

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

How UAE adults with moderate-to-severe ulcerative colitis or Crohn's disease pursue vedolizumab, the gut-selective integrin antagonist, when systemic biologic options have not delivered the response the gastroenterologist expected.

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

Quick orientation

Entyvio (vedolizumab) is a gut-selective humanised monoclonal antibody targeting the alpha-4-beta-7 integrin, developed by Takeda. The US Food and Drug Administration approved Entyvio in May 2014 for adult patients with moderately-to-severely active ulcerative colitis and Crohn's disease. The intravenous formulation is given as a 300 mg infusion at weeks 0, 2, and 6, then every 8 weeks. A subcutaneous formulation marketed as Entyvio Pen (108 mg every 2 weeks) was approved for ulcerative colitis maintenance in September 2023 and for Crohn's disease maintenance in April 2024. The gut-selective mechanism is the clinical differentiator from systemic anti-TNF or anti-IL-23 biologics. Reserved for you.

Why UAE patients need Entyvio via a named-patient pathway

Inflammatory bowel disease prevalence has been rising across the GCC, including the UAE, with regional gastroenterology services routinely treating moderate-to-severe ulcerative colitis and Crohn's disease. The first-line biologic in most UAE IBD practices is infliximab or adalimumab, both anti-TNF agents with established MoHAP registration and wide regional stock. Ustekinumab (Stelara, anti-IL-23 in IBD) and risankizumab (Skyrizi) cover the IL-23 mechanism. The clinical case for Entyvio specifically rests on gut selectivity, which the treating gastroenterologist may prefer for the older patient with infection risk, the patient with prior systemic immunosuppression concerns, or the patient who has not responded adequately to anti-TNF therapy and prefers a non-systemic mechanism.

Entyvio holds a Takeda registration in many regional markets but is not consistently held in UAE federal stock at the level of the anti-TNF agents. When the gastroenterologist documents the clinical case for vedolizumab, the EDE named-patient pathway is the established route.

The EDE / MoHAP named-patient pathway applied to Entyvio

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 Entyvio, the clinical justification packet is structured around the IBD disease state. The treating gastroenterologist documents the diagnosis (moderately-to-severely active ulcerative colitis or Crohn's disease, with endoscopic and histopathologic confirmation), severity (Mayo score, partial Mayo, CDAI for Crohn's disease, faecal calprotectin), prior therapy trail (corticosteroids, immunomodulators including thiopurines or methotrexate, anti-TNF agents with response and reason for switching), and the rationale for gut-selective integrin antagonism now. The letter typically references the Takeda US label and the chosen formulation (intravenous induction-and-maintenance or intravenous induction followed by subcutaneous maintenance).

A complete EDE application for Entyvio typically includes the gastroenterologist's clinical justification letter, the treating physician's MoHAP, DHA, DoH, or Sharjah Health Authority licence verification, an anonymised patient identifier, full product details (Entyvio 300 mg single-dose vial for intravenous infusion or Entyvio Pen 108 mg/0.68 mL subcutaneous injection), the destination dispensing facility name with licence number and pharmacy in charge, the cold-chain handling plan, and the patient informed consent. Approval timelines for routine cases are 5 to 15 business days. Complex submissions extend to 4 to 6 weeks.

Where Entyvio gets dispensed in the UAE

Entyvio intravenous infusion is administered at an infusion suite attached to a gastroenterology or internal medicine service. Entyvio Pen subcutaneous injection can be administered in the clinic for initial doses and self-administered at home after training. The most natural dispensing sites for Entyvio cases are the gastroenterology services at Cleveland Clinic Abu Dhabi, American Hospital Dubai, Mediclinic City Hospital in Dubai

Healthcare City, Sheikh Khalifa Medical City, NMC Royal Hospital in Khalifa City, and Tawam Hospital. The drug must be stored refrigerated at 2 to 8 degrees Celsius until the infusion or injection is prepared.

Real cost picture for Entyvio in the UAE

The US wholesale acquisition cost for Entyvio at the maintenance schedule is approximately USD 8,000 to 12,000 per 300 mg infusion at every-8-week dosing for the intravenous formulation, translating to a monthly equivalent of approximately USD 4,000 to 6,000 (AED 15,000 to 22,000) at the 3.67 peg. The Entyvio Pen subcutaneous maintenance regimen runs in a similar monthly range. The induction phase (weeks 0, 2, and 6) carries higher upfront cost.

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 fees where applicable, and the Reserve Meds concierge coordination fee. Insurance in the UAE handles IBD biologic cases case by case. Pre-authorization is the norm. Thiqa, administered by Daman for UAE nationals in Abu Dhabi, has the broadest specialty coverage. Daman, GIG Gulf, Sukoon, ADNIC, and Orient each assess IBD cases individually. We supply the documentation set; we do not promise coverage.

Typical timeline for Entyvio in the UAE

The EDE permit processes in 5 to 15 business days for a routine submission with a clear clinical rationale and a documented anti-TNF trail. 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 induction dose in week three to week five. Maintenance dosing follows the every-8-week intravenous schedule or the every-2-week Entyvio Pen schedule per the gastroenterologist's protocol.

What your physician needs to provide

The clinical justification letter for an Entyvio EDE submission is pattern-matched to the IBD biologic structure. The treating gastroenterologist's letter typically addresses the diagnosis (ulcerative colitis or Crohn's disease with endoscopic and histopathologic confirmation), the disease activity quantification, the prior therapy trail (corticosteroid dependence or failure, thiopurine or methotrexate exposure, anti-TNF agents trialed with response and reason for switching), the rationale for gut-selective integrin antagonism (older patient with infection risk, prior systemic immunosuppression concerns, anti-TNF inadequate response, patient

preference for a non-systemic mechanism), and the chosen formulation. The letter references the Takeda US label.

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 for the named-patient route. The pharmacy in charge at the dispensing facility holds the establishment licence the EDE verifies.

Pharmacovigilance and cold-chain considerations

Entyvio 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. Pharmacovigilance follow-up includes baseline tuberculosis screening (the gut-selective mechanism reduces but does not eliminate the consideration), hepatitis B screening, and monitoring for infusion reactions during the intravenous schedule. The historic theoretical concern about progressive multifocal leukoencephalopathy that affected the broader integrin antagonist class (driven by natalizumab) has not materialised in vedolizumab post-marketing surveillance through more than a decade of use. Adverse events identified by the treating team route to Takeda's safety reporting channel and to the EDE post-market surveillance address.

Common questions about Entyvio in the UAE

Why Entyvio rather than infliximab, adalimumab, or ustekinumab? The biologic choice in IBD rests on multiple clinical considerations: prior anti-TNF response or loss of response, infection risk, the patient's tolerance of systemic immunosuppression, formulation preference (intravenous versus subcutaneous), and the treating gastroenterologist's experience. Entyvio's gut-selective mechanism is the differentiator. The clinical choice rests with the treating gastroenterologist.

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

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

Can I switch from intravenous Entyvio to the subcutaneous Entyvio Pen? Yes, the US label supports a transition from intravenous induction to subcutaneous maintenance. The treating gastroenterologist defines the timing.

What patients ask when they first call

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

"Do I have to commit to the intravenous formulation or can I start with Entyvio Pen?" The US label sequence is intravenous induction at weeks 0, 2, and 6 followed by either intravenous maintenance every 8 weeks or a transition to Entyvio Pen subcutaneous maintenance every 2 weeks. Most UAE gastroenterologists prefer to do intravenous induction so the response can be assessed under clinical observation, then transition motivated patients to the subcutaneous maintenance. The choice rests with the treating gastroenterologist.

"What if I'm scheduled for surgery during induction?" Surgical timing decisions in IBD are coordinated by the treating gastroenterologist and the colorectal surgical team. Entyvio is generally compatible with elective and emergent surgery, but the team typically structures the dosing relative to the surgical window. Reserve Meds coordinates supply continuity around the surgical schedule.

"How is induction response assessed?" The treating gastroenterologist evaluates clinical response at week 6 (the third induction dose) with symptom assessment, faecal calprotectin, and CRP, and may pursue early endoscopic assessment at month 6 in patients with insufficient symptom response.

Where Reserve Meds fits in Entyvio cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating gastroenterologist, the EDE, or the dispensing pharmacy. For an Entyvio case, our work is the regulatory documentation assembly, the US-side procurement coordination with the Takeda specialty distributor, the refrigerated logistics, the customs handoff, and a single named coordinator for the patient through the multi-month onboarding and the recurring maintenance supply. We hold the cold chain end to end. Reserved for you.

Documentation kit for the treating gastroenterologist

The documentation kit Reserve Meds sends the treating gastroenterologist after a waitlist confirmation contains the EDE clinical-justification letter template tailored to the IBD biologic class with the gut-selective rationale, the disease-activity capture sheet (Mayo or partial Mayo for UC, CDAI for Crohn's, faecal calprotectin and CRP), the prior anti-TNF outcome capture sheet, the formulation selection guide (intravenous induction-and-

maintenance vs intravenous induction with Entyvio Pen subcutaneous transition), the patient informed consent template, the infusion suite intake checklist, the cold-chain receipt log, the post-induction response-assessment template at week 6 and month 6, and the maintenance dosing calendar. The kit is built so the gastroenterology team focuses on the patient conversation and the response assessment that anchor the chronic biologic regimen.

Next step

If a treating gastroenterologist in the UAE is weighing Entyvio for an adult patient, 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

- Entyvio clinical resource
- Ulcerative colitis
- Crohn's disease
- United Arab Emirates country page

Sources

1. FDA approval, Entyvio (vedolizumab), Takeda, BLA approval May 2014 for ulcerative colitis and Crohn's disease; Entyvio Pen subcutaneous approval September 2023 (UC) and April 2024 (CD).
2. UAE Federal Decree-Law No. 38 of 2024 and the Emirates Drug Establishment portal at ede.gov.ae.
3. Takeda US prescribing information for Entyvio, 300 mg single-dose vial intravenous; Entyvio Pen 108 mg subcutaneous; refrigerated 2 to 8 degrees Celsius.