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## Entresto access in Pakistan: the DRAP named-patient pathway

How families and patients in Pakistan obtain Entresto (sacubitril/valsartan) for chronic heart failure through the Drug Regulatory Authority of Pakistan Personal Use Import framework.

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

### Quick orientation

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Entresto is the Novartis brand name for the fixed-dose combination of sacubitril and valsartan, the first member of the angiotensin receptor neprilysin inhibitor (ARNI) class. Sacubitril is a neprilysin inhibitor that raises levels of beneficial vasoactive peptides including the natriuretic peptides, and valsartan is an angiotensin II receptor blocker. Together they reduce cardiac wall stress in chronic heart failure. The US FDA first approved Entresto in July 2015 to reduce the risk of cardiovascular death and hospitalization in adults with chronic heart failure with reduced ejection fraction (HFrEF), expanded it in October 2019 to pediatric patients aged one year and older with symptomatic heart failure due to systemic left ventricular dysfunction, and in February 2021 broadened the adult indication to chronic heart failure across a wider ejection fraction range. For Pakistani families whose cardiologist has decided ARNI is the right next step but the local supply is generic-only or stocked-but-inconsistent for the titrated dose, the DRAP Special Permission for Personal Use Import is the operative pathway.

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### Why patients in Pakistan reach for Entresto through NPP

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Entresto is registered in more than 115 countries and is well-known to Pakistani cardiologists, both through the major tertiary teaching programs and through the international cardiology guidelines that name ARNI as a Class I recommendation for symptomatic HFrEF. Pakistan's named-patient demand for Novartis-manufactured Entresto specifically is driven by three patterns. First, branded-Entresto preference. Multiple branded-generic versions of sacubitril/valsartan are stocked in regional markets, but a subset of cardiologists and patients prefer Novartis-manufactured Entresto for reasons of perceived quality consistency, prior treatment continuity (a patient titrated to 97/103 mg twice daily on Novartis Entresto in the US, the UK, or the Gulf seeking to continue on the same product after returning to Pakistan), or trial-protocol matching.

Second, stocking gaps in secondary cities and across all three strengths. Entresto registration in Pakistan does not guarantee that every pharmacy carries the 24/26 mg, 49/51 mg, and 97/103 mg strengths consistently, particularly the 97/103 mg target dose for fully titrated patients. A patient in Multan, Faisalabad, Peshawar, or Quetta may find the local pharmacy can supply 49/51 mg intermittently but not 97/103 mg reliably. Third, pediatric heart failure. The FDA pediatric indication from age 1 is meaningful for a small but growing pediatric cardiology cohort at AKUH, the Children's Hospital and Institute of Child Health in Lahore, and tertiary pediatric cardiology

services. For these families, weight-based dosing requires accurate strength availability that local supply does not always guarantee.

## **The DRAP Personal Use Import pathway for Entresto**

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The Drug Regulatory Authority of Pakistan (DRAP), established in 2012 under the DRAP Act, regulates the import of medicines through its Quality Assurance and Laboratory Testing (QA&LT) Division's Import and Export Section. For unregistered or stocked-but-unavailable medicines required by a specific patient, DRAP issues a Special Permission, commonly referred to as the No Objection Certificate (NOC) for Personal Use Import. Applications are filed through DRAP's Online Import and Export System (OIES) portal.

For Entresto the clinical justification angle is heart-failure-specific and includes documentation of the ACE inhibitor washout where applicable. A complete application typically includes:

- A clinical justification letter on hospital letterhead from the treating cardiologist or pediatric cardiologist (for patients aged 1 to 17), documenting the FDA-approved on-label indication: adult chronic heart failure (particularly with below-normal LVEF for clearest benefit) or pediatric symptomatic heart failure due to systemic left ventricular dysfunction from age 1
- Documentation of prior or concurrent guideline-directed medical therapy (beta-blockers, MRAs such as spironolactone or eplerenone, SGLT2 inhibitors such as dapagliflozin or empagliflozin), and explicit confirmation that any ACE inhibitor has been discontinued with a 36-hour washout period to reduce angioedema risk (Entresto must not be combined with an ACE inhibitor)
- Echocardiographic and clinical assessment documenting LVEF and NYHA functional class, plus baseline blood pressure, serum creatinine, eGFR, and serum potassium
- A recent prescription specifying brand name (Entresto), generic name (sacubitril/valsartan), strength (24/26 mg, 49/51 mg, or 97/103 mg film-coated tablet), quantity, and dosing schedule
- The treating physician's PMDC license verification
- The patient identifier: CNIC for adult patients, B-Form for pediatric patients aged 1 to 17, passport for foreign nationals receiving treatment in Pakistan
- Product details: brand name, generic name (INN), manufacturer Novartis Pharmaceuticals Corporation (US subsidiary of Novartis AG, Basel, Switzerland), strength, dosage form, quantity, batch number where available
- The destination dispensing facility license
- A manufacturer or authorized distributor letter confirming the product is genuine Novartis-manufactured Entresto with intact pedigree documentation under DSCSA (Drug Supply Chain Security Act)
- The chain-of-custody plan from the US source through international shipment (ambient temperature acceptable; protection from heat extremes during summer transit)

Routine personal-use cases for established cardiology indications typically clear in 4 to 8 weeks from a complete submission. Pediatric cases involving weight-based dosing documentation may extend slightly.

## Where Entresto gets dispensed in Pakistan

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Entresto is a film-coated oral tablet stored at room temperature, 20 to 25 degrees Celsius. It is one of the least demanding modalities in the named-patient program portfolio: no cold chain required, no reconstitution, no in-pharmacy compounding. Standard ambient pharma courier service with humidity protection is sufficient. This widens the dispensing-facility set in Pakistan considerably. Aga Khan University Hospital in Karachi, with its tertiary cardiology service and 24/7 pharmacy network, is a natural home for the Entresto case. Shaukat Khanum Memorial Cancer Hospital in Lahore, the Indus Hospital and Health Network in Karachi, Liaquat National Hospital in Karachi, the Pakistan Kidney and Liver Institute (PKLI) in Lahore, the Combined Military Hospitals network at CMH Rawalpindi and CMH Lahore, and Shifa International Hospital in Islamabad all maintain import pharmacies that can serve as the dispensing facility.

For pediatric heart failure patients aged 1 to 17, the pediatric cardiology services at AKUH and the Children's Hospital and Institute of Child Health in Lahore are the natural homes. Smaller hospitals outside Karachi, Lahore, and Islamabad typically partner with a DRAP-licensed specialty importer based in Karachi or Lahore that files the OIES application, handles FBR Customs clearance, and arranges dispensing through one of the major-city tertiary facilities. Entresto's room-temperature stability and 36-month shelf-life from manufacture make multi-month supply windows practical, aligning well with cardiology titration check-in cadences every 2 to 4 weeks during initiation and every 3 months during maintenance.

## Real cost picture for Entresto in Pakistan

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Reserve Meds quotes Pakistani patients in US dollars and accepts USD wire transfers from any USD-accessible source. The Pakistani Rupee has been volatile, with the USD to PKR rate in the 278 to 280 range in May 2026 and April 2026 CPI inflation at 10.9 percent. Quoting in USD insulates the patient from intra-case currency drift over the indefinite duration of chronic heart failure maintenance therapy.

The US wholesale acquisition cost for Entresto is approximately USD 12.50 per day, equating to roughly USD 4,500 per year at WAC for daily dosing across the three strengths. Cash-pay retail pricing in the United States ranges from approximately USD 600 to USD 700 per 30-day supply without insurance, equating to USD 7,200 to USD 8,400 per year at retail without discount. The Medicare Part D Maximum Fair Price under the Inflation Reduction Act, effective January 1 2026, is USD 295 per 30-day supply or approximately USD 3,540 per year, but that price is restricted to Medicare beneficiaries inside the United States and is not available for international named-patient procurement. International ambient logistics from US source to Karachi, Lahore, or Islamabad typically runs USD 250 to USD 700 per shipment, materially less than the cold-chain biologics in the matrix. On the insurance side, Adamjee Insurance, Jubilee General Insurance and Jubilee Life Insurance, EFU General Insurance, State Life Insurance Corporation, IGI Insurance, and Pak-Qatar Family Takaful each assess named-patient imports case by case, but coverage for unregistered or branded-specific specialty imports is uncommon. The realistic default is cash-pay, frequently funded through pooled household resources including overseas remittances.

## Typical timeline for Entresto in Pakistan

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For an established HFREF or chronic heart failure patient with confirmed echocardiographic diagnosis and a cardiology referral, the typical end-to-end cycle for the first fill is 5 to 9 weeks. The DRAP NOC step generally runs 4 to 8 weeks. US-side sourcing through an authorized Novartis distributor with DSCSA-compliant pedigree adds 1 to 2 weeks. International ambient

transit, FBR Customs clearance, and final delivery to the dispensing hospital pharmacy are typically 4 to 6 days. The 36-month shelf-life lets Reserve Meds verify expiry dating at procurement and provide a minimum acceptable remaining shelf life on arrival. Recurring fills on 30-day or 90-day supply windows run faster once the first fill is complete and the file is on record. Cases involving pediatric weight-based dosing or ACE inhibitor washout documentation may extend by 1 to 2 weeks. Timelines are typical ranges, not promises.

## What your physician needs to provide

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The clinical justification letter for Entresto is the centerpiece of the DRAP package. For this product the letter typically includes:

- The confirmed indication: adult chronic heart failure (with explicit documentation of LVEF, NYHA class, and the clinical rationale for ARNI versus an ACE inhibitor or ARB alone), or pediatric symptomatic heart failure due to systemic left ventricular dysfunction from age 1
- Documentation that any prior ACE inhibitor has been discontinued with a 36-hour washout to reduce angioedema risk, or confirmation that the patient is ACE-inhibitor-naive (in which case the reduced starting dose of 24/26 mg twice daily applies)
- Baseline blood pressure, serum creatinine and eGFR, and serum potassium values, with the monitoring plan during titration and maintenance
- The dosing schedule chosen: for adults, starting dose 49/51 mg twice daily in patients previously tolerating moderate-to-high doses of an ACE inhibitor or ARB, or 24/26 mg twice daily in ACE-naive patients, patients on low doses, patients with eGFR less than 30 mL/min/1.73 m squared, or patients with moderate hepatic impairment; titration by doubling every 2 to 4 weeks to the target maintenance dose of 97/103 mg twice daily; for pediatric patients aged 1 and older, weight-based dosing per the package insert dosing table, starting at lower mg/kg doses and titrating upward over 2 weeks as tolerated
- The monitoring plan: blood pressure, serum creatinine and eGFR, and serum potassium at baseline and periodically during titration and maintenance; more frequent monitoring during dose titration, in patients with chronic kidney disease, in patients on potassium-sparing diuretics or potassium supplements, and in elderly patients; vigilance for angioedema (facial, lip, tongue, or airway swelling requires immediate discontinuation)
- Confirmation of guideline-directed concomitant medical therapy (beta-blockers, MRAs, SGLT2 inhibitors) and the absence of concurrent ACE inhibitor or aliskiren (in patients with diabetes or renal impairment)
- Confirmation that the patient is not pregnant and counseling on pregnancy contraindication

The treating physician's PMDC license verification anchors the application. Cardiologists, pediatric cardiologists, and internal medicine physicians with heart-failure-clinic experience all have signing authority on Personal Use Import clinical justification letters.

## Common questions about Entresto in Pakistan

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**Why import Novartis Entresto if Pakistani branded generics of sacubitril/valsartan are available?** Some patients and cardiologists prefer Novartis-manufactured Entresto for continuity (a patient titrated abroad on Novartis Entresto), quality-consistency considerations, or trial-

protocol matching. Reserve Meds does not promote one over the other; we coordinate on the prescription written. If your cardiologist is comfortable with a local branded generic, that is the simpler and usually less expensive path.

**Will Adamjee, Jubilee, EFU, or State Life cover Entresto?** Coverage for branded-specific named-patient imports is uncommon across Pakistani health plans, even where the molecule itself is locally available as a branded generic. Some plans pay a partial percentage on a case-by-case basis. We supply the documentation the insurer needs; the claim is yours or your hospital's to file.

**My child has pediatric heart failure and is on a low-dose oral suspension prepared at the hospital. Can Entresto be imported as a tablet for an older child?** The FDA pediatric indication from age 1 covers tablet dosing. For pediatric patients who cannot swallow tablets, an extemporaneous oral suspension can be compounded per the package insert at a licensed pharmacy. The dispensing facility, typically AKUH pediatric cardiology pharmacy or the Children's Hospital pharmacy in Lahore, manages the compounding decision.

**My family pools funds across Pakistan and the Gulf. How does Reserve Meds handle that?** Reserve Meds quotes in USD and accepts USD wire transfers from any USD-accessible source. Pakistani families routinely consolidate funds across overseas relatives in Saudi Arabia, the UAE, the UK, the United States, and Canada before treatment can start.

**Is there a competitor or alternative?** Within the ARNI class, Entresto is currently the only marketed option. Alternative heart failure regimens include ACE inhibitors (enalapril, lisinopril, ramipril), ARBs (losartan, valsartan monotherapy, candesartan), and the broader guideline-directed medical therapy stack including beta-blockers, MRAs, and SGLT2 inhibitors. The choice between ARNI and an ACE inhibitor or ARB alone is a cardiologist-led decision based on patient-specific factors.

**What is the safety profile?** The most frequent adverse events in clinical trials were hypotension, hyperkalemia, cough, dizziness, and renal impairment. Angioedema occurred at a low rate (0.1 to 0.5 percent) with higher incidence in Black patients. Pregnancy is contraindicated.

## **Where Reserve Meds fits in Entresto cases**

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Reserve Meds is a US-based concierge coordinator. We do not replace your cardiologist or pediatric cardiologist, do not replace DRAP, and do not replace the dispensing hospital pharmacy or the in-country importer. For Entresto specifically we orchestrate the US-side sourcing through an authorized Novartis distributor with DSCSA-compliant T3 pedigree documentation, prepare the regulatory documentation kit your physician needs for the DRAP filing through OIES (heart-failure indication letter template, ACE inhibitor washout documentation, baseline laboratory summary, titration plan, monitoring plan), coordinate the international ambient-temperature logistics with humidity protection to Karachi, Lahore, or Islamabad, and run a single named coordinator throughout the case in English and Urdu. For chronic heart failure patients pursuing indefinite therapy, we structure recurring fill cadence on 30-day or 90-day supply windows aligned to cardiology check-in cadence so the next shipment is on its way before the current supply runs out.

## Next step

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If your cardiologist has decided Entresto is the right next step for your chronic heart failure case and local stocking, dose-strength availability, or branded preference is the bottleneck, the named-patient pathway through DRAP is the route. Join the waitlist below and we will confirm eligibility within 24 to 48 hours and route the documentation kit to your physician and to the dispensing hospital pharmacy.

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**Review & oversight.** Content on this page is reviewed by Reserve Meds's clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. [Review methodology >](#)

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