1. Introduction and Who Guideline applies to

a) Pancreatic Enzyme Replacement Therapy (PERT) is prescribed to treat people who cannot digest food normally due to pancreatic exocrine insufficiency (PEI). PERT is required to prevent malnutrition. PERT provides enzymes including lipase, protease and amylase, which digest fat, protein and carbohydrate respectively.

b) PEI is treated by administration of PERT, which mimics the action of the pancreas by replacing the amylase, protease and lipase, therefore minimising malabsorption of carbohydrate, protein and fat from the diet.

c) PEI occurs due to the pancreas not being able to release digestive enzymes. Digestion and absorption of fat, protein, carbohydrate and fat soluble vitamins A, D, E and K are impaired. Due to the lack of digestive enzymes, energy from food is lost in stools.

d) The main groups of patients with PEI requiring PERT are those with cystic fibrosis, pancreatic cancer, chronic pancreatitis, those who have underdone a partial and total gastrectomy and gastric bypass surgery.

e) All currently available PERT preparations are porcine (a non-porcine PERT formulation was in development, but it failed to meet its primary endpoint in a phase III clinical trial). Patients should be made aware of the porcine origin of PERT before commencing therapy. Jewish and Muslim faith leaders consent to the use of PERT as there are no alternatives available. (Konstan MW, 2018).

f) This guideline is for use by all medical, dietetic staff, nursing and midwifery and pharmacy staff employed by UHL, including bank, agency and nursing staff.

g) The aim of this guideline is to ensure appropriate and timely prescribing and dose adjustment of PERT for adult patients presenting with PEI.

2. Guideline Standards and Procedures

a) The pancreatic enzyme dose required varies on an individual basis; this may depend on residual pancreatic function. Fat malabsorption is best controlled when pancreatic enzymes are adjusted according to fat eaten at each meal, snacks, milky drinks and nutritional supplements.

b) As dietary intake is best assessed by the Dietitian, it is appropriate for the Dietitian to also assess whether the amount of enzymes given, matches the amount of fat consumed at each meal, snacks, milky drinks and nutritional supplements.

c) The Dietitian is also best placed to assess adherence to pancreatic enzymes. In conjunction with a symptom evaluation sheet, the Dietitian will also assess food diaries, diet histories, monitor weight gain and ensure the patient is adjusting their enzyme doses appropriately. Often it is possible to identify foods where under-dosing is consistent e.g. missing out PERT for butter in sandwiches. Patient information resources to support practice and education of patients and carers are available on insite.

d) **PEI is highly likely in the following groups**

- Head of pancreas cancer
- Pre-surgery and post-surgery for head of pancreas cancer with or without pylorus preserving operation
- Total pancreatectomy
- Steatorrhoea or malabsorption symptoms in patients with CP with dilated pancreatic duct or severe pancreatic calcification
- Severe necrotising pancreatitis
- Cystic Fibrosis

2.1 Cystic Fibrosis

a) 80-90% of people with Cystic Fibrosis (CF) are pancreatic exocrine insufficient due to the pancreas not being able to release digestive enzymes. Malnutrition in children and adults with CF is associated with worse general health, more severe pulmonary disease and shorter life expectancy. Therefore nutritional status is desirable for overall wellbeing, better prognosis and survival.

b) In CF, Body Mass Index (BMI) is independently associated with lung function, with children's BMI centile below the 50th being linked with worse clinical outcomes. It is important to identify if poor weight gain is due to inadequate nutritional intake, high energy requirements related to CF lung disease or Cystic Fibrosis Related Diabetes.

c) The Trust has a dedicated paediatric CF Multi-disciplinary team (MDT) looking after paediatric CF people and their families under the care of Paediatrics in Women and Children's CMG. The MDT includes a Senior Specialist Dietitian who is an expert in PERT dosage, monitoring and adjustment. Children are outside the scope of this guideline.

d) The Trust has a dedicated adult CF Multi-disciplinary team (MDT) looking after 120 adult CF people and their families under the care of Respiratory in RRCV CMG. The MDT includes a Senior Specialist Dietitian who is an expert in PERT dosage, monitoring and adjustment.

e) The paediatric and adult CF MDTs undertake annual reviews and also deliver a transitional outpatient clinic.

f) All patients should be referred to this team for monitoring and adjustment of PERT.

2.2 Pancreatic Cancer and Chronic Pancreatitis

a) Pancreatic exocrine insufficiency (PEI) is almost consistently present in patients with pancreatic cancer located in the head of the pancreas (Davidson et. al, 2004). It has been reported that PEI is a major cause of weight loss in pancreatic cancer (Bruno M et al. 1998) Furthermore Around 80-90% of chronic pancreatitis patients suffer with PEI to some degree (Keller & Layer 2005)

b) PEI is often accompanied by fat soluble vitamin and antioxidant deficiencies and symptoms of carbohydrate, fat and protein malabsorption.

c) It is also well known that weight loss and cachexia are associated with a short survival and poor quality of life in patients with pancreatic cancer. (Davidson *et. al*, 2004; Bachmann J *et. al* 2009*)*

d) The only treatment option is to commence pancreatic enzyme replacement therapy, with the aim of the therapy to not only relieve symptoms but mainly to avoid the malnutrition-related morbidity and mortality by maintaining a normal nutritional status (Dominguez-Munoz JE *et. al* 2010)

e) Patients with chronic pancreatitis benefit from intensive and regular nutritional support, with PEI occurring within 5-10 years of diagnosis. (Dumasy *et al.* 2004).

f) The Trust has a dedicated HPB Cancer Multi-disciplinary team (MDT) looking after 80-120 people with a diagnosis of pancreatic cancer /annum and their families under the care of the HPB Service in CHUGGS CMG. The MDT includes a Senior Specialist Dietitian who is an expert in PERT dosage, monitoring and adjustment.

g) There is no current dietetic resourcing in the Trust for Senior Specialist Dietitian sessions for surgical in and out patients with acute and chronic pancreatitis and those in gastroenterology medicine with pancreatic exocrine insufficiency in CHUGGS CMG or other areas of the Trust for outliers requiring PERT.

2.3 Assessment and diagnosis pancreatic exocrine insufficieny

a) A number of tests have been used for the diagnosis of PEI, including the coefficient of fat absorption (CFA), direct pancreatic function test (PFT), indirect ^{13}C-labelled mixed triglyceride breath test and secretin injection at magnetic resonance cholangiopancreatography (sMRCP). Unfortunately these tests are not used routinely in UK clinical practice, therefore I only option is the faecal pancreatic elastase (FEL-1) test. (Phillps *et al.* 2021)

b) FEL-1 is a measurement of a pancreatic exocrine-specific enzyme that is not degraded in the bowel lumen, is concentrated during intestinal passage and reflects the total overall pancreatic secretion. FEL-1 testing requires a small amount of faeces (Dominici R & Franzini C, 2004)

c) False-positive results occur when water contaminates a specimen, such as in diarrhoea as samples can become diluted. Fischer B, Hoh S, Wehler M, *et al, 2001)* If watery diarrhoea is reported, discussion with the laboratory is advised to ensure adjustment to a standard water content; one study showed that lyophilisation to a standardised water content of 75% was successful. DiMagno EP, Go VL, (Summerskill WH, 1973).

d) As FEL-1 only tests for human elastase, the result is unaffected if the patient is taking PERT. (Stein J et al. 1996).

e) All Cystic Fibrosis patients should have FEL-1 measured for diagnosis of pancreatic insufficiency. All young people who are pancreatic sufficient (PS) should have an annual FEL-1 to check for development of PEI. See table 1 for diagnostic criteria There are currently no guidelines on how often FEL1 should be checked in PS adolescents and adults; as a minimum FEL-1 should be checked if there are new signs and symptoms suggestive of maldigestion and malabsorption or any nutritional decline (Nutritional management of cystic fibrosis, CF Trust 2016)

Table 1: Diagnosing PEI using FEL1

Pancreatic Function	Faecal Elastase microgram E1/g stool
Normal	>200 microgramEI/g
Mild PEI	100-200 microgramEI/g
Severe PEI	<100 microgramEI/g
CF PEI	<15 microgramEI/g
Normal FE1 levels are expected by day 3 in term infants and by 2 weeks of age in those born before 28 weeks gestation. Tests should be performed after this time.	

a) For pancreatic cancer and pancreatic disease patients the practitioner is led by clinical symptoms (see table 2 below) of pancreatic insufficiency and thus starts PERT in the absence of a FEL-1 test. However if there is suspicion and minimal clinical signs to suggest malabsorption then the Dietitian will request a stool sample to assess for PEI(FEL-1)

Table 2: Symptoms of pancreatic exocrine insufficiency

Abdominal symptoms	• Steattorhoea • Oily or fatty stools (stools may be surrounded by an orange oil) • Pale or floating stools (stools may appear creamy in colour) • Frequent or urgent bowel motions • Stools difficult to flush away • Bloating, distension and flatulence • Offensive smelling stools • Undigested food in the stool • Reflux • Abdominal pain or pain on opening bowels
Endocrine Function	• Hypoglycaemia • Reduced insulin requirements in patients already on insulin therapy
Nutritional assessment	• Unexplained weight loss • Failure to gain weight and thrive in children • Weakness/fatigue • Restricting fat intake/ overall food restriction • Decrease in lean mass tissue
Biochemical disturbances	• Fat soluble vitamin deficiency (A, D, E, K) • Low serum selenium, zinc, magnesium, potassium, phosphate • Osteopenia/osteoporosis

b) Steatorrhoea becomes apparent when >90% of exocrine function is lost (DiMagno*et al*, 1973), but this is a late symptom of malabsorption, fat malabsorption may occur even without abdominal symptoms (Caliari*et al*, 1996).

2.4 Treating PEI

Table 3: Available preparations of PERT

Enzyme preparations	Lipase (Units per capsule)	Amylase (Units per capsule)	Protease (Units per capsule)
*Creon Micro®	5000	3600	200
*Creon 10,000U®	10000	8000	600
*Creon 25,000U®	25,000	18000	1000
*Nutrizym 22®	22000	19800	1100
Pancrease HL®	25000	22500	1250
Pancrex V capsules®	8000	9000	430
Pancrex V powder®	25,000 in 1g of powder	30,000 in 1g of powder	1400 in 1g of powder
Those denoted with a * are the most commonly used PERT in UHL			

a) A single solid stool sample is required and should be collected in a stool sample specimen bottle (blue top microbiology container) and sent to the Special Biochemistry lab at Leicester Royal Infirmary. Following verbal advice from Microbiology the specimen must reach the lab within one day following the sample. The samples are run weekly in batches, with results available on iLAB

b) The most effective form of PERT are capsules containing enteric coated microspheres (small beads containing enzymes), which are acid resistant. This protects the enzymes from denaturing in the stomach acid and are only activated in the higher pH (5.5 and above) of the duodenum (small intestine), thereby minimising the possible effect of gastric pH on inactivation of PERT

2.5 Administration Route: Oral

a) PERT should be swallowed whole and taken with all meals, snacks and drinks containing fat. The aim is to mimic the body's normal pancreatic enzyme excretion. Foods containing minimal fat tend not to require PERT, however this must be assessed on an individual basis.

b) Prescribe regular dose three times a day at meal times and then prescribe a prn dose which can be taken with snacks and milky drinks.

c) Patients on a fat based oral nutritional supplement (ONS) will require PERT prescribed at the same times of ONS administration.

d) Where possible PERT should be taken at the beginning of a meal, snack or drink. Enzyme capsules should be swallowed whole.

e) PERT should not be crushed, chewed or sprinkled on food as this will reduce enzyme effectiveness, and may cause mucosal irritation in the mouth. If a patient cannot swallow the capsules, they can be opened and taken on a spoonful of fruit puree, jam or any soft cold food, followed by a drink to wash the granules down. The capsule should be opened, the contents put on the spoon of food and swallowed immediately, not left to stand. This should then be washed down with a cold/ room temperature drink to ensure that no granules remain in the mouth where they can cause ulcers. For further information please see Administration of Medicines to Adult Patients who cannot Swallow Solid Dosage Forms (Tablets or Capsules) Guideline B31/2008 – not sure this adds anything from looking at the. Could add discuss with pharmacist or dietitian for further support

f) Enzymes should be taken with a cold/ room temperature drink e.g. water.

g) There are certain foods and drinks that enzymes do not need to be taken with these include

- Fruit (except avocado) and dried fruit
- Vegetables (other than potatoes, beans and pulses)
- Sugary sweets: jelly babies, wine gums, marshmallows, fruit pastilles, chewing gum, mints
- Sugar, jam, honey, syrup
- Drinks that are less than half milk e.g. cup of tea, non-milky coffee
- Fruit juice, fizzy drinks, and squash
- Sorbet or fruit lolly's
- Small quantities of a food containing fat e.g. an individual piece of chocolate

h) Fat in the diet should not be restricted to control symptoms of malabsorption as this may exacerbate malnutrition (Taylor JR, 2010), and will result weight loss and micronutrient deficiency.

2.6 Administration Route: Enteral Feeding Tubes

a) People on PERT that are intubated, ventilated or NBM will be unable to swallow PERT capsules, therefore the PERT should be administered via the enteral feeding tube.

b) Semi-elemental (peptide) feeds require less PERT to achieve complete lipolysis than polymeric feeds123; therefore, peptide feeding is recommended for patients with PEI who are receiving enteral feeds.

c) If the patient can not have a peptide feed then Pancrex V powder is the preferred PERT to use when administering down a feeding tube (whilst the patient is feeding). It is not recommended to mix enzymes into feeds, which can coagulate.

d) If a patient is being bolus fed through an enteral feeding tube, PERT should be given immediately before the administration of bolus and if the bolus is taking longer than 30 minutes, then additional PERT can be given in the middle of the feed, as it would be with a meal or snack.

Table 4 Powdered enzymes and feeding tubes

Once mixed, use all products immediately. Do not leave to stand
Giving PERT as flushes: mix 1 g scoop pancreatin powder (Pancrex V Powder, Essential Pharmaceuticals, UK) with 50 mL sterile water. Shake well and immediately flush via a feeding tube. Do not give with other medication. Do not flush between the feed and the enzyme as this will reduce the mixing of the feed with the PERT. Administer every 2 hours hours throughout enteral feeding, increase dose of PERT if needed.

2.7 Dosing

a) Cystic Fibrosis

- In CF a guideline of 10,000units Lipase/kg/day and 2,500units Lipase/kg/meal is given, however sometimes it is necessary to exceed this to control symptoms of fat malabsorption.

- Doses above 2,500units lipase/kg/meal (or over 10,000units Lipase/kg/day) can be given but should be used with caution. Doses above 6,000units Lipase /kg of body weight per meal have been associated with mucosal irritation or fibrosing colonopathy (FC).

Table 5: Recommended starter dose for Cystic Fibrosis patients

	Adolescents and Adults
When to start PERT	Start Creon 10, 000 units or 25, 000 units with all food and fat containing drinks. Usually 3 meals plus 2-3 snacks/ day.
What dose to start on	3 - 5 Creon 10,000 units per meal 1 - 2 Creon 10, 000 units with fat containing snacks
IU Lipase per meal	500 units Lipase / kg /meal
Units of Lipase / g fat	10, 000 units Lipase per 4-10g fat.

Limit	10,000 units lipase per kg body weight

b) <u>Dosing in Pancreatic disease</u>

- For other pancreatic diseases (pancreatitis, pancreatic cancer patients) starting dose of Creon 50 000- 75000 units with meals and 25,000units with snacks and milky drinks or an equivalent preparation of Nutrizym 22 for example 44 000-66 000 units with meals and 22 000units with snacks and milky drinks.

- All pancreatic cancer patients diagnosed in UHL have access to Macmillan Senior Specialist Dietitian to manage their nutrition and PERT adjustments.

- Patients with other pancreatic conditions e.g. pancreatitis or other cancers resulting in a Whipples procedure e.g. ampulla or duodenal cancer/ benign lesion will need a referral to the Dietitian should they present with nutritional issues.

- The Hepatobiliary (HPB) Unit in Leicester General Hospital utilise a symptom tracker to monitor for signs of malabsorption and patients are encouraged to self-manage their symptoms and contact the Specialist Dietitian for further support.

- Some HPB centres routinely give a multivitamin and mineral supplement to all patients with PEI but there are no national guidelines for this. There can be significant consequences of micronutrient deficiencies including night blindness, osteopenia, reduced wound healing and immune function. It is at the discretion of the clinician whether to commence therapy.

- When PERT is commenced in a patient with pre-existing diabetes, blood glucose levels could rise and thus oral hypoglycaemic agents or insulin therapy may need to be adjusted accordingly.

- Starting enzymes in patients with severe symptoms may unmask diabetes, it is important to monitor blood glucose levels regularly and assess for symptoms of Type 3c Diabetes.

<u>Table 6: Recommended starter dose for adult patients with pancreatic disease &/or have undergone pancreatic surgery</u>

Creon 10 000®	• 4-5 capsules per meal e.g. 4-5 with lunch • 2-3 per snack, milky drink and oral nutritional supplements **(Please note Creon 10, 000 is only used for adults who struggle to swallow larger capsules)**
Creon 25 000®	• 2-3 per meal e.g. 2 with breakfast • 1-2 per snack, milky drinks & oral nutritional supplements
Nutrizym 22®	• 2-3 per meal • 1-2 per snack, milky drinks & oral nutritional supplements

2.8 Storage

Consent to keep the medication at bedside

a) If patients have the capacity and understand how and when to take PERT then the medication is safe to be left at the bedside. It is recommended that the staff on the ward should assess the patient and ascertain the apporpaiteness of the patient self administering it. The patient should indicate to the nurse when they have taken any so that it can be documented on Nerve Centre.

Chapter 9 section 9:10 has the information where this is allowed http://insitetogether.xuhl-tr.nhs.uk/pag/pagdocuments/Security%20and%20storage%20of%20medicines%20LMC%20Chapter%209.pdf

b) Do not store above 25º C. After opening use within 3 months. Keep container tightly closed in order to protect from moisture.

c) Avoid storage in direct sunlight, cars, near heat sources such as kettles, glove department, trouser pockets.

2.9 Monitoring a patient on PERT and adjusting doses

a) Adjustment of PERT dose is dependent on malabsorption symptoms being present. When assessing their efficacy you would check (where possible asking the patient): stool frequency, texture, colour, appearance, presence of oil/ greasy, floating/ difficult to flush, flatulence and abdominal pain. A change in these twice/three times in a week is enough to warrant an adjustment of PERT

b) It is also good to check for drugs that may mask symptoms including anti-diarrhoeals and opiates. As well as checking with patients that their PERT has not been left somewhere hot, eg a window sill, trouser pocket or in a car, and they are in date.

c)

Table 7: Monitoring for signs of continued malabsorption

Assess	Check	Why
Anthropometry	Weight loss	Fat malabsorption may lead to weight loss. Assess in relation to oral intake to ensure this hasn't reduced. Comparing energy intake to estimated requirements can be a helpful tool to check for malabsorption.
Biochemistry	Micronutrient deficiencies including Vitamin A, D, E and K levels	Micronutrient status can be a long-term aggregate marker of fat malabsorption. Consequences of fat soluble vitamin deficiencies include; night blindness; osteopenia; osteoporosis; reduced wound healing and immune function. For Cystic Fibrosis patients these are checked at their

		annual check up. *Please note micronutrients are not routinely screened for in pancreatic cancer and pancreatic disease due to the lack of robust evidence to support the need for doing so.
Clinical	Changes in stool frequency, texture, colour, appearance, presence of oil/ grease, floating/ difficult to flush, flatulence.	Presence of fat in stools is characterised by Steattorrhoea. ** Some patients will not have overt gastrointestinal signs of fat malabsorption, hence the reason for conducting the faecal elastase 1 test for a clinical diagnosis of PEI.
	Abdominal pain or bloating	
	Intestinal pH/ reflux	Gastric acidity can denature enzyme rending them ineffective. Medications to reduce pH may be required.
Dietary	Compliance with PERT, dose adjustment, timing of PERT administration.	
	Check the patient is not missing PERT with something they should be taking it with, e.g. snacks or milky drinks.	
	Check that PERT is taken with a cool drink to improve its efficacy.	
	If food is eaten over more than 30 minutes, split PERT between the start and the middle. Consider if this will reduce compliance or enjoyment of the meal.	
	A food and symptom diary can help the dietitian to identify dosing of PERT and fat content. Check compliance and whether the patient calculates a ratio or not, look for disparity in the amount of PERT given or the ratio across the day. Cystic Fibrosis patients will have a food diary completed each year at their annual review. It can also be a helpful educational tool.	
Education	Knowledge of fat content of commonly eaten foods.	
	Ability to identify high fat snacks and meals where additional PERT is required.	
	Knowledge of personal ratio of fat: PERT, they should be taking 10, 000units to 4-10g fat for Cystic Fibrosis patients	
	Knowledge of how many capsules to take with each meal should be checked.	

	Knowledge can be assessed as either: • How many capsules would normally be taken with a meal, snack or drink • How much fat a food contains depending on how they dose adjust their PERT
Environment	Check PERT has not been left somewhere hot, e.g. left near a radiator, window sill, oven, trouser pocket or in a car.
	Patients may have a number of pots open in different places, check they are all in date. Sometimes opening a new pot will resolve symptoms of fat malabsorption, if so, dispose of other open containers of PERT.
	To aid compliance, it may be helpful to provide an enzyme carrier case, for patients to carry smaller quantities of capsules around with them. The manufacturer can usually provide these.
Medications	Check that PERT is not being chewed, as this will reduce its efficacy and may cause mucosal breakdown of the mouth tissue.
	Check that capsules are not being opened and taken with food. The outer casing protects the enzymes for degradation in the acidic stomach.
	Consider a Proton Pump Inhibitor or H2 antagonists medications, as the increased acidity of the stomach can affect the duodenal pH. If the patient is already on one, check they are taking them regularly and if the dose can be maximised. A CF patient does not need to reach 10,000units Lipase/kg/day to be started on a PPI, or have their PPI dose increased. Many patients will benefit from this at a lower PERT dose.
	Children under 3 will take their PERT as an opened Creon 10000 capsule or Creon micro mixed in apple puree. As children approach the age of 3, they should be encouraged to practice swallowing of capsules. NB. PERT may be reduced and a PPI may no longer be required.
	Some antibiotic treatment can affect stool consistency. Ask about any recent changes, or patterns they've noticed with particular drugs.
	Check for medications/ drugs that may mask symptoms including anti-diarrhoeals, laxatives, steroids and opiates.
	Some patients will require loperamide or codeine to control their symptoms. Patients on high dose opiate pain killers may require laxatives.
	PERT doses should not be reduced to treat constipation.
	During hospital admissions, it is best if patients self-medicate as this enables the best timing of PERT administration with all meals, snacks

	and drinks.
	If on Creon 10, 000 and taking 2 or more for snacks and meals, consider a higher strength dose such as Creon 25, 000 to reduce burden of capsules taken at mealtimes. Ensure the dose of lipase remains the same.
	Consider supplementation of Vitamins A, D, E and K if serum levels are low. Interpret results alongside other signs of fat malabsorption, and consider poor compliance with vitamins. Fat Soluble Vitamins are routinely supplemented in CF and serum levels are checked annually. Some centres routinely give a multivitamin and mineral supplement to all patients with PEI but there are no national guidelines for this. Ref: Fat Soluble Vitamins in Adult Cystic Fibrosis UHL RRCV Guideline Trust Reference B36/2021

2.10. Monitoring an enterally fed PEI patient

a) In patients not taking oral PERT, If the patient is experiencing symptoms on the starting dose of 1g Pancrex V® powder every 2-4 hours, then the dose would be increased to 2g every 2-4 hours while feeding.

b) If after 48 hours on this dose the patient is still experiencing symptoms of insufficiency then the dose should be increased to 3g every 2-4 hours.

c) Note if a patient's feed rate is increased or they are changed to a more concentrated formula, their PERT dose may need to be increased in line with this. The dietitian could calculate the fat to PERT ratio in a well-tolerated feeding regime and maintain that ratio with a new regime as a guide to an increase in PERT dose. Consideration must also be made to protein and complex carbohydrate content.

2.11 Issues specific to pancreatic disease/ resection/ cancer patients

a) Should diarrhoea persist, despite optimal PERT, send a stool sample to exclude infective diarrhoea.

b) Add a proton pump inhibitor or H2 antagonist; this is routinely prescribed for patients who have undergone pancreatic surgery.

c) Consider use of anti-diarrhoeals to manage diarrhoea, should it continue despite optimal PERT.

d) If the patient has a blind loop (an area of bowel that food does not pass through) consider small intestinal bacterial overgrowth in the blind loop, considering cyclical antibiotics for the treatment of this.

e) Bile acid malabsorption should also be considered, particularly if the patient has had a recent cholecystectomy/ biliary reconstruction (proven via a SeHCAT test). After a definitive diagnosis of bile acid malabsorption, people can be treated with bile acid sequestrants that bind with bile acids in the small bowel, preventing the secretory action of bile acids into the colon

3. Education and Training

There are no skills per se that is required to implement this guideline; however it is important that prescribers are aware of the correct prescribing practices of PERT and those who administer the capsules are aware of the importance of doing so in a safe and correct manner. Joint training from dietetics and pharmacy is available for ward based teams.

4. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Appropriate prescribing of PERT doses in patients presenting with PEI	Audit prescribing practices of PERT in respective clinical areas. To include: a) Whether dose is correct and within safe limits, b) Whether the patient takes PERT correctly and c) Signs of malabsorption.	Ruth Boyce & Liz McKechnie	12 monthly	Trust Nutrition and Hydration assurance committee
ICE discharge letters	Audit of correct prescribing practices	Ruth Boyce & Liz McKechnie	6 monthly	Trust Nutrition and Hydration assurance committee
Patient Satisfaction	Audit patients perceptions of whether they feel they have a) maintained weight, b) have signs of malabsorption, 3) are confident with PERT dosing	Ruth Boyce & Liz McKechnie	Annually	Trust Nutrition and Hydration assurance committee

5. Patient Information leaflets

PERT patient information leaflet

https://yourhealth.leicestershospitals.nhs.uk/library/chuggs/hepatobiliary/420-advice-on-taking-enzyme-replacement-capsules/file

Track Your Symptoms

https://yourhealth.leicestershospitals.nhs.uk/library/chuggs/hepatobiliary/316-tracking-your-symptoms/file

6. Supporting documents and references

Administration of Medicines to Adult Patients who cannot Swallow Solid Dosage Forms (Tablets or Capsules) Guideline B31/2008.

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Fat Soluble Vitamins in Adult Cystic Fibrosis UHL RRCV Guideline Trust Reference B36/2021

Insertion and Management of Nasogastric and Orogastric Tubes in Adults Trust Ref B39/2005.

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7. Key Words

List of words, phrases that may be used by staff searching for the Policy on SharePoint

Pancreatic disease

Pancreatic enzyme replacement therapy (PERT)

Pancreatic cancer

Cystic fibrosis

Enteral feeding & PERT

Faecal elastase

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title) Liz McKechnie, Patient Safety Manager,Pharmacy Cathy Steele, Head of Service, Nutrition and Dietetics Ruth Boyce, Senior Specialist Dietitian (HPB and Pancreatic Cancer Care) Lydia Stevens, Senior Specialist CF Dietitian Nikki Stokes, Gastro-Surgical Dietitian Rachel Fox, Specialist Paediatric CF Dietitian	Executive Lead Medical Director
Details of Changes made during review: • Added in additional papers that have been published since the last review • Signposted to patient information leaflets to underpin the document • Adjusted the frequency of the audit times under section 'Monitoring Compliance' • Omitted medications no longer in stock e.g. Creon 40 000U • Made the PERT with enteral feeds more explanatory	