



## **Position Statement: Pancreatic enzyme replacement therapy (PERT) shortage – advice for clinicians on the management of adults with pancreatic exocrine insufficiency**

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Position statement and advice for prescribers from the <sup>1</sup>Nutrition Interest Group of the Pancreatic Society of Great Britain and Ireland (NIGPS), <sup>2</sup>Cystic Fibrosis Specialist Group and <sup>3</sup>Gastroenterology Specialist Group, British Dietetic Association.

Endorsed by the British Society of Gastroenterology (Pancreas section); Pancreatic Society of Great Britain and Ireland, Pancreatic Cancer UK, GUTS UK, Cystic Fibrosis Trust, CF Medical Association, Pancreatic Cancer Action, Neuroendocrine Cancer UK and the British Dietetic Association.

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Please ensure you are reading the most up to date version, which is available on the Pancreatic Society of Great Britain and Ireland website:

<https://www.psgbi.org/position-statement-pert-shortage/>

**This document has been extensively revised to include the licenced alternatives as well as imported medications that are available to fill the gap in supply of UK licenced products.**

**It is expected that with these imported products available, no patient needing PERT should go without it.**

# Introduction

The ongoing supply issues surrounding pancreatic enzyme replacement therapy (**PERT**) preparations under the product brand: **Creon**<sup>®</sup> is predicted to continue until the end of 2026. However, there are alternative products (**Nutrizym**<sup>®</sup> and **Pancrex**<sup>®</sup>) and the UK is now well supplied by imports of other preparations of PERT which are suitable for use as an alternative (predominantly **Pangrol**<sup>®</sup>). This position paper is designed to meet the needs of the clinicians managing patients with pancreatic exocrine insufficiency (PEI) and provides advice for prescribers and dietitians. A separate document is available providing advice for patients.

Pancreatic enzyme replacement therapy is prescribed to support adequate digestion in patients with PEI, most commonly due to pancreatic cancer, pancreatitis, pancreatic surgery, cystic fibrosis (CF) and neuroendocrine tumours (NETs) – also known as neuroendocrine neoplasms (NENs). There are many other clinical situations where patients may have primary or secondary PEI, such as following gastrectomy or gastric bypass surgery (1). Patients who take somatostatin analogues [Lanreotide (Somatuline<sup>®</sup>) / Octreotide (Sandostatin<sup>®</sup>)] for the treatment of neuroendocrine neoplasms (NENs) are also at risk of PEI. Regardless of aetiology, the impact of maldigestion varies from person to person in both the type of symptoms and their severity.

Symptoms of untreated PEI may include bloating, excess wind, diarrhoea, crampy abdominal pain, faecal urgency, steatorrhoea (pale floating stools), hard to manage blood glucose levels, vitamin and mineral deficiencies, weight loss and malnutrition (1). These symptoms are usually managed with PERT and will recur if patients are unable to take adequate doses.

There are many clinical impacts of inadequate PERT, which will affect all patients, and the advice in this document is targeted at all patient groups.

The advice in this paper may be updated as we receive further guidance. The most up to date version will be available at: <https://www.psgbi.org/position-statement-pert-shortage/>

Please note the advice in this document is designed for adults with PEI, specialist advice should be sought for children with PEI. Patients with cystic fibrosis will be under the care of a specialist centre, and they should contact their specialist team if they have any concerns.

## Customer Services

The two main suppliers of PERT in the UK have set up customer support lines to help identify areas with recent deliveries. However, it is possible these deliveries may have already been allocated to specific patients.

- Viatris (Creon<sup>®</sup>) 0800 8086410 (for patients and pharmacists)
- Zentiva (Nutrizym<sup>®</sup>): 08448 793188 (for pharmacists) and 08000 902408 (for patients)

## Advice for Prescribers

The current supplies of PERT available through the normal prescribing routes are not sufficient to meet the needs of the UK population. Up to 1 in 10 prescriptions will not be filled via this route. **Patients must not run out of these medications.** The advice in previous versions of this document has been revised as there is no longer a reason for patients to run out of PERT. **Hospitals no longer receive priority orders, so may not be able to issue rescue prescriptions.**

Each ICB has developed a plan for the medicine shortage in line with the NatPSA/2024/013/DHSC, and in most cases that includes the use of imported medication. These imports have been added to local Formulary's and to electronic prescribing databases, and in many places specific prescribing and dispensing advice has been issued.

If a patient has less than 2 weeks supply of PERT left, please prescribe an alternative (which may include an imported medication if licenced alternatives are not available).

It is acknowledged that prescribing imported alternative incurs a cost. However, this is an essential medication, and there will be detrimental health outcomes, adverse events, increased healthcare utilisation and considerable anxiety associated with undertreatment (2). This results in human, clinical and financial costs, that clinicians strongly believe outweigh the additional prescription cost.

Where possible ICBs have imported medications that match the doses of existing medications to make it easier for prescribers and patients to use both interchangeably. There is no evidence to suggest that there is any difference between European and American units of enzymes in these preparations (3)

PERT product prioritisation:

- Creon Micro<sup>®</sup> is prioritised for infants and those with dysphagia who are also unable to open the Creon 25,000<sup>®</sup> capsules.
- Creon 10,000<sup>®</sup> should be prioritised for children and those unable to swallow larger capsules
- Nutrizym 22<sup>®</sup> has limited availability and should be prioritised for those unable to tolerate Creon
- Pancrex capsules are available, but unable to support the uplift in demand (see Appendix 2 for dose calculations)
- Pancrex V<sup>®</sup> powder should only be prescribed for patients receiving enteral feeding

**Patients cannot “go without” this medication. This can have significant adverse health effects.**

## Logistical recommendations

- Liaise with your ICB (medicines management teams) regarding regional plans for imported medicines and accessing emergency supplies for patients who have run out.
- Allow an override of any electronic systems that block prescription requests if they are placed less than 4 weeks since the previous request.
- Patients should be advised to place their next prescription request as soon as the previous one has been dispensed to allow time for a supply to be sourced.
- If you have an “in house” pharmacy – identify if they are able to place orders that sit on a back-order list at the wholesalers, if not, leave prescriptions on the NHS Spine in order that patients can take these to a pharmacy that can dispense them.
- Please provide PERT prescriptions on singular prescriptions to allow patients to take prescriptions to a different pharmacy, if needed, to those who dispense their other medicines.
- In line with the Medicines Supply Notification from the Department of Health and Social Care (issued 16/2/24 MSN/2024/022). Please ensure that only one-month supply is issued at a time. (4).

## CAUTIONS – impact of inadequate PERT on other medication / medical conditions

Whilst no one should go without PERT, we recognise that some patients are restricting their doses, and some patients are still experiencing difficulties in obtaining alternatives. This section of this document is designed to highlight the issues this may present.

- **DIABETES:** Be aware that patients on insulin or oral hypoglycaemic agents that can cause hypoglycaemia may experience worsening control and be more susceptible to hypoglycaemia.
  - Patients with diabetes **MUST NOT go without PERT – they are at risk of life-threatening hypoglycaemia.**
  - Please ensure patients with diabetes have adequate testing equipment to allow for increased monitoring.
  - Patients on insulin should (subject to local guidelines) have continuous glucose monitoring devices and these should have the low glucose alarm set.
  - Patients should be encouraged to monitor glucose levels more frequently, especially when undertaking activities such as driving or exercise.
  - **Patients who have had a total pancreatectomy are especially vulnerable to hypoglycaemia as they have an absence of glucagon as well as endogenous insulin.**
- Please be aware that malabsorptive diarrhoea is osmotic and results in rapid transit time. This may impact the **absorption of other medication** (including medication prescribed for seizure control, anti-hypertensives, arrhythmia drugs, antibiotics and the oral contraceptive pill etc.,)
  - Secondary forms of contraception should be recommended.
  - Please increase monitoring for people with dose sensitive medication.
  - Use loperamide to reduce transit speed where necessary (Not for patients with CF – refer to specialist centre).
- **ANTI-COAGULATION:** Please be aware that Vitamin K is a fat-soluble vitamin and uptake may be impaired with inadequate PERT – additional monitoring may be needed for patients on anti-coagulation.
- **FALLS:** Uncontrolled PEI results in faecal urgency which is a risk factor for falls in vulnerable patients. Consider the use of loperamide to control faecal urgency where necessary.

## CAUTIONS – differential diagnosis

- Distal intestinal obstruction syndrome (DIOS) is a unique feature of CF and is characterised by the accumulation of viscid mucofaecal material in the terminal ileum and caecum. Being a common complication in people with CF, it needs to be considered if someone with CF presents with symptoms following a change in their PERT prescription.
- Be aware that patients with small bowel NENs may be at risk of Carcinoid syndrome, mesenteric fibrosis, short bowel syndrome etc, please refer to their specialist teams if you have concerns.
- Consider that patients with PEI, may also have bile acid malabsorption, small intestinal bacterial overgrowth, coeliac disease etc., please investigate and treat in line with current guidelines (2).

### IMPORTANT

For patients with CF please contact the patients' CF Specialist team. For all other patients please contact your local tertiary hepato-pancreatico-biliary (HPB) / pancreatic / neuroendocrine unit. Depending on the local service available, this may be either the specialist HPB / pancreatic / NEN dietitian or pancreatologist. The Specialist Pharmacy Service Medicines Supply Tool can be accessed by Prescribers for more information on supply at: <https://www.sps.nhs.uk>

## Advice for Dietitians

In addition to the above advice, please consider the following to optimise the use of PERT:

- Remind patients to spread the dose of their PERT out throughout their meals to optimise absorption – taking some PERT at the beginning, some in the middle and some towards the end of their meal.
- Remind patients to store their enzymes properly – all products should be stored below 25 degrees, and some may require refrigeration in hot weather. Excess heat causes irreversible denaturation.
- Refer patients not responding to treatment back to their managing physician to ensure other causes of diarrhoea have been excluded.
- When PERT doses have been escalated in response to ongoing symptoms, please ensure symptoms are re-evaluated. If a clinical benefit is not observed, please reduce the dose back down.
- Please support patients who are having difficulty accessing PERT by escalating concerns to the medicines management team at the ICB. This is a relatively unusual prescription in primary care, and some practices and pharmacies may not be aware of the guidelines to access alternatives. Please forward this document where necessary. We have advised patients to make a same day appointment with their GP if they run out completely.
- Consider using peptide based oral nutritional supplements (ONS) for patients struggling to access PERT. i.e., **VITAL 1.5 kcal® / Survimed OPD 1.5kcal®/ Peptisip Energy HP®** in place of polymeric supplements to reduce the need for PERT with polymeric ONS. **Peptamen® Vanilla** contains less energy (1kcal/ml), but these could be used if supplies of **VITAL 1.5 kcal® / Survimed OPD 1.5kcal®/ Peptisip Energy HP®** are limited.
- Ensure patients with diabetes on **insulin** or **sulphonylureas (e.g. Gliclazide, Glipizide or Glimpiride)** are regularly monitoring their blood glucose levels and aware of how to treat a hypo.
- Please ensure patients with signs of malabsorption and taking anti-coagulation are highlighted to their managing physician as Vitamin K absorption may be impaired.
- Seek advice from specialist centres for specific advice for patients with CF.
  - CF Dietitians will review and optimise PERT dosing and adherence.
  - CF Dietitians will optimise vitamins and minerals and adjust as appropriate.

## Nutritional composition of additional products

**Vital 1.5kcal®** 300kcal, 13.5g protein (as peptide), 64% MCT. ACBS approved. 200ml bottle, suitable for vegetarians (not vegan), once open store in a refrigerator and discard after 24 hours

**Peptisip Energy HP®** 300kcal, 15g protein (as peptide), 60% MCT, ACBS approved, 200ml bottle, suitable for vegetarians (not vegan), once open store in a refrigerator and discard after 24 hours.

**Survimed® OPD 1.5kcal** drink – 300kcal, 15g protein (as peptide), 50% MCT, ACBS approved, 200ml bottle, once open store in a refrigerator and discard after 24 hours.

**Peptamen Vanilla®** 200kcal, 8g protein (as peptide), 68% MCT, ACBS approved. 200ml bottle, best served chilled, once open refrigerate and discard after 24 hours.

## Appendix 1: Content of imported pancreatin products

There are multiple options for imports. These are the most commonly available:

### PANGROL®

Enteric coated capsules with mini tabs

Preparation	Pack size	Presentation	Amylase	Protease	Lipase
Pangrol 10,000	200	Capsule	9000	500	10,000
Pangrol 25,000	200	Capsule	22,500	1250	25,000

### CREON®

Creon can be imported in the same doses as licenced in the UK, we recommend this is done to reduce confusion for patients. (10,000 and 25,000)

## Appendix 2 Dose calculations to use if you prescribe an alternative product (5)

Creon® 25,000 Dose	Equivalent in Nutrizym® 22	Equivalent in Creon® 10,000	Equivalent in Pancrex® 340mg (8,000 units lipase)	Equivalent in Pancrex® 125mg (2,950 units lipase)	Equivalent in Creon® Micro*
1 x Creon 25,000	1 x Nutrizym 22	3 x Creon 10,000	3 x Pancrex 8,000	8 x Pancrex 2,950	5 scoops Creon Micro
2 x Creon 25,000	2 x Nutrizym 22	5 x Creon 10,000	6 x Pancrex 8,000	16 x Pancrex 2,950	10 scoops Creon Micro
3 x Creon 25,000	3 x Nutrizym 22	8 x Creon 10,000	9 x Pancrex 8,000	24 x Pancrex 2,950	15 scoops Creon Micro
4 x Creon 25,000	4 x Nutrizym 22	10 x Creon 10,000	12 x Pancrex 8,000	32 x Pancrex 2,950	20 scoops Creon Micro
5 x Creon 25,000	5 x Nutrizym 22	13 x Creon 10,000	15 x Pancrex 8,000	40 x Pancrex 2,950	25 scoops Creon Micro
6 x Creon 25,000	6 x Nutrizym 22	15 x Creon 10,000	18 x Pancrex 8,000	48 x Pancrex 2,950	30 scoops Creon Micro

\*Mix with a mildly acidic puree (fruit yoghurt / apple sauce), rinse mouth with water and ensure thorough mouth care as at risk of ulceration if powder / granules get stuck in the gums / under dentures

## References / sources of further information

- 1) Phillips ME, Hopper AD, Leeds JS, *et al* Consensus for the management of pancreatic exocrine insufficiency: UK practical guidelines *BMJ Open Gastroenterology* 2021 ;8:e000643. doi: 10.1136/bmjgast-2021-000643
- 2) <https://gutscharity.org.uk/2024/11/sharing-the-results-from-our-pert-shortages-survey/>
- 3) <https://lp.thieme.de/emag/CP/11525-Drug-Report-Pankreatin-2024/#6>
- 4) <https://cks.nice.org.uk/topics/diarrhoea-adults-assessment/> accessed 16/3/24
- 5) <https://bnf.nice.org.uk/drugs/pancreatin/> accessed 27/3/26