

Update For Primary Care:

Pancreatic Enzyme Replacement Therapy (PERT) shortages

This is a memo for primary care regarding the ongoing shortage of PERT medicines, summarising the available guidance to date. This memo is for adult patients. Advice for children should be sought from the specialist teams.

Pancreatic Enzyme Replacement Therapy (PERT) is indicated for the treatment of pancreatic exocrine insufficiency (PEI) such as in cystic fibrosis, pancreatic cancer, and pancreatitis. There have been ongoing intermittent supply issues surrounding PERT product brands: Creon®, Nutrizym® and Pancrex®) meaning some people are running out of PERT or experiencing difficulties or delays in accessing PERT. At present there is no clinical alternative to PERT.

NatPSA Alert

There has been a [National Patient Safety Alert](#) (NatPSA), (24th May 2024) issued in response to ongoing limited supplies of PERT:

- Creon® 10,000 and 25,000 capsules are in limited supply until 2026.
- Nutrizym® 22 capsules are out of stock until mid-August 2024.
- Pancrex V® capsules and powder are available, but unable to support increased demand.

Serious Shortage Protocols

Alongside the NatPSA, the government has issued two [serious shortage protocols](#) for Creon® 10,000 capsules and 25,000 capsules, enabling clinicians and pharmacists to supply a maximum of one month's supply of PERT to patients at a time, even if the prescription is for longer.

NIGPS (Nutrition Interest Group of the Pancreas Society of Great Britain and Ireland) Position Statement for Adults

A [Joint Position Statement](#) on supply issues with PERT products has also been published (endorsed by British Society of Gastroenterology, Pancreatic Society of Great Britain and Ireland, Pancreatic Cancer UK, GUTS UK, Cystic Fibrosis Trust, CF Medical Association and the British Dietetic Association). It is designed for **adult patients**, includes product equivalences and clinical management suggestions for prescribers and dietitians, as well as specific advice for adult patients, depending on their supply status and symptoms.

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.

Practical Advice

In response to the supply problems, local specialists in BNSSG have provided the following pragmatic approach to support adult patients during this time.

- Although there is limited supply, some community pharmacies may still be able to order supplies of PERT medicines from wholesalers. Therefore, patients should be advised to check multiple pharmacies (both independents and pharmacy multiples/chains) for stock as they may use different suppliers and be able to obtain PERT supplies.
- Only one month's supply of PERT should be prescribed at a time as a Serious Shortage Protocol has been issued for [Creon® 10000](#) and [Creon® 25000](#) capsules, meaning no more than one month's supply can be issued by a pharmacy even if the prescription is longer. Clinicians should ensure that the patient's prescription is for the correct amount of PERT medicine as per their individual usage as this may vary from patient to patient.
- Whilst the supply issues are ongoing, please do NOT encourage patients to stockpile these medicines, as this will further drive the shortage. Wholesaler stock levels are fluctuating so patients should place their prescription requests in good time and discuss current supply situation with their community pharmacist.
- Clinicians should not switch between PERT products as there are supply issues with Creon® 10000 and 25000 capsules and Nutrizym® 22 capsules, and while Pancrex V® capsules and powder remain available they are unable to support an increase in demand. Stocks of Creon 10,000 capsules should be preserved for those who are unable to take Creon 25,000, such as children.
- Clinicians should prioritise remaining stock of Nutrizym 22 capsules for patients unable to tolerate Creon® capsules.
- The NatPSA also included a list of specialist importers, who have confirmed they will be able to supply unlicensed PERT preparations but availability to community pharmacies and lead times may vary. It is understood these are not yet available to order. The availability of unlicensed PERT preparations is being scoped out currently and further guidance will follow.
- Due to the number of patients on PERT, primary care is being asked to manage shortages for patients under GP prescribing where they can. Primary care clinicians should escalate to secondary care/specialist for advice in exceptional circumstances e.g. patients who are immediately running out, patients no longer under secondary care teams (e.g. post-surgery patients) or for advice on alternative treatments if above options are not suitable.
- It is NOT recommended that patients buy PERT preparations (e.g., from Amazon) as they are not regulated, and strength/efficacy may not be equivalent.

Clinical Advice – All Patients

For PERT prescribed for **all indications**, clinicians should consider:

- Prescribing a **proton pump inhibitor** or **H2 receptor antagonist** to optimise efficacy. Local specialists recommend that patients (including for cystic fibrosis patients) are co-prescribed omeprazole 20mg BD or equivalent.
- Dietitians may recommend certain oral nutritional supplements for patients during this shortage as appropriate to supplement nutritional intake. Refer to dietetic team if advice needed. GPs are not currently recommended to start patients on any new oral nutritional supplements during this supply disruption.

Clinical Advice- Cystic fibrosis patients

- Please contact specialist teams for clinical advice regarding cystic fibrosis patients.
- Dose reductions should not be attempted by cystic fibrosis patients without specialist advice.

Clinical Advice – Non-Cystic Fibrosis patients

The NIGPS position statement provides some advice for prescribers on how they can support patients where there are limited supplies of PERT.

- Reduce the dose of PERT with snacks before reducing doses with meals as meals tend to be more nutritious.
 - Reduce the dose of PERT by one capsule with each meal and snack, rather than skip whole meal doses.
 - If patients have some high dose PERT left, take this with them when they go out, and use the low dose capsules when they are at home to reduce the number of capsules you need to take out with you.
 - Prioritise meals that have the most protein and energy in them.
- For PERT prescribed for **non-cystic fibrosis indications**, clinicians should consider:
Once PPI has been optimised, a dose reduction may be suitable for non-cystic fibrosis patients based on severity of symptoms. Local specialists recommend reducing dose of PERT by one capsule with a snack and with one meal to start with, and assess patient tolerance for this, which would manifest through symptoms of diarrhoea, steatorrhoea, nausea, abdominal pain and bloating. If no change in these symptoms on the optimised dose of PPI, suggest the patient continues on the reduced dosage of PERT with meals and snacks and continues to find an optimal reduced dose.
 - Where symptoms remain despite a dose of $\geq 10,000$ units lipase/kg/day or 100,000 units lipase with a meal, other causes of symptoms should be investigated.

- Prescribing medication to manage symptom control e.g. **loperamide** for diarrhoea. Please note loperamide capsules may not be as effective in patients with malabsorption. Therefore delivering loperamide in a form such as **loperamide tablets, Imodium melts®, or loperamide capsules opened and dispersed** may be more effective.
- In patients who have *ongoing* bowel symptoms and were undergoing dose escalation to manage this, please only continue to increase the dose until the patient is able to maintain their weight.
- If they have ongoing bowel symptoms after this, **loperamide / hyoscine butylbromide** and other appropriate medications can be used to manage their symptoms rather than continuing to increase the doses to preserve supplies.
- Consider prescribing a calcium and vitamin D supplement as per [local guidance](#) if patients are not already taking one
- If due to symptoms there are concerns about malabsorption of critical medications (e.g. antiretrovirals, anticonvulsants, anticoagulants) please refer to specialist teams for advice regarding ongoing management.
- For concerns regarding malabsorption of oral contraceptives please advise patients to use barrier methods as per manufacturer's advice.

Useful Resources:

- NIGPS Position statement **for patients** - <https://www.psqbi.org/position-statement-pert-shortage/>
- NIGPS Position statement **for clinicians** - <https://www.psqbi.org/position-statement-pert-shortage/>
- Specialist Pharmacy Services Medicines Supply Tool - <https://www.sps.nhs.uk/shortages/shortage-of-pancreatic-enzyme-replacement-therapy-creon-nutrizym/>