

Mitigation plan for pancreatic enzyme replacement therapy (PERT) supplies

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NHS Cornwall and Isles of Scilly Integrated Care Board

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Version control

Version number	Revision date	Revision by	Nature of revisions
V1.1	May 2025	Medicines optimisation team	Reviewed and no change

1. Introduction

Pancreatic Enzyme Replacement Therapy (PERT) is prescribed to aid adequate digestion in patients with pancreatic exocrine insufficiency (PEI) such as in cystic fibrosis, pancreatic cancer, neuroendocrine cancers, and pancreatitis. Other clinical situations may also involve primary or secondary PEI, such as type 3c diabetes or following gastrectomy or gastric bypass surgery. The impact of maldigestion varies from person to person.

Untreated PEI symptoms may include bloating, excess wind, diarrhoea, crampy abdominal pain, faecal urgency, steatorrhea, hard-to-control blood glucose levels, vitamin and mineral deficiencies, weight loss, and malnutrition. The correct dose of PERT usually controls all of these. At present, there is no clinical alternative to PERT.

Following ongoing shortages of PERT, patients have been running out or experiencing a delay in obtaining their prescriptions for PERT. A <u>National Patient Safety Alert (NPSA)</u> was sent out in December 2024 asking ICBs to put in place a local mitigation plan for instances when patients are unable to obtain stock of their PERT from their community pharmacy or dispensing GP. This follows the <u>NPSA alert in May 2024</u>, which detailed the supply disruption with Creon 10,000 and 25,000 capsules.

It is predicted that these supply issues will continue until 2026.

2. Purpose

To provide colleagues in general practice (GP) and community pharmacy with clear guidance on the local mitigation plan for instances when adult patients are unable to obtain stock of PERT from their community pharmacy or dispensing GP. This policy is to be followed when alternative options for supply have been exhausted. Therefore, we expect this only to be used in **exceptional circumstances**.

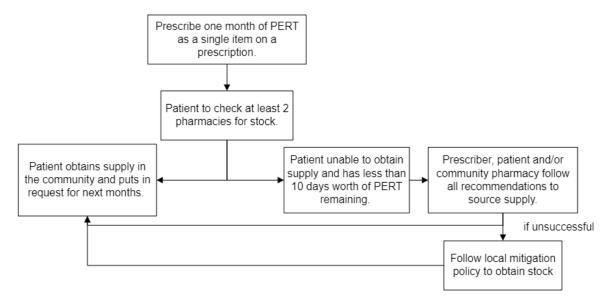
If stock issues arise for children with PEI, specialist advice should be sought.

3. Summary of Current Issues

The supply disruption of Creon is due to the limited availability of raw ingredients and manufacturing capacity constraints to produce volumes needed to meet demand. Currently, there are regular deliveries to wholesalers, two to three times each month, of both strengths to allow for equitable distribution. However, the volumes are not sufficient to meet the full demand. Therefore, out-of-stock periods continue between each delivery.

Other brands of PERT (Nutrizym and Pancrex V) are intermittently available but are unable to fully cover the gap in supply. Nutrizym 22 capsules production has increased, but this increase is unable to fully cover the gap in supply. There are also intermittent deliveries of Pancrex V capsules and powder, but again these are unable to support an uplift.

4. Steps to Undertake to Source PERT



Supporting Steps to Source PERT

Prescribers and community pharmacies should work together to source supplies of PERT for their patients. In addition to the above flow chart, the following steps should be strongly considered:

- Primary Care Networks should maintain local intelligence on medicine supplies within community pharmacies.
- The SPS website has information on stock availability supplied by the Department of Health and Social Care.
- Patients should be encouraged to check multiple pharmacies, including chains and independents, as they may use different suppliers.
- Some pharmacy chains have stock checkers available on their websites. These can be used by healthcare professionals and patients.
- Viatris (manufacturers of Creon) have a free customer service line for both patients and healthcare professionals. The service will aim to provide information on the nearest pharmacies which have recently received supply. To identify potential pharmacies with stock of Creon, patient consent is required before sharing their post code. The Creon customer service line can be reached via 0800 8086410. Operators will respond from UK and handle enquiries in real time. The service will be active from Monday to Friday from 9:00 to 17:00.
- The SPS website has a <u>tool</u> to guide prescribers on alternatives and equivalences where a patient needs to change brands.
- There is a Serious Shortage Protocol (SSP) in place for community pharmacies.
- Option of sourcing unlicensed products where suppliers have this available for community pharmacy

Where PERT is prescribed for indications other than cystic fibrosis, clinicians and prescribers should consider:

- Prescribing a proton pump inhibitor or H2 receptor antagonist to optimise efficiency.
- If a dose reduction may be suitable for patients based on the severity of symptoms.
- Prescribing medication to manage symptom control, noting that this will not treat malabsorption and is not an alternative to PERT.
- Where symptoms remain despite a dose of ≥10,000 units lipase/kg/day or 100,000 units lipase with a meal, whether other causes of the symptoms should be investigated.

Further steps can be taken to protect the supply and ensure patients do not run out:

- Ensure patients are aware not to stockpile this medication, as this will worsen the supply issues.
- Allow and encourage patients to reorder their PERT as soon as they have collected their current prescription.
- Remind patients to take their PERT throughout the meal, rather than all at the start or the end.

Further information for both healthcare professionals and patients can be found in the following <u>Position Statements</u>.

If after exhausting all these options a patient is unable to obtain a supply of PERT, then the local mitigation plan should be followed.

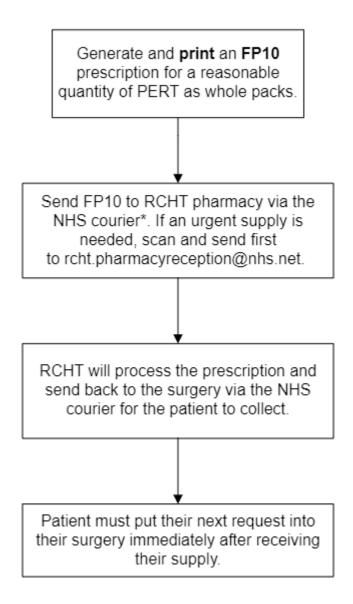
5. Local Mitigation Plan

This plan remains in place until supply issues are resolved and will be terminated with immediate effect once these issues are resolved.

If the prescriber can be assured that all reasonable steps have been taken to exhaust the options given in step 4, and the patient has less than 10 days' supply of PERT left, the local mitigation plan can be followed.

If prescribing any brand of PERT other than Creon, supplies should be checked with the RCHT pharmacy (switch board 01827 250000) first.

Due to limited stocks at RCHT, this should only be followed in emergency situations. Use of the mitigation plan will be monitored to ensure that supplies are equally available across the county.



^{*}If the courier does not visit the surgery, then the prescription can be emailed and then posted to RCHT. See appendix 1 for a list of surgeries this applies to. The medication will then be posted via special delivery.

To protect the supplies of PERT, clinicians are asked to only prescribe a reasonable quantity of PERT (i.e., enough to cover the patient until they can obtain a supply from their usual pharmacy or dispensary).

Patients can present their FP10 directly to RCHT pharmacy where an immediate supply is required.

If a patient is still unable to obtain a suitable supply of PERT despite following this mitigation plan, advice should be sought from the individual's specialist team.

6. Implementation Plans

This document will be shared with GP colleagues via prescribing shots, the LMC and the primary care bulletin and with community pharmacy colleagues via the LPC. It will be uploaded onto the formulary website.

7. Update and Review

This policy will be reviewed every 6 months, or sooner if the supplies issues are resolved, as it will be terminated with immediate effect at this point.

Appendix 1.

Surgeries that the courier does NOT visit		
Old Bridge Surgery		
Quay Lane Surgery		
Rame Group Practice		
Rosedean Surgery		
Stratton Medical Centre		
Tamar Valley Health		