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

How UAE patients with ALK-positive metastatic non-small cell lung cancer pursue lorlatinib, the third-generation ALK tyrosine kinase inhibitor with CNS penetration, in the first line and after disease progression on prior ALK TKI therapy.

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

Quick orientation

Lorbrena (lorlatinib) is an oral third-generation anaplastic lymphoma kinase (ALK) tyrosine kinase inhibitor developed by Pfizer. The US Food and Drug Administration approved Lorbrena in November 2018 for ALK-positive metastatic non-small cell lung cancer after disease progression on prior ALK-directed therapy, and in March 2021 in the first-line setting based on the CROWN trial demonstrating improved progression-free survival versus crizotinib. The standard daily dose is 100 mg, given as one 100 mg tablet or four 25 mg tablets. Lorlatinib's defining clinical feature is robust central nervous system penetration, which is the principal differentiator from earlier-generation ALK TKIs in patients with intracranial disease. Reserved for you.

Why UAE patients need Lorbrena via a named-patient pathway

ALK rearrangements account for approximately 3 to 7 percent of metastatic non-small cell lung cancer, with a meaningful representation in the never-smoker and lighter-smoker adult populations the UAE serves. UAE oncology services routinely test for ALK rearrangement as part of the molecular pathology workup for advanced NSCLC. The locally available first-line and later-line ALK TKIs typically include crizotinib (Xalkori), alectinib (Alecensa), and brigatinib (Alunbrig), each with established regional registration and stock. The case for Lorbrena specifically is built when the treating oncologist wants third-generation CNS penetration in the first line (the CROWN trial demonstrated a striking intracranial response rate), when the patient has progressed on prior ALK TKI therapy and

the resistance mutation profile supports lorlatinib, or when intracranial disease is the dominant clinical concern.

Lorbrena is not consistently held in UAE federal stock at the level of the earlier-generation ALK TKIs. The EDE named-patient pathway is the established route when the molecular oncology workup supports the ALK-positive diagnosis and the treating oncologist has documented the clinical case for lorlatinib specifically.

The EDE / MoHAP named-patient pathway applied to Lorbrena

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 Lorbrena, the clinical justification packet rests on the molecular pathology report and the line-of-therapy rationale. The treating thoracic oncologist documents the diagnosis (metastatic non-small cell lung cancer), the molecular pathology confirmation of ALK rearrangement by FISH, IHC, NGS, or RT-PCR with a CAP-accredited or comparable laboratory, the staging workup including brain imaging (MRI is the standard for ALK-positive NSCLC because intracranial disease is common), the prior ALK TKI line where applicable with the resistance pattern, and the rationale for lorlatinib specifically (first-line CNS-active selection or post-progression resistance pattern).

A complete EDE application for Lorbrena typically includes the oncologist's clinical justification letter, the molecular pathology report, the brain imaging report where intracranial disease is part of the rationale, the treating physician's MoHAP, DHA, DoH, or Sharjah Health Authority licence verification, an anonymised patient identifier, full product details (Lorbrena 25 mg or 100 mg oral tablets), the destination dispensing pharmacy name with licence number and pharmacy in charge, and the patient informed consent. Approval timelines for routine cases are 5 to 15 business days.

Where Lorbrena gets dispensed in the UAE

Lorbrena is an oral tablet with standard ambient storage at 20 to 25 degrees Celsius. The dispensing site is the outpatient oncology pharmacy attached to the treating thoracic oncology service. The most natural dispensing sites are the thoracic oncology services at Cleveland Clinic Abu Dhabi, the Tawam Hospital National Reference Cancer Centre in Al Ain,

Sheikh Khalifa Medical City, American Hospital Dubai (Mayo Clinic Care Network member), and Mediclinic City Hospital in Dubai Healthcare City.

Real cost picture for Lorbrena in the UAE

The US wholesale acquisition cost for Lorbrena is approximately USD 21,000 to 25,000 per month at the 100 mg daily dose, translating to approximately AED 77,000 to 92,000 monthly at the 3.67 peg. The figure is the drug acquisition cost only.

All-in delivered cost stacks the drug acquisition, international logistics (USD 400 to 800 per shipment, ambient), EDE handling and customs (USD 300 to 600 per case), the dispensing pharmacy fee, and the Reserve Meds concierge coordination fee. We quote each case after the documentation review. Insurance in the UAE handles ALK-directed therapies 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 oncology cases individually. We do not promise coverage.

Typical timeline for Lorbrena in the UAE

The EDE permit processes in 5 to 15 business days for a routine submission with a clear molecular pathology rationale and a well-defined line-of-therapy position. International logistics for an ambient-shipped oral oncology agent adds 3 to 7 business days. Customs clearance is typically 1 to 3 business days. A patient who completes the documentation in week one typically receives the first cycle in week three to week five. Subsequent supply is coordinated to a monthly rhythm with the thoracic oncology team.

What your physician needs to provide

The clinical justification letter for a Lorbrena EDE submission carries the standard solid-tumour-targeted-therapy structure. The treating thoracic oncologist's letter typically addresses the cancer diagnosis with stage and disease distribution, the molecular pathology confirmation of ALK rearrangement (laboratory report attached), the prior systemic therapy and prior ALK TKI line where applicable with response and resistance pattern, the brain imaging where intracranial disease is part of the rationale, the rationale for lorlatinib (first-line CNS-active selection or post-progression position), and the dose proposal (100 mg daily). The letter references the Pfizer US label and the CROWN or post-second-generation evidence base.

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 CNS adverse-event profile.

Pharmacovigilance considerations

Lorbrena's adverse-event profile is distinct from the earlier-generation ALK TKIs. The CNS effects (mood disorder, cognitive effects, speech effects) are well characterised in the Pfizer US label and require a structured monthly clinical assessment by the treating team and family observation. Hyperlipidaemia is common and may require statin initiation. Hypertension, weight gain, oedema, peripheral neuropathy, and atrioventricular block are the other principal considerations. Lorlatinib is a strong CYP3A4 inducer and the US label provides specific guidance on contraceptive coverage and on concurrent medication review. Adverse events identified by the treating team route to Pfizer's safety reporting channel and to the EDE post-market surveillance address.

Common questions about Lorbrena in the UAE

Why Lorbrena rather than alectinib in the first line? Alectinib (Alecensa) is the most widely used second-generation ALK TKI in the first line for ALK-positive metastatic NSCLC and has substantial regional experience. The CROWN trial demonstrated that lorlatinib in the first line achieves a longer progression-free survival than crizotinib and a striking intracranial response rate. Whether lorlatinib or alectinib is the right first-line choice depends on the patient's intracranial disease burden, comorbidities, the treating team's experience, and tolerability considerations. The clinical choice rests with the treating thoracic oncologist.

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

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

Will Lorbrena reach my brain metastases? Lorlatinib is designed with CNS penetration as a defining property. The CROWN trial demonstrated a high intracranial response rate in the first-line setting. Treatment response in any individual patient is documented by the treating oncologist.

What patients and families ask when they first call

"How does the case actually start?" The patient, family, or treating thoracic oncologist contacts Reserve Meds through the waitlist form. Within 24 to 48 hours, a coordinator confirms eligibility (the molecular pathology ALK confirmation 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.

"How are the CNS adverse events identified in practice?" The CNS effects of lorlatinib (mood disorder, cognitive effects, speech effects) typically emerge in the first weeks of therapy and are picked up by the treating oncology team and by family observation. The US label structures monthly clinical assessment. Dose interruption and reduction algorithms are part of the standard management. Family members are typically more sensitive to early changes than the patient.

"What if I have an isolated CNS progression on my prior ALK TKI?" Isolated CNS progression on a first or second-generation ALK TKI is a recognised clinical scenario where lorlatinib's CNS penetration is the rationale for switching. The treating thoracic oncologist documents the imaging and the systemic disease control as part of the rationale.

"Does lorlatinib treat the underlying ALK rearrangement permanently?" No. ALK TKIs control the disease for the duration of therapy. Resistance can develop. The treating oncology team monitors the disease at the standard imaging cadence (typically every 2 to 3 months) and reassesses the regimen at progression.

Where Reserve Meds fits in Lorbrena cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating thoracic oncologist, the EDE, or the dispensing pharmacy. For a Lorbrena case, our work is the regulatory documentation assembly, the US-side procurement coordination with the Pfizer specialty distributor, the logistics, the customs handoff, and a single named coordinator for the patient through the multi-month treatment course. Reserved for you.

Documentation kit for the treating thoracic oncology team

The documentation kit Reserve Meds sends the treating thoracic oncology team after a waitlist confirmation contains the EDE clinical-justification letter template tailored to the third-generation ALK TKI position, the molecular pathology capture sheet (ALK rearrangement laboratory report attached), the prior ALK TKI capture sheet with resistance pattern where applicable, the brain imaging summary template, the dose proposal (100 mg daily), the CNS adverse-event monitoring template (monthly clinical assessment with family observation prompts), the hyperlipidaemia monitoring template, the patient informed consent template covering the CNS adverse-event profile, and the dispensing pharmacy intake checklist. The kit is built so the thoracic oncology team focuses on the patient conversation and the multidisciplinary tumour board coordination.

Next step

If a treating thoracic oncologist in the UAE has a confirmed ALK-positive metastatic NSCLC and is weighing Lorbrena, 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

- Lorbrena clinical resource
- Non-small cell lung cancer
- United Arab Emirates country page
- Named-patient pathway overview

Sources

1. FDA approval, Lorbrena (lorlatinib), Pfizer, accelerated approval November 2018 (post-progression) and regular approval March 2021 (first-line).
2. UAE Federal Decree-Law No. 38 of 2024 and the Emirates Drug Establishment portal at ede.gov.ae.
3. Pfizer US prescribing information for Lorbrena (lorlatinib), 25 mg and 100 mg oral tablets, 100 mg daily.