions). The dispensing site is an infusion suite attached to a neurology service. The most natural dispensing sites are the neurology services at Cleveland Clinic Abu Dhabi, Sheikh Khalifa Medical City, American Hospital Dubai, Mediclinic City Hospital in Dubai Healthcare City, and the dedicated neuroimmunology programmes that have developed within the SEHA network and Dubai Healthcare City. The drug must be stored refrigerated at 2 to 8 degrees Celsius until the infusion is prepared.

Real cost picture for Uplizna in the UAE

The US wholesale acquisition cost for Uplizna is approximately USD 165,000 to 180,000 for the first year (including the two loading doses plus one maintenance dose), and approximately USD 150,000 to 170,000 annually on maintenance (two 300 mg infusions per year). In AED at the 3.67 peg, the maintenance annual cost is approximately AED 550,000 to 625,000. The figure is the drug acquisition cost only.

All-in delivered cost stacks the drug acquisition, refrigerated international logistics (USD 800 to 1,500 per shipment), the EDE handling and customs fees (USD 300 to 600 per case), the dispensing facility's infusion administration fees, and the Reserve Meds concierge coordination fee. Insurance in the UAE handles NMOSD and generalised myasthenia gravis biologics case by case. Pre-authorisation is the norm. Thiqa, administered by Daman, has the broadest specialty coverage for UAE nationals in Abu Dhabi. Daman, GIG Gulf, Sukoon, ADNIC, and Orient each assess rare-disease biologic cases individually. We do not promise coverage.

Typical timeline for Uplizna in the UAE

The EDE permit processes in 5 to 15 business days for a routine submission with a clear autoimmune disease rationale and a documented prior therapy trail. A first-of-kind Uplizna submission for an institution typically falls in the 4-to-6-week complex band the first time. Refrigerated logistics from the US to the UAE add 5 to 10 business days. Customs clearance is typically 1 to 3 business days. A patient who completes the documentation in week one typically receives the first loading infusion in week four to week six. The second loading infusion is two weeks later. Maintenance dosing is every 6 months thereafter.

What your physician needs to provide

The clinical justification letter for an Uplizna EDE submission is anchored on antibody status and prior therapy. The treating neurologist's letter typically addresses the diagnosis (NMOSD by 2015 international consensus criteria with AQP4 antibody-positive status, or generalised myasthenia gravis with AChR antibody-positive status), the antibody laboratory report, the relapse or symptom history with timing and severity, the prior therapy trail with response and reason for switching, and the rationale for CD19-directed B-cell depletion. The letter references the Horizon/Amgen US label and the proposed dose schedule. Hepatitis B screening and tuberculosis screening status is documented.

The treating physician's licence must be in active standing in the emirate of the dispensing facility (MoHAP for the Northern Emirates, DHA for Dubai, DoH for Abu Dhabi and Al Ain, Sharjah Health Authority for Sharjah). The patient signs informed consent reflecting the chronic B-cell depletion implications and the infection risk.

Pharmacovigilance and cold-chain considerations

Uplizna is a refrigerated biologic stored at 2 to 8 degrees Celsius. The shipment chain runs cold from the US specialty distributor to the UAE dispensing facility. Each shipment carries calibrated temperature monitors and a chain-of-custody log. On arrival, the pharmacy in charge confirms the temperature record before release. The B-cell depletion is durable and chronic, which means infection risk (urinary tract infection, upper respiratory infection, more rarely opportunistic infection) is the principal long-term consideration. Hepatitis B and tuberculosis screening are mandatory before initiation. Live vaccines are avoided during therapy. Hypogammaglobulinaemia can develop with chronic dosing; serum immunoglobulin levels are monitored. Adverse events identified by the treating team route to the Horizon/Amgen safety reporting channel and to the EDE post-market surveillance address.

Common questions about Uplizna in the UAE

Why Uplizna rather than rituximab off-label for NMOSD? Rituximab targets CD20 and has long off-label use in NMOSD with substantial regional experience. Inebilizumab targets CD19, which produces a deeper B-cell depletion including the CD19+CD20- plasmablast and short-lived plasma cell populations that drive AQP4 autoantibody production. Inebilizumab also holds a dedicated FDA NMOSD indication based on the N-MOmentum trial, where rituximab does not. The clinical choice rests with the treating neurologist.

Why Uplizna rather than eculizumab or satralizumab for NMOSD? All three biologics hold FDA NMOSD indications based on different mechanisms (eculizumab = complement, satralizumab = IL-6, inebilizumab = anti-CD19 B-cell depletion). The choice depends on

antibody status, comorbidities, prior immunotherapy history, dosing-schedule preference, and the treating neurologist's experience. The clinical choice rests with the treating team.

Will Daman, Thiqa, or my private insurer cover this? Each insurer assesses rare-disease biologics case by case. Pre-authorisation is the norm. Thiqa has the broadest specialty coverage in Abu Dhabi. We do not promise coverage.

Is Uplizna a controlled substance? No. Uplizna is not a DEA scheduled substance.

What patients ask when they first call

"How does the case actually start?" The patient or the treating neurologist contacts Reserve Meds through the waitlist form. Within 24 to 48 hours, a coordinator confirms eligibility (the AQP4 or AChR antibody status is the central screening question), sends the documentation kit to the physician, and outlines the EDE submission sequence. No payment is taken at this stage.

"What happens during a relapse on Uplizna?" Relapses on B-cell-depleting therapy are uncommon but do occur. Acute relapse management follows the standard NMOSD or myasthenia gravis playbook (high-dose corticosteroids, plasma exchange where indicated). The treating neurology team reassesses whether the relapse reflects insufficient B-cell depletion (requiring an interim dose), a non-AQP4 or non-AChR mechanism, or another diagnosis.

"How is infection risk managed long-term?" Chronic B-cell depletion increases susceptibility to bacterial infections, particularly urinary and respiratory. The treating team monitors serum immunoglobulin levels, addresses vaccination strategy (with live vaccines avoided during therapy), and discusses prophylactic measures where appropriate. The post-COVID period has improved the regional clinical experience with B-cell-depleting therapy infection management.

"What if I become pregnant or wish to become pregnant?" Inebilizumab is a monoclonal antibody and crosses the placenta. Pre-conception counselling is part of the standard care for women of childbearing age on B-cell-depleting therapy. The treating neurologist coordinates with obstetric specialists on the timing and the monitoring of the infant for B-cell depletion at birth.

Where Reserve Meds fits in Uplizna cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating neurologist, the EDE, or the dispensing pharmacy. For an Uplizna case, our work is the regulatory documentation assembly, the US-side procurement coordination with the Horizon/Amgen specialty distributor, the refrigerated logistics, the customs handoff, and a

single named coordinator for the patient through the loading set and the recurring twice-yearly maintenance supply. The every-6-month maintenance schedule means we hold a long, light cadence with the patient. We hold the cold chain end to end. Reserved for you.

Documentation kit for the treating neurologist

The documentation kit Reserve Meds sends the treating neurologist after a waitlist confirmation contains the EDE clinical-justification letter template tailored to anti-CD19 B-cell depletion in NMOSD or generalised myasthenia gravis, the antibody capture sheet (AQP4 for NMOSD, AChR for gMG, laboratory report attached), the relapse-history capture sheet, the prior immunotherapy capture sheet with response and reason for switching, the hepatitis B and tuberculosis screening template, the loading-and-maintenance dosing calendar, the infusion suite intake checklist, the cold-chain receipt log, the immunoglobulin and infection-risk monitoring template, the patient informed consent template covering chronic B-cell depletion implications, and the maintenance every-6-month reminder calendar. The kit is built so the neuroimmunology team focuses on the patient conversation and the long-term care plan.

Next step

If a treating neurologist in the UAE has a confirmed AQP4-positive NMOSD or AChR-positive generalised myasthenia gravis and is weighing Uplizna, 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

- Uplizna clinical resource
- Neuromyelitis optica spectrum disorder
- Myasthenia gravis
- United Arab Emirates country page

Sources

1. FDA approval, Uplizna (inebilizumab-cdon), Horizon Therapeutics (Viela Bio originally, now Amgen), BLA approval June 2020 for AQP4-positive NMOSD; April 2025 for generalised myasthenia gravis.

2. UAE Federal Decree-Law No. 38 of 2024 and the Emirates Drug Establishment portal at ede.gov.ae.
3. Horizon/Amgen US prescribing information for Uplizna (inebilizumab), 100 mg/10 mL single-dose vial intravenous infusion; refrigerated 2 to 8 degrees Celsius; loading a