1. Gastro-intestinal system

Also see Appendix 1B Guidance on Management of Dyspepsia

Also see NICE CG184 Gastro-oesophageal reflux disease and dyspepsia in adults: investigation and management

Also see NICE CG17 - Dyspepsia – Management of Dyspepsia in Adults in Primary Care, August 2004
http://www.nice.org.uk/guidance/CG17

1.1 - Dyspepsia and gastro-oesophageal reflux disease

1.1.1 Antacids and simeticone

Aluminium- and magnesium-containing antacids

1st Choice Co-magaldrox (Mucogel®)

Prescribing Points

- Lifestyle changes are often required, such as raising the head of the bed, weight reduction, reduction of alcohol, smoking cessation and avoidance of aggravating foods.
- Antacids are suitable for mild indigestion and reflux.
- A mixture of aluminium hydroxide and magnesium hydroxide balances the tendency of aluminium to constipate against that of magnesium to cause diarrhoea.
- Liquid preparations are normally more effective than tablets and quicker acting.
- Antacids, taken at the same time as other drugs, may impair their absorption. They may also damage enteric coatings designed to prevent irritant drugs from dissolving in the stomach.
- Mucogel® has a low Na+ content (less than 1mmol of Na+ per tablet/10ml) and is sugar-free.
- There is no evidence that simeticone containing products like Infacol® are any more effective than placebo in reducing colic episodes.
- An unlicensed mixture containing antacid + oxetacaine (previously marketed as Mucaine®) is approved for use in patients presenting with mucositis after treatment with radiotherapy.

1.1.2 Compound alginates and proprietary indigestion preparations

1st Choice Peptac®

Child Gaviscon Infant® sachets

Prescribing Points

- Compound alginate preparations contain multiple ingredients; prescribe by brand name to avoid any confusion.
- Compound alginate preparations are less powerful antacids than aluminium/magnesium containing preparations but are more effective for reflux.
- Peptac® is the preferred choice in Fife as it is considerably cheaper than Gaviscon Advance®. Peptac® contains exactly the same ingredients as Gaviscon® original.
- Peptac® has a high sodium content (6.2mmol per 10ml dose) and should be used with care when salt restriction is important.
- All formulary choice liquid compound alginate preparations are sugar-free.
A dose of Gaviscon Infant® sachet is equivalent to half a dual sachet.

1.2 Antispasmodics and other drugs altering gut motility

Also see NICE CG 61 - Irritable Bowel Syndrome in Adults - Diagnosis and Management of Irritable Bowel Syndrome in Primary Care, February 2008 [Link](http://www.nice.org.uk/guidance/CG61)

<table>
<thead>
<tr>
<th>1st Choice</th>
<th>2nd Choice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mebeverine (standard tablets)</td>
<td>Hyoscine butylbromide</td>
</tr>
<tr>
<td>Peppermint oil</td>
<td></td>
</tr>
</tbody>
</table>

Prescribing Points

- Antispasmodics have limited effectiveness in the management of irritable bowel syndrome. They should be used in conjunction with other measures such as reassurance, diet, fluid intake, exercise, bulking agents and lifestyle modifications.
- Antimuscarinics relax the oesophageal sphincter and should be used with caution in patients with symptoms of reflux.
- Peppermint oil capsules should be reserved for patients presenting with symptoms of bloating.
- Peppermint oil capsules should not be chewed as they can cause irritation to mouth and/or oesophagus, causing symptoms of heartburn.

Motility stimulants

Prescribing Points

- Domperidone and metoclopramide are no longer recommended as motility stimulants. Licensed use is now restricted to short-term treatment of nausea and vomiting only (See section 4.6).
- Neither agent should be used for the treatment of bloating nor heartburn related symptoms as the benefits do not outweigh the risks.
- A trial withdrawal of motility stimulants should be considered in all patients who are being prescribed these drugs for an off-label use or in patients with contraindications. Patients should only be continued on long-term treatment after a discussion of risk:benefits. The discussion should be documented in the patient’s notes.
- Domperidone is associated with an increased risk of serious cardiac events especially in those aged over 60 or those who take more than 30mg daily. Domperidone should be only used for the shortest duration of time (normally no longer than 7 days) and the maximum licensed oral dose in adults is now 30mg daily. Domperidone is contraindicated in patients who are taking concomitant medication known to cause QT prolongation (such as erythromycin and ketoconazole), in patients with underlying cardiovascular disease or in conditions where cardiac conduction is, or could be, impaired and also in patients with severe hepatic impairment. (For further advice see MHRA Drug Safety Update, May 14. [Link](http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON418518))
- Due to the risk of neurological side-effects, metoclopramide is now only licensed for use in nausea and vomiting, the maximum duration of treatment is 5 days in all patients. For further advice, see MHRA Drug Safety Update, August 2013. [Link](http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON300404) 

KEY:-

| H | Hospital Use Only |
| S | Specialist Initiation or Recommendation |
| R | Restricted Use Only |

Fife Formulary  December 16
Last amended March 19
Domperidone Use In Paediatric Patients

- In children under 12 years of age and weighing less than 35kg, the recommended maximum dose in 24 hours is now 0.75mg/kg body weight (dose interval: 0.25mg/kg body weight up to three times a day).
- Domperidone does not have strong evidence of efficacy in the paediatric population but many patients, particularly those with gastrointestinal dysmotility, appear to benefit from its use.
- The pharmacological alternatives to domperidone in infants and children in particular are extremely limited.
- Children on long term domperidone should have regular review to assess ongoing need for treatment, establishing the minimum dose required and assessing risk factors for ongoing treatment (including any ECG changes and use of medications that can cause prolongation of QT). Domperidone should be used at the lowest effective dose for the shortest possible time.

1.3 - Antisecretory drugs and mucosal protectants

Also see Appendix 1B Guidance on Management of Dyspepsia

Also see Also see NI CE CG184 Gastro-oesophageal reflux disease and dyspepsia in adults: investigation and management

Also see NICE CG17 - Dyspepsia - Management of Dyspepsia in Adults in Primary Care, August 2004
http://www.nice.org.uk/guidance/CG17

1.3.1 H2-receptor antagonists

Prescribing Points

- H2-receptor antagonists are useful in functional dyspepsia and peptic ulcer treatment but of less value in NSAID gastroprotection and GORD.
- H2-receptor antagonists may be used at night along with a PPI as an adjunct in nocturnal reflux.

1.3.3 Chelates and complexes

Prescribing points

- Sucralfate may be initiated in secondary care for management of bleeding in large or complex peptic ulcers.

1.3.5 Proton Pump Inhibitors

Prescribing Points

KEY:

H - Hospital Use Only
S - Specialist Initiation or Recommendation
R - Restricted Use Only

Fife Formulary December 16
Last amended March 19
Lifestyle changes are often required, such as raising the head of the bed, weight reduction, reduction of alcohol, smoking cessation and avoidance of aggravating foods.

Proton pump inhibitors (PPIs) are indicated for gastro-oesophageal reflux disease, peptic ulcer disease, eradication of H. pylori and prophylaxis of NSAID-induced ulcers. There is little to choose between PPIs in terms of efficacy and NICE recommends that the cheapest PPI for a licensed indication should be used.

Patients should be regularly assessed and maintained on the lowest possible dosage of PPI. Those with GORD without oesophagitis are encouraged to use PPIs 'on demand'.

Maintenance therapy with PPIs may be indicated for patients with complications of reflux disease such as severe erosive ulceration, strictureing oesophagitis, Barrett's oesophagus, Zollinger-Ellison syndrome and laryngopharyngeal reflux or in the prophylaxis of NSAID induced peptic ulceration and may require long term treatment with full or high dose PPI.

PPIs are most effective when taken on an empty stomach, 20-30 minutes before food.

Treatment dose of lansoprazole is 30mg and maintenance dose is 15mg.

Treatment dose of omeprazole is 20-40mg and maintenance is 10-20mg.

In resistant cases, especially if nocturnal symptoms persist, split the dose of omeprazole i.e. 20mg twice daily rather than increasing to 40mg once daily. Patients with nocturnal symptoms on lansoprazole 30mg daily should be advised to take the lansoprazole at night time.

Patients unable to swallow oral formulations of PPIs should be prescribed either lansoprazole orodispersible tablets or omeprazole dispersible tablets (MUPS).

For paediatric patients unable to swallow solid oral formulations, omeprazole dispersible tablets (MUPS) are preferred. Esomeprazole granules may be used when omeprazole dispersible tablets (MUPS) are unsuitable e.g. patients unable to tolerate omeprazole MUPS; patients with a jejunal tube; nasogastric or gastrostomy tube fed children if there are issues with tube blockage with omeprazole MUPS.

Omeprazole suspension is non-formulary as it is unlicensed and is more expensive than dispersible formulations. Patients currently prescribed omeprazole suspension should be reviewed and switched to dispersible tablets or when appropriate esomeprazole granules (see above).

Formulary PPIs should be increased to the maximum tolerated licensed dose before considering a switch to alternative PPIs.

PPIs should be considered for prophylaxis against gastroduodenal damage by NSAIDs in all patients with risk factors – age >65, dyspepsia, history of peptic ulcer disease, concomitant steroids, aspirin, clopidogrel or SSRI antidepressants.

Due to a theoretical risk of an interaction. Patients taking clopidogrel should not be co-prescribed omeprazole/esomeprazole.

Long-term (>1 year) high-dose PPIs may be associated with increased fracture risk. Prescribers should advise patients and regularly review continued prescribing. Patients at risk of osteoporosis should be advised to maintain an adequate intake of calcium and vitamin D.

The use of PPIs is associated with an increased risk of infection with Clostridium difficile which can cause severe illness, particularly in those aged 65 and over and is also associated with an increased risk of Community Acquired Pneumonia.

Eradication of H. Pylori
Also see Appendix 1B Guidance on Management of Dyspepsia

Prescribing Points

- In the absence of alarm symptoms, current practice is to treat empirically or ‘test and treat’ all patients with suspected GORD or peptic ulcer disease.

The following eradication regimes are recommended - **all regimes are for 7 days.**

<table>
<thead>
<tr>
<th>1st Choice</th>
<th>2nd Choice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clarithromycin (500mg twice daily)</td>
<td>Metronidazole (400mg twice daily)</td>
</tr>
<tr>
<td>plus</td>
<td>plus</td>
</tr>
<tr>
<td>Amoxicillin (1 gram twice daily)</td>
<td>Clarithromycin (500mg twice daily)</td>
</tr>
<tr>
<td>Proton pump inhibitor*</td>
<td>Proton pump inhibitor*</td>
</tr>
</tbody>
</table>

* (Suitable for penicillin allergy)

<table>
<thead>
<tr>
<th>Alternatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metronidazole (400mg twice daily)</td>
</tr>
<tr>
<td>plus</td>
</tr>
<tr>
<td>Amoxicillin (1 gram twice daily)</td>
</tr>
<tr>
<td>plus</td>
</tr>
<tr>
<td>Proton pump inhibitor*</td>
</tr>
</tbody>
</table>

* If eradication fails then a second regime should be tried. If eradication still unsuccessful and symptoms persist, confirm compliance with therapy and consider referral for endoscopy and H. pylori culture and sensitivity.

1.4 Acute diarrhoea

**Oral Rehydration Therapy**

<table>
<thead>
<tr>
<th>1st Choice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dioralyte®</td>
</tr>
</tbody>
</table>

**Prescribing Points**

- First line treatment in acute diarrhoea is the correction of fluid and electrolyte imbalance.
- When indicated, send a stool sample in a standard blue topped container to microbiology. If norovirus is suspected and the patient is in hospital or institutional care, discuss with the infection control team or public health (respectively) and if necessary then also send a stool swab in Viral transport medium (Remel® test) for viral PCR.

**Antimotility drugs**

<table>
<thead>
<tr>
<th>1st Choice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loperamide</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2nd Choice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codeine</td>
</tr>
</tbody>
</table>

**Prescribing Points**

- Patients with blood or pus in stools, high fever, colitis or acute inflammatory bowel disease should not be prescribed antimotility drugs.
- In older patients, “overflow” diarrhoea can be the result of faecal impaction and this should be excluded before antimotility drugs are initiated.
- Antimotility drugs are not recommended for acute diarrhoea in young children.
- Bulk-forming drugs, such as ispaghula are useful in controlling faecal consistency in ileostomy and

**KEY:**

- **H** - Hospital Use Only
- **S** - Specialist Initiation or Recommendation
- **R** - Restricted Use Only

Fife Formulary December 16

Last amended March 19
colostomy patients, and in controlling diarrhoea associated with diverticular disease.

### 1.5 Chronic bowel disorders

Also see NICE CG 152 - Crohn's Disease, October 2012

[http://guidance.nice.org.uk/CG152/NICEGuidance/pdf/English](http://guidance.nice.org.uk/CG152/NICEGuidance/pdf/English)

Also see British Society of Gastroenterology Guidelines for the Management of Inflammatory Bowel Disease in Adults, 2010.


The choice of preparation depends on the site of the disease for both the oral and rectal preparations. For example, enemas may be used where areas up to the splenic flexure are involved, whereas suppositories are used where the distal rectum is involved.

#### 1.5.1 Aminosalicylates

**Systemic treatment**

<table>
<thead>
<tr>
<th>1st Choice</th>
<th>S - Mesalazine (Pentasa®)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>S - Mesalazine (Octasa®) [Not for new initiations only for patients currently on Asacol®]</td>
</tr>
</tbody>
</table>

**Prescribing Points**

- Mild disease affecting the proximal colon can be treated with an oral aminosalicylate alone; a combination of a local and an oral aminosalicylate can be used in proctitis or distal colitis.
- Several oral controlled release preparations of mesalazine are available. They are not interchangeable and therefore should always be prescribed by brand name due to differing sites of action. The NHS Fife Formulary choice is Pentasa®.
- The brand should be maintained as per instructions from initiating consultant.
- Sulfasalazine can be continued in established patients but should not be initiated in patients newly diagnosed with inflammatory bowel disease.

**Local treatment**

| S - Mesalazine suppositories (Salofalk®) |
| S - Mesalazine foam enema (Salofalk®) |
| S - Mesalazine retention enema (Salofalk®) |

**Prescribing Points**

**Local Treatment**

- Acute mild to moderate disease affecting the rectum (proctitis) or the recto-sigmoid is treated initially with local application of aminosalicylate. Alternatively if this is not tolerated or not effective, a local corticosteroid can be considered.

**KEY:**

- H - Hospital Use Only
- S - Specialist Initiation or Recommendation
- R - Restricted Use Only

Fife Formulary  December 16
Last amended March 19
A combination of a local and an oral aminosalicylate can be used in proctitis or distal colitis.

### 1.5.2 Corticosteroids

#### Systemic treatment

**1st Choice**  
S - Prednisolone (standard tablets)

**2nd Choice**  
S - Budesonide (Budenofalk®, Cortiment®)

### Prescribing Points

#### Systemic Treatment

- Corticosteroids may be administered rectally or orally to treat inflammatory bowel disorders.
- See section 6.3.2 for information on oral prednisolone.
- Due to the potential for erratic absorption from the gastrointestinal tract enteric coated tablets of prednisolone should be avoided.
- Budesonide oral capsules may be used for inducing remission in ileo-caecal Crohn’s disease and microscopic colitis but patients should be reviewed by a specialist before maintenance therapy is considered.
- The 9mg granule formulation of Budenofalk® is restricted to patients who have swallowing problems with the capsule formulation.
- Budenofalk® 3mg capsules may be used as a 2nd choice alternative to prednisolone tablets for the treatment of autoimmune hepatitis in non-cirrhotic patients who are intolerant of prednisolone due to severe corticosteroid related side-effects (actual or anticipated) such as psychosis, poorly controlled diabetes or osteoporosis. Hospital use only for this indication.
- Cortiment® 9mg tablets may be used for inducing remission in patients with mild to moderate ulcerative colitis (UC) where 5-ASA treatment is not sufficient.
- For patients on long term oral steroids, the risk of osteoporosis should be considered - see Appendix 6A appendix-6a-diagnosis-and-management-of-osteoporosis.aspx

#### Local treatment

S - Hydrocortisone foam enema (Colifoam®)

S - Prednisolone Enema (Predsol®)

S - Prednisolone Suppositories

### Prescribing Points

- Hydrocortisone is available as a foam preparation (Colifoam®) and prednisolone is available as a retention enema (Predsol®) or as suppositories.
- Rectal foam preparations are generally easier for patients to retain than retention enemas.
- Maintenance rectal therapy is an appropriate treatment strategy for rectal disease. Suppositories are the treatment of choice for patients with inflammation confined to the rectum, enemas are effective for disease extending to the splenic flexure.
- Some systemic absorption of steroid occurs from steroid foam enemas; prolonged use may lead to adrenal suppression and steroid side-effects.
- If the patient does not respond to local enema therapy, or presents with severe disease, systemic corticosteroids and specialist advice should be considered.

**KEY:-**

H - Hospital Use Only  
S - Specialist Initiation or Recommendation  
R - Restricted Use Only

Fife Formulary  
December 16  
Last amended March 19
Acute exacerbation of extensive disease requires systemic corticosteroids.

### 1.5.3 Drugs affecting the immune response

- **Also see NICE MTA 187 - Infliximab and adalimumab for the treatment of Crohn’s disease**
- **Also see NICE MTA 329 - Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy**
- **Also see NICE CG 152 - Crohn’s Disease Management, October 2012**

<table>
<thead>
<tr>
<th>H</th>
<th>Adalimumab (Amgevita®)</th>
</tr>
</thead>
<tbody>
<tr>
<td>H</td>
<td>Golimumab (Simponi®)</td>
</tr>
<tr>
<td>H</td>
<td>Infliximab (Inflectra®)</td>
</tr>
<tr>
<td>H</td>
<td>Ustekinumab (Stelara®)</td>
</tr>
<tr>
<td>H</td>
<td>Vedolizumab (Entyvio®)</td>
</tr>
</tbody>
</table>

**Prescribing Points**

- **Infliximab and adalimumab** are recommended as treatment options for adults with severe active Crohn’s disease whose disease has not responded to conventional therapy (including immunosuppressive and/or corticosteroid treatments), or who are intolerant of or have contraindications to conventional therapy. Choice of treatment should be on an individual basis. If more than one treatment option is suitable then the least expensive should be chosen (taking into account administration costs, dosage and price per dose).

- **Infliximab** is also recommended as a treatment option for people with active fistulising Crohn’s disease whose disease has not responded to conventional therapy (including antibiotics, drainage and immunosuppressive treatments), or who are intolerant of or have contraindications to conventional therapy.

- **Adalimumab, golimumab or infliximab** are recommended as treatment options for the treatment of moderately to severely active ulcerative colitis in adult patients whose disease has not responded to conventional therapy (including immunosuppressive and/or corticosteroid treatments), or who are intolerant of or have contraindications to conventional therapy. Choice of treatment should be on an individual basis. If more than one treatment option is suitable then the least expensive should be chosen (taking into account administration costs, dosage and price per dose).

- **Inflectra®** is a biosimilar formulation of infliximab. It is recommended in all new patients. To avoid confusion infliximab should be prescribed by generic and brand name.

- **Ustekinumab (Stelara®)** is approved for the treatment of adult patients with moderately to severely active Crohn’s disease who have had inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor alpha (TNFa) antagonist or have contraindications to such therapies.

- **Vedolizumab (Entyvio®)** is approved for restricted use in patients with moderately-severely active disease –
  - in patients with Crohn’s disease who have had an inadequate response with, lost response to, or were intolerant to a TNF-α antagonist.
  - in patients with ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNF-α antagonist.

- All the above drugs should be given as a planned course of treatment until treatment failure (including the need for surgery), or until 12 months after the start of treatment, whichever is shorter. The disease should be reassessed to determine whether ongoing treatment is still clinically appropriate. Patients
should be reassessed at least every 12 months.

- Disease modifying agents such as azathioprine, mercaptopurine and methotrexate may be used off-label in inflammatory bowel disease but should only be initiated by specialists.

### 1.6 - Laxatives

**Also see Appendix 1C - Management of Constipation in Adults**

[appendix-1c-constipation-in-adults.aspx](#)

#### Acute constipation

<table>
<thead>
<tr>
<th></th>
<th>1st Choice</th>
<th>2nd Choice</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bisacodyl</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Senna</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sodium picosulfate</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Glycerol suppositories</strong></td>
<td></td>
<td></td>
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</tbody>
</table>

**Prescribing Points**

- Bisacodyl, senna, sodium picosulfate and glycerol are all types of stimulant laxatives. They are suitable for short-term use in acute constipation as they resolve symptoms rapidly.
- Stimulant laxatives increase intestinal motility and often cause abdominal cramp. They should be avoided in intestinal obstruction and in the elderly in the presence of faecal impaction.
- Senna has an onset of action of 8-12 hours. It is particularly useful where a rapid effect is required or where stools are soft, but difficult to pass or the patient complains of inadequate emptying.
- Glycerol suppositories have a rapid effect (15-30 mins.) and can be used for hard or soft stools. They are suitable for acute moderate-to-severe constipation.
- Long-term use of stimulant laxatives is not recommended other than for the treatment of opioid induced constipation.

#### Chronic constipation

**Bulk-forming laxative**

<table>
<thead>
<tr>
<th></th>
<th>1st Choice</th>
<th>2nd Choice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ispaghula Husk (Ispagel®, Regulan®)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methylcellulose (Celevac®)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Osmotic laxative**

<table>
<thead>
<tr>
<th></th>
<th>1st Choice</th>
<th>2nd Choice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macrogols (Laxido®, Laxido® Paediatric, Cosmocol®-Plain, Cosmocol®-Half)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Lactulose</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Prescribing Points**

**Bulk-forming laxatives**

- Bulk-forming laxatives take several days to work and are useful in chronic, simple constipation.
- They should not be taken immediately before bed and adequate fluid intake is important, to prevent intestinal obstruction especially in the elderly.
- Suitable for adults and children over 6 years.
- Bulk forming laxatives should be avoided in opioid induced constipation and in patients with faecal impaction.

**Osmotic Laxatives**

- May take 48 hours to act and are not suitable for use on a ‘when required’ basis.
- Laxido® produces less flatulence than lactulose and may be used in faecal impaction.
- Lactulose is relatively expensive and is frequently prescribed inappropriately. Lactulose should not be used routinely in the elderly and should be avoided if the stool is already soft.

**Opioid induced constipation**

<table>
<thead>
<tr>
<th>1st Choice</th>
<th>2nd Choice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bisacodyl + Docusate sodium</td>
<td>Senna + Docusate sodium</td>
</tr>
</tbody>
</table>

**Prescribing Points**

- Laxatives are of value for prophylaxis of opioid-induced constipation, a combination of a stimulant and a stool softener laxative should be used. Bulk-forming laxatives should be avoided.
- Docusate sodium is approved for restricted use in addition to a stimulant laxative for the prevention of opioid-induced constipation.

**Palliative Care**

**Prescribing Points**

- For Laxative use in palliative care please refer to the national palliative care guidelines. [http://www.palliativecareguidelines.scot.nhs.uk/](http://www.palliativecareguidelines.scot.nhs.uk/)
- Co-danthramer and co-danthrusate are restricted to use in terminal care due to concerns about possible carcinogenicity.
- Patients should be warned that they discolour urine red (occasionally blue or green) and that prolonged contact with the skin (e.g. faecal or urinary incontinence) can cause a dantron burn - an erythematous rash with a sharply demarcated border.

**Enemas**

<table>
<thead>
<tr>
<th>1st Choice</th>
<th>2nd Choice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium citrate</td>
<td>Phosphates (Fletchers®)</td>
</tr>
</tbody>
</table>

**Prescribing Points**

- Rectal enemas are licensed for occasional use only.
- In general, enemas should be reserved for pre-operative bowel clearance and for the treatment of impacted faeces if response to oral laxatives or suppositories is insufficient.
- Enemas are routinely used in patients with hepatic failure.

**1.6.5 Bowel cleansing preparations**


**KEY:-**

- H - Hospital Use Only
- S - Specialist Initiation or Recommendation
- R - Restricted Use Only

Fife Formulary

December 16

Last amended March 19
1st Choice  |  H - Macrogols (Moviprep®)
2nd Choice  |  H - Sodium picosulfate (Picolax®)

Prescribing Points

- Bowel cleansing products are used before colonic surgery, colonoscopy or radiological examination of the bowel. Choice of preparation should be guided by advice from the specialist area performing the procedure.
- Patients should be advised to follow carefully the instructions provided.

1.6.6  Peripheral opioid-receptor antagonists

S - MethylNaltrexone (Relistor®)

Prescribing Points

- Use is restricted to the treatment of opioid-induced constipation in advanced illness patients who are receiving palliative care when response to usual laxative therapy has not been sufficient.

1.6.7  Other drugs used in Constipation

R - Linaclotide (Constella®)

Prescribing Points

- R - Linaclotide is approved for restricted 3rd line use only, for the symptomatic treatment of moderate to severe irritable bowel syndrome with constipation in adults who have not responded adequately to or cannot tolerate all other suitable treatment options (antispasmodics, laxatives and off-label antidepressants). Specialist initiation only. Patients should be reviewed after 4 weeks of treatment by a specialist to determine clinical benefit. Prescribing may be transferred to primary care at this stage if ongoing treatment is considered beneficial.
- Prucalopride (Resolor®) and lubriprostone (Amitiza®) are not recommended by the Scottish Medicines Consortium (SMC). They should not be prescribed unless a Peer Approved Clinical System (PACS2) Request Form has been approved by NHS Fife.
- Prucalopride (Resolor®) is only licensed for the symptomatic treatment of chronic constipation in women in whom other laxatives fail to provide an adequate response.

1.7  Local preparations for anal and rectal disorders

1.7.1  Soothing haemorrhoidal preparations

1st Choice  |  Anusol®

Prescribing Points

- Suppositories are suitable for internal haemorrhoids whereas creams and ointments are suitable for external haemorrhoids.

1.7.2  Compound haemorrhoidal preparations with corticosteroids

1st Choice  |  Anusol HC®
2nd Choice  |  Scheriproct®

Prescribing Points

KEY:
H - Hospital Use Only
S - Specialist Initiation or Recommendation
R - Restricted Use Only
After exclusion of infections, compound products are suitable for occasional short-term use (up to 7 days) in patients with severe symptoms. Prolonged use can cause atrophy of the anal skin, contact dermatitis and skin sensitisation.

Suppositories are suitable for internal haemorrhoids whereas creams and ointments are suitable for external haemorrhoids.

1.7.3 Rectal sclerosants

Prescribing Points

- This product is used by specialists to inject unprolapsed haemorrhoids.

1.7.4 Management of Anal Fissures

Prescribing Points

- Management of anal fissures requires stool softening by dietary fibre (bran) or bulk-forming laxative.
- Short-term use of local anaesthetics e.g. lidocaine may help. If these measures are inadequate, hospital referral should be considered.
- Diltiazem 2% cream or ointment is available as an unlicensed product from a ‘Specials’ manufacturer.
- Glyceryl trinitrate 0.4% ointment (Rectogesic®) is the only licensed product available for treatment of anal fissures but it has been classed as ‘Not recommended’ by SMC. Rectogesic® should not be prescribed in new patients unless a Peer Approved Clinical System (PACS2) Request Form has been approved by NHS Fife.

1.9 Drugs affecting intestinal secretions

1.9.1 Drugs affecting biliary composition and flow

Prescribing Points

- Ursodeoxycholic acid is restricted to use on the advice of consultant gastroenterologists for treatment of primary biliary cirrhosis and sclerosing cholangitis.
- Obeticholic acid is restricted to use on the advice of consultant gastroenterologists for the treatment of primary biliary cholangitis (cirrhosis) in combination with ursodeoxycholic acid in adults with an inadequate response to ursodeoxycholic acid or as monotherapy in adults unable to tolerate ursodeoxycholic acid.

1.9.2 Bile acid sequestrants

See NHS Fife Gastroenterology Colesevelam Protocol

Prescribing Points

- Colestyramine

KEY:

H - Hospital Use Only
S - Specialist Initiation or Recommendation
R - Restricted Use Only

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Prescribing Points

- Colestyramine may be used to treat pruritus associated with biliary obstruction.
- Colestyramine may also be used for diarrhoea caused by bile acid malabsorption.
- Colesevelam (Cholestagel®) should be initiated by consultant gastroenterologists only, for patients experiencing diarrhoea caused by bile acid malabsorption who are unable to tolerate colestyramine due to adverse drug reactions or formulation issues.

### 1.9.4 Pancreatin

<table>
<thead>
<tr>
<th>1st Choice</th>
<th>2nd Choice</th>
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<tbody>
<tr>
<td>Creon®</td>
<td>Pancrex V®</td>
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</table>

Prescribing Points

- There is great variation in patient response to pancreatin products. Fat malabsorption has the most bearing on the clinical picture. Theoretically 60,000 BPU of lipase should enable a completely achylic patient to digest the fat in a normal meal; the quantity of protease and amylase that comes with this dose of lipase is more than sufficient to digest the protein and carbohydrate.
- Doses are adjusted to individual patient requirements and often this is by gradually increasing the dose.
- Creon Micro® is restricted to use in young cystic fibrosis sufferers who are unable to swallow capsules.
- If a patient on any pancreatin preparation develops new abdominal symptoms (or any change in existing abdominal symptoms) the patient should be reviewed to exclude the possibility of colonic damage.
- Ensure adequate hydration at all times in patients taking higher-strength pancreatin preparations.
- Pancreatin is inactivated by gastric acid and so high doses are required. Adding an antisecretory drug, such as an H2-receptor antagonist or PPI, may help patients unresponsive to high doses of pancreatin.
- Pancreatin is inactivated by heat and so care is needed if preparations are mixed with food or drink.

**KEY:**

- **H** - Hospital Use Only
- **S** - Specialist Initiation or Recommendation
- **R** - Restricted Use Only

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_Last amended March 19_