Xdemvy access in Pakistan: the DRAP Special Permission pathway

How patients in Pakistan access Xdemvy (lotilaner ophthalmic solution 0.25%) for adult Demodex blepharitis.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.

1. Quick orientation

Xdemvy is the brand name for lotilaner ophthalmic solution 0.25%, a topical sterile aqueous ophthalmic drop developed and commercialised by Tarsus Pharmaceuticals. It is not a biologic, not an antibiotic, and not a steroid. The mechanism is selective antagonism of the Demodex mite gamma-aminobutyric acid-gated chloride channel, producing parasiticidal effect against the underlying mite rather than treating downstream inflammation alone. The US Food and Drug Administration approved Xdemvy on July 25, 2023 for the treatment of Demodex blepharitis in adults. It is the first and only FDA-approved therapy that directly targets the underlying mite infestation. In Pakistan, ophthalmology practice has historically relied on lid hygiene, hypochlorous acid sprays, tea tree oil derivatives, and off-label antiparasitic compounds, none of which carries a regulator-endorsed Demodex blepharitis indication. Pakistani patients whose ophthalmologist has confirmed Demodex blepharitis reach Xdemvy through the Drug Regulatory Authority of Pakistan (DRAP) Special Permission / Personal Use Import No Objection Certificate. Reserved for you.

2. Why Pakistan patients need Xdemvy via the named-patient pathway

Three patterns of access gap apply across Pakistan: a drug is on the DRAP register but the patient's hospital pharmacy does not have it on hand; a drug is registered for a different indication; or a drug is FDA-approved but the manufacturer has not yet completed DRAP registration. Xdemvy sits cleanly in the third pattern. Tarsus Pharmaceuticals has not completed DRAP registration in Pakistan, and the product is not in routine commercial stocking. There is no Pakistani ophthalmic equivalent with a regulator-endorsed Demodex blepharitis indication.

Three structural reasons converge in Pakistan. First, prevalence. Demodex blepharitis is highly prevalent globally and is estimated to account for roughly two-thirds of all blepharitis cases worldwide. Pakistani ophthalmology clinics see chronic recalcitrant blepharitis routinely, and a meaningful subset present with collarette signs on slit-lamp examination consistent with Demodex involvement. Second, the absence of a registered local alternative. Lid hygiene reduces bacterial load and debris, tea tree oil has variable anti-mite activity with significant tolerability concerns at therapeutic concentrations, and off-label antiparasitic compounds carry no regulator endorsement for this indication. None demonstrates the collarette cure and mite eradication rates documented for lotilaner in the randomised vehicle-controlled Saturn-1 and Saturn-2 trials. Third, the case profile is favourable for cross-border coordination. Xdemvy is a finite-course product (6 weeks of twice-daily bilateral drops, one complete course in two 5 mL bottles), room-temperature stable, and lower clinical acuity than oncology cases. The named-patient pathway functions cleanly for a single-shipment finite course at a mid-tier specialty price point.

3. The DRAP Special Permission pathway for Xdemvy

DRAP regulates the import of medicines through the Quality Assurance and Laboratory Testing (QA&LT) Division's Import and Export Section, with Drug Registration Board oversight for new product registration matters. For unregistered medicines required by a specific patient, DRAP issues a Special Permission, also known as the Personal Use Import No Objection Certificate (NOC). The framework covers Personal Use Import by an individual patient on physician prescription and Special Permission for Import of Unregistered Therapeutic Goods by hospitals or institutions, filed through DRAP's Online Import and Export System (OIES) electronic portal.

A complete DRAP application for Xdemvy includes the clinical justification letter from the treating ophthalmologist; the treating physician's PMDC license verification with specialist registration in ophthalmology; the patient identifier (CNIC for adults, given the adults-only label); full product details (Xdemvy, lotilaner ophthalmic solution 0.25%, Tarsus Pharmaceuticals, 5 mL multi-dose bottle, two bottles per complete course); the destination dispensing facility license; the manufacturer or authorised distributor letter confirming legitimate supply chain sourcing through Tarsus's contracted US specialty pharmacy network (AllianceRx Walgreens Pharmacy, CVS Specialty, and ophthalmology-aligned specialty pharmacies); and a chain-of-custody plan for ambient shipment.

The clinical justification angle for Xdemvy turns on diagnostic confirmation and prior-therapy documentation. The treating ophthalmologist documents the diagnosis of Demodex blepharitis with explicit reference to slit-lamp examination findings (collarettes at the lash base are the cardinal sign), prior therapies attempted (lid hygiene, hypochlorous acid sprays, tea tree oil derivatives, in-office microblepharoexfoliation, off-label antiparasitics where used), and the clinical rationale for the only FDA-approved directly indicated product. The letter states the planned dosing regimen (one drop in each eye, twice daily approximately 12 hours apart, for 6 weeks, with the full 6-week course completed even if symptoms resolve earlier, no loading dose, no taper, no defined re-treatment interval established by the label). Routine DRAP personal-use cases typically clear in four to eight weeks from a complete submission. Because the case profile is straightforward (adult patient, ambient product, finite course, low clinical acuity), faster turnaround is plausible but Reserve Meds plans on the routine range and treats anything quicker as upside.

4. Where Xdemvy gets dispensed in Pakistan

Xdemvy is supplied as a sterile ophthalmic solution in a 5 mL multi-dose bottle, stable a