CHAPTER 1: GASTRO-INTESTINAL SYSTEM
Updated: January 2024

The following prescribing guidelines are relevant to the gastro-intestinal system chapter and can be found here

- Bile Salt Diarrhoea/Malabsorption: Alternatives to Questran/cholestyramine
- Constipation guidelines – Prucalopride
- Gastro-Oesophageal Reflux Disease (GORD) & dyspepsia in adults
- Gastro-Oesophageal Reflux Disease (GORD) in children & young people
- Irritable Bowel Syndrome – Primary care management of IBS
- Proton Pump Inhibitors (when to initiate with a NSAID or antiplatelet)

Relevant Resources:

- NHS England » Constipation and people with a learning disability

1.1 DYSPEPSIA & GORD

1.1.1 Antacids & simeticone

For treatments of minor self-limiting conditions such as infant colic, indigestion and heartburn, self-care including lifestyle changes is encouraged. Treatments such as antacids are available to purchase over-the-counter.

Mucogel (co-magaldrox 195mg/220mg/5ml) suspension *Low Na^+, sugar free*

1. *For Self-treatment* with an antacid and/or alginate may be used for short-term symptom control, but long-term, continuous use is not recommended.
2. Regular dosage can relieve dyspepsia, the pain of gastric ulcer, and gastritis.
3. Low Na^+ indicates a sodium content of less than 1mmol per 10mL dose and are suitable for the majority of patients including those with cardiac or hepatic failure.
4. Co-magaldrox (Mucogel) is used in patients with chronic magnesium loss or asymptomatic moderately severe hypomagnesaemia (Derbyshire shared care pathology- calcium and bone section)
5. Simeticone alone (Dentinox, Infacol) – there are no data available on its effectiveness for infant colic. JAPC has classified as **Do Not Prescribe (DNP).**
6. Colief infant drops (**GREY**) is classed as a borderline substance. It can only be prescribed for the relief of symptoms associated with lactose intolerance, provided that lactose intolerance is confirmed by the presence of reducing substances and/or excessive acid in stools, a low concentration of the corresponding disaccharide enzyme on intestinal biopsy or by breath hydrogen test or lactose intolerance test. The prescription should be endorsed 'ACBS'.

1.1.2 Alginates

Peptac sugar free suspension *1st line*
Acidex Advance suspension *lower Na^+concentration than Peptac*

1. Alginic acid preparations are specifically indicated for the alleviation of symptoms arising from gastric reflux and have low acid neutralising capacity.
2. Acidex Advance has a higher alginate content with lower (2.55mmol/5ml) sodium concentration than Peptac (3.1mmol/5ml) and is a cost-effective alternative to Gaviscon Advance.
3. Gaviscon advance **Grey** - use by exception only after formulary choice Acidex advance is thought to be inappropriate due intolerance or inadequate symptom control. Not to be routinely used as first-line choice. GP can prescribe Acidex advance if specialist has prescribed Gaviscon advance for severe reflux e.g. laryngopharyngeal reflux, however, if symptoms persist or intolerance then patients should be switched back to Gaviscon Advance for minimum of 3 months prior to re-referral.

1.2 ANTISPASMODICS AND OTHER DRUGS ALTERING GUT MOTILITY

See primary care management of IBS- treatment should be based on predominant symptoms.

Mebeverine 135mg tabs *1st line antispasmodic for IBS*
Hyoscine butylbromide 10mg tablets
Peppermint oil 0.2ml gastro-resistant capsules

1. A statement from PHE and NHSE has been issued to raise awareness of the misuse of hyoscine butylbromide (Buscopan) in HM prisons.
2. Dicycloverine has been classified as **Do Not Prescribe (DNP)**. Use alternatives formulary items above.
3. Eluxadoline is **RED** as per NICE TA471 for treating irritable bowel syndrome with diarrhoea. Not to be used in patients who have undergone cholecystectomy or in those with biliary disorders due to risk of pancreatitis. MHRA December 2017.

Motility Stimulants
Metoclopramide 10mg tabs
Domperidone 10mg tabs

1. Metoclopramide – MHRA Dec 2014 risk of neurological adverse effect:
   - In adults, metoclopramide remains indicated for prevention of postoperative/ radiotherapy-induced/ delayed chemotherapy-induced nausea and vomiting (N&V) and symptomatic treatment of N&V including that associated with acute migraine (where it may also be used to improve absorption of oral analgesics). The maximum dose in 24 hours is 30mg (or 0.5mg per kg for patients up to 60kg bodyweight). The usual dose is 10mg three times a day and should only be prescribed for short-term use (up to 5 days)
   - in children aged 1–18 years, metoclopramide should only be used as a 2nd line option for short-term use (up to 5 days) for prevention of delayed chemotherapy-induced N&V, and for treatment of established postoperative N&V.
   - Use of metoclopramide is contraindicated in children younger than 1 year.
   - Off label use of metoclopramide is recognised as standard practice in palliative medicine. JAPC recognises that long term use of metoclopramide may be appropriate in some palliative care patients when given orally/parentally
2. Domperidone – MHRA April 2014 risk of cardiac side effects:
   - Domperidone may be associated with a small increased risk of serious ventricular arrhythmia or sudden cardiac death. These risks may be higher in patients older than 60 years and in patients who receive daily oral doses of more than 30 mg.
   - For adults, the maximum dose in 24 hours is 30mg. Usually, the maximum treatment duration should not exceed one week.
   - Domperidone is preferred in patients where the risk of dystonic reactions is high i.e. young women, children, the elderly, and those with Parkinson's disease.
3. MHRA December 2019 - Domperidone for nausea and vomiting is no longer licensed for children under 12 years of age due to lack of efficacy. Where it is used outside of its authorised indications in children for gastro-kinetic effects in conditions other than nausea and vomiting, specialist input is required.
4. For use in gastroparesis and other gastric outlet physiological impairment, metoclopramide and domperidone are classified as **GREY** after specialist initiation – see the Derbyshire JAPC position statement (Domperidone off licence use; metoclopramide use in gastro-paresis)

1.3 ANTISECRETORY DRUGS & MUCOSAL PROTECTANTS

See Dyspepsia & GORD guideline (includes H. pylori eradication regimes). For the management of un-investigated dyspepsia use clinical judgement to offer either H. pylori "test-and-treat" or full dose PPI for one month.

1.3.1 H_2-antagonists (H2RA)

JAPC has classified ranitidine **GREY** (May 2020) as per EMA's human medicines committee (CHMP) recommendation to suspend all ranitidine medicines in the EU due to the presence of low levels of an impurity called N-nitrosodimethylamine (NDMA).

Existing patients prescribed oral ranitidine should be reviewed to establish if ongoing treatment is still required, and to consider switching to an PPI where clinically appropriate. If a PPI was unsuitable then an alternative H2RA may be considered.

There are ongoing supply disruptions for ranitidine and all other H2RAs. JAPC advises the types of patients who may require an alternative H2RA to ranitidine include:

1. those needing acid suppression who are genuinely allergic or intolerant or contraindicated to all PPIs, which is rare;
2. those needing acid suppression where low magnesium occurs, which is felt as very rare;
3. those who have needed upward titration for reflux symptoms despite high dose PPIs, where addition of H2RA, generally at night time, helps*.
4. occasionally there seems to be a small number who claim not to do well on PPI yet symptomatically get better on H2RA.

** Patients suitable for antireflux procedures should be referred at this point, but generally the H2RA+PPI combination is used for those not suitable for or who would not do well with antireflux surgery (e.g. elderly frail, or those where there is a functional element to symptoms). Patient may be advised to go back to PPI+ antacid.*

For all cases, those not responding well to PPIs should be investigated to make sure diagnosis correct e.g. to rule out bile reflux, functional pain etc. No particular problems should arise with stopping H2RA as the rebound hyper acid phase tends not to occur (compared to PPIs).

Alternative H2RA- **Grey**. H2RAs cost significantly more than PPIs. Check caution e.g. renal impairment and interactions. e.g. azol antifungals, protease inhibitors.

Drug	Standard Dose
Cimetidine**	400mg twice a day
Nizatidine	150mg twice a day
Famotidine	20mg twice a day

***CKS does not recommend cimetidine for treatment of GORD as there is a higher risk of drug interactions, due to inhibition of cytochrome P450 enzymes.*

1.3.3 Chelates and complexes

1. Sucralfate is **GREY** after consultant/specialist recommendation for empirical management of patients with severe GORD, or post-cholecystectomy, alongside use of PPIs. Sucralfate enema is **RED**.
2. Sucralfate liquid is licensed and the tablets are special order.

1.3.5 Proton pump inhibitors

Lansoprazole caps 15mg, 30mg *Orodispersible for patients with swallowing difficulties/PEG tubes*
Omeprazole caps 10mg, 20mg

1. The dose of proton pump inhibitor (PPI) should always be reduced to the appropriate maintenance dose where possible.
2. Prescribing on an 'as required' basis should be considered for patients with intermittent symptoms.
3. The use of lansoprazole orodispersible should be restricted to those patients with genuine swallowing difficulties or with PEG tubes. Omeprazole dispersible gastro-resistant tablets (MUPs) are not recommended except for the management of GORD in children (see Guideline).
4. Omeprazole GR capsules may be suitable for patients with swallowing difficulties. Open capsule and swallow the contents with half a glass of water or after mixing the contents in a slightly acidic fluid e.g. fruit juice or applesauce, or in non-carbonated water, take immediately (or within 30minutes) and rinsed down with half a glass of water. Alternatively, suck the capsule and swallow the pellets with half a glass of water. The enteric-coated pellets must not be chewed.
5. Esomeprazole is **GREY** restricted after the use of formulary PPIs.
6. A PPI and clopidogrel given concurrently may interact, resulting in reduced effectiveness of the clopidogrel (see MHRA April 2010). This is the agreed advice, which is supported by cardiologists at Chesterfield and Derby:
   a. Is gastroprotection actually required i.e. is the patient at high risk of bleeding e.g. history of GI tract bleeding?
   b. If a PPI is required lansoprazole or pantoprazole are preferred options. Alternatively consider a H2 antagonist (off-label).

See **PPI guidance** on when to initiate a PPI with an NSAID (or antiplatelet). For gastroprotection, lansoprazole 15mg daily is the 1st line choice. To aid bioavailability of lansoprazole it should be taken 30 minutes before food.

Known risks associated with long term PPI use: *Clostridium difficile* infection, osteoporotic fractures.
Other adverse effects associated with PPI: hypomagnesaemia, pneumonia, rebound hypersecretion, Tubulo-interstitial nephritis (TIN).

1.4 ACUTE DIARRHOEA

NB. fluid and electrolyte replacement ***first line***

For treatments of minor, short-term medical conditions such as diarrhoea (adults) patients are encouraged to self-care. Treatments are available to purchase over-the-counter e.g. loperamide, rehydration sachets.

1.4.2 Antimotility drugs

Loperamide 2mg caps

1. Codeine phosphate is listed in BNF as an antimotility drug for the treatment of diarrhoea. Be aware of risk of drug dependence and addiction. See MHRA Sept 2020 Opioids: risk of dependence and addiction; MHRA March 2020 Benzodiazepines and opioids: reminder of risk of potentially fatal respiratory depression.
2. The bulk forming laxatives Ispaghula husk may be reconstituted with minimum fluid volume to control diarrhoea and also to provide ileostomy and colostomy control.

1.5 CHRONIC BOWEL DISORDERS

NB not for GP initiation

1.5.1 Aminosalicylates

Sulfasalazine (Salazopyrin) is **AMBER** *see shared care guideline*
Tablets 500mg (licenced for ulcerative colitis and crohn's disease)
e/c (gastro-resistant) tablets 500mg (licenced for UC, crohn's disease and for rheumatoid arthritis)

1. Despite theoretical advantages, there is little clear evidence that the newer aminosalicylates are more effective than sulfasalazine, although they may cause slightly fewer adverse effects. If a patient is receiving sulfasalazine and this is well tolerated it should be continued.

Mesalazine is **GREEN** after specialist initiation- initiated by secondary care and requires continued monitoring in primary care. **Prescribe by brand**. See prescribing notes below.
Balsalazide is **GREEN** alternative after specialist initiation – initiated by secondary care for patients who are unresponsive to mesalazine, and requires continued monitoring in primary care.

1. The choice of aminosalicylate should be driven by patient preference and cost.
2. There is no evidence to show that any one oral preparation of mesalazine is more effective than another. However, the delivery characteristics of oral mesalazine preparations may vary.
3. If it is necessary to switch a patient to a different brand of mesalazine, the patient should be advised to report any changes in symptoms. Asacol MR and Octasa, however, are virtually identical and are interchangeable. Octasa MR 400mg, 800mg; Pentasa 500mg, 1g; Salofalk MR 250mg, 500mg are cost effective oral options. see SPS 'difference in oral tablet mesalazine preparations and considerations when switching' for further information
4. Monitoring information (For formulations other than tablets/capsules see individual SPCs)

Drug	Notes
Mesalazine	Monitoring for mesalazine may vary between products and brands- consider individual SPC. SPS Medicines monitoring tool recommends ongoing monitoring once stable- FBC, LFT, U&E, urine dipstick 6-12 monthly depending on risk factors.
Balsalazide	Monitor renal function (serum creatinine) prior to starting treatment and at 3 months then annually thereafter.
Olsalazine	Monitor renal function (serum creatinine) prior to starting treatment, every 3 months for the first year, every 6 months for the next 4 years, and annually after 5 years of treatment.

1.5.2 Corticosteroids

Prednisolone 20mg/100ml retention enemas
Budesonide 2mg foam enema, 2mg/100ml enema

1. Budesonide modified release oral preparations have been classified as **GREY** after consultant gastroenterologist initiation. Long-term maintenance with low dose (off-label) may be required in exceptional circumstances e.g. autoimmune hepatitis, microscopic colitis.
2. Beclometasone (Clipper) 5mg modified-release tablets have been classified as **RED** as an adjunct to aminosalicylates in acute mild to moderate ulcerative colitis.
3. Advise patients to report any blurred vision or other visual disturbances due to rare risk of central serous chorioretinopathy with corticosteroids (MHRA August 2017).
4. VSL#3 is classified locally as **Do Not Prescribe (DNP)** (February 2019)
5. Prednisolone foam enemas is **Do Not Prescribe (DNP)** significantly more expensive than similar treatment options e.g. budesonide foam enema.

1.5.3 Drugs affecting the immune response

The following drugs are **AMBER** i.e. may be prescribed by GPs under a shared care agreement. Shared care guidelines are available here

Azathioprine
Ciclosporin *Prescribe by brand*
Mercaptopurine
Methotrexate *Prescribe injection (North Derbyshire only) by brand (e.g. Metoject)*

- North Derbyshire – oral, subcutaneous and intramuscular injection preparations
- Southern Derbyshire –injection is RED; oral preparations only.

1. Methotrexate is normally given as a weekly dose. It is good practice to state the day of the week on the prescription and to give the dose as number of tablets and mgs e.g. 4 tablets (10mg). See MHRA Sept 2020
2. Folic acid is usually given to reduce the possibility of methotrexate toxicity at a dose of 5mg each week, on a different day to methotrexate, preferably the day after the methotrexate.
3. In North Derbyshire, for methotrexate injections, prescribing the purple-lidded cytotoxic waste bins (FP10) and accepting the full bins back will be the responsibility of the practice from 1st April 2023.

1.6 LAXATIVES

NB dietary and lifestyle modification first line- *see appendix 1*.
For treatments of minor short-term conditions such as infrequent constipation patients are encouraged to self-care.

MHRA August 2020. Constipation can be effectively managed with a change in diet or lifestyle (such as increasing dietary fibre, fluid intake, and activity levels), and short-term use of over-the-counter laxatives. Advise patients that if symptoms of constipation persist after dietary and lifestyle changes and short-term laxative treatment (under the advice of pharmacist), or in case of persistent abdominal pain or passing blood, consult a doctor.

Usually a bulk-forming laxative would be used first, followed by an osmotic laxative in addition to, or instead of, a bulk-forming laxative. If these are not effective, then a stimulant laxative may be added in addition to a bulk-forming laxative. All of these laxatives are available as over-the-counter medicines and should only be taken occasionally.

1.6.1 Bulk forming agents

Ispaghula husk 3.5g sachet

1. Avoid using bulk-forming laxatives for opioid-induced constipation as their mode of action is to distend the colon and stimulate peristalsis, but opioids prevent the colon responding with propulsive action. This may cause abdominal colic and rarely bowel obstruction.

1.6.2 Stimulant laxatives

Bisacodyl tablets 5mg, suppository 10mg

Senna tablets/liquid
Docusate sodium caps 100mg, solution 50mg/5ml, 12.5mg/5ml
Glycerol suppositories *infants 1g, children 2g, adults 4g*

1. MHRA August 2020 Stimulant laxatives should only be used if other laxatives (bulk-forming and osmotic) are ineffective. Children younger than 12 years should not use stimulant laxatives without advice from a prescriber and clinical guidance (NICE CG99 Constipation in children and young people) should be followed.
2. Dantron-containing laxatives have a limited indication because *rodent* studies indicate potential carcinogenic risk. Co-danthramer and Co-danthrusate should only be used in terminally ill patients. They are expensive.

1.6.3 Faecal softeners

1. Docusate sodium also has stool-softening properties.

1.6.4 Osmotic Laxatives

Lactulose solution
Macrogol compound oral powder sachets SF *1st line for faecal impaction*
Sodium citrate micro enemas (Relaxit)

1. Lactulose and macrogol compound oral powders are not suitable for rapid relief of constipation. It can be up to three days before an effect is seen. Regular dosing is required for full effect.
2. NICE CG61 recommends laxatives should be considered for the treatment of constipation in patients with irritable bowel syndrome, but patients should be **discouraged** from taking lactulose.
3. Macrogol compound oral powder is licensed for patients aged 12 and above. For children aged 2 – 11 years use Laxido Paediatric as per SPC.
4. When macrogol compound oral powder is used for faecal impaction treatment should be for no longer than 3 days.
5. Phosphate enema is **GREY**. It should be administered with caution to patients with renal impairment. Cleen ready-to-use enema is the preferred cost effective choice.
6. Macrogol 3350 (Transisoft) and Movicol Ready To Take are classified as Do Not Prescribe (DNP).

1.6.5 Bowel cleansing preparations

See University Hospital of Derby and Burton guideline for bowel prep for GI endoscopy.

1.6.6 Peripheral opioid-receptor antagonists

Naloxegol (NICE TA345) is classified as **GREY** consultant/specialist initiation and stabilisation for 3 months for treating opioid induced constipation in palliative care patients.

1.6.7 $5HT_4$-receptor agonist and guanylate cyclase-C receptor agonists

1. Prucalopride (NICE TA211) has been classified as **GREY** after gastroenterology consultant/specialist initiation – for frequency of reviews see Refractory Symptomatic Chronic Constipation guideline.
2. Linaclotide has been re-classified as **GREY** after gastro-consultant initiation and assessment of efficacy within a 4 week period for severe irritable bowel syndrome with constipation in adults. See IBS guideline

1.7 LOCAL PREPARATIONS FOR ANAL AND RECTAL DISORDERS

1.7.1 Soothing haemorrhoidal preparations

For treatments of minor self-limiting conditions such as haemorrhoids, patients are encouraged to self-care. Treatments are available to purchase over-the-counter.

Anusol (available OTC) cream, ointment, suppositories

1. Bland preparations such as “Anusol” are safe and inexpensive and may help relieve pruritus and soreness.

1.7.2 Compound haemorrhoidal preparations with corticosteroids

Anusol-HC ointment, suppositories (Anusol HC plus available OTC)
Scheriproct ointment, suppositories
Xyloproct ointment

1. Topical corticosteroids can be used to relieve inflammation but should not be used in the presence of untreated local infection.
2. Prolonged use should be avoided – "Anusol HC" limited to 7 days.

1.7.3 Management of anal fissures

Glyceryl trinitrate 0.4% ointment

1. Topical diltiazem hydrochloride 2% ointment may be used twice daily (unlicensed preparation, included in Drug Tariff Part VIIIB) in patients with chronic anal fissures unresponsive to topical nitrates.

1.9 DRUGS AFFECTING INTESTINAL SECRETIONS

NB not for GP initiation

1.9.1 Drugs affecting biliary composition and flow

Ursodeoxycholic acid tablets 150mg, 250mg, 300mg

1. For the oral Ursodeoxycholic acid 250mg preparation, tablets and capsules are available. Check current Drug Tariff price before prescribing. 300mg strength tablets are less cost-effective.

1.9.2 Bile acid sequestrants

Colestyramine 4g sachets *see Familial Hypercholesterolaemia guideline*

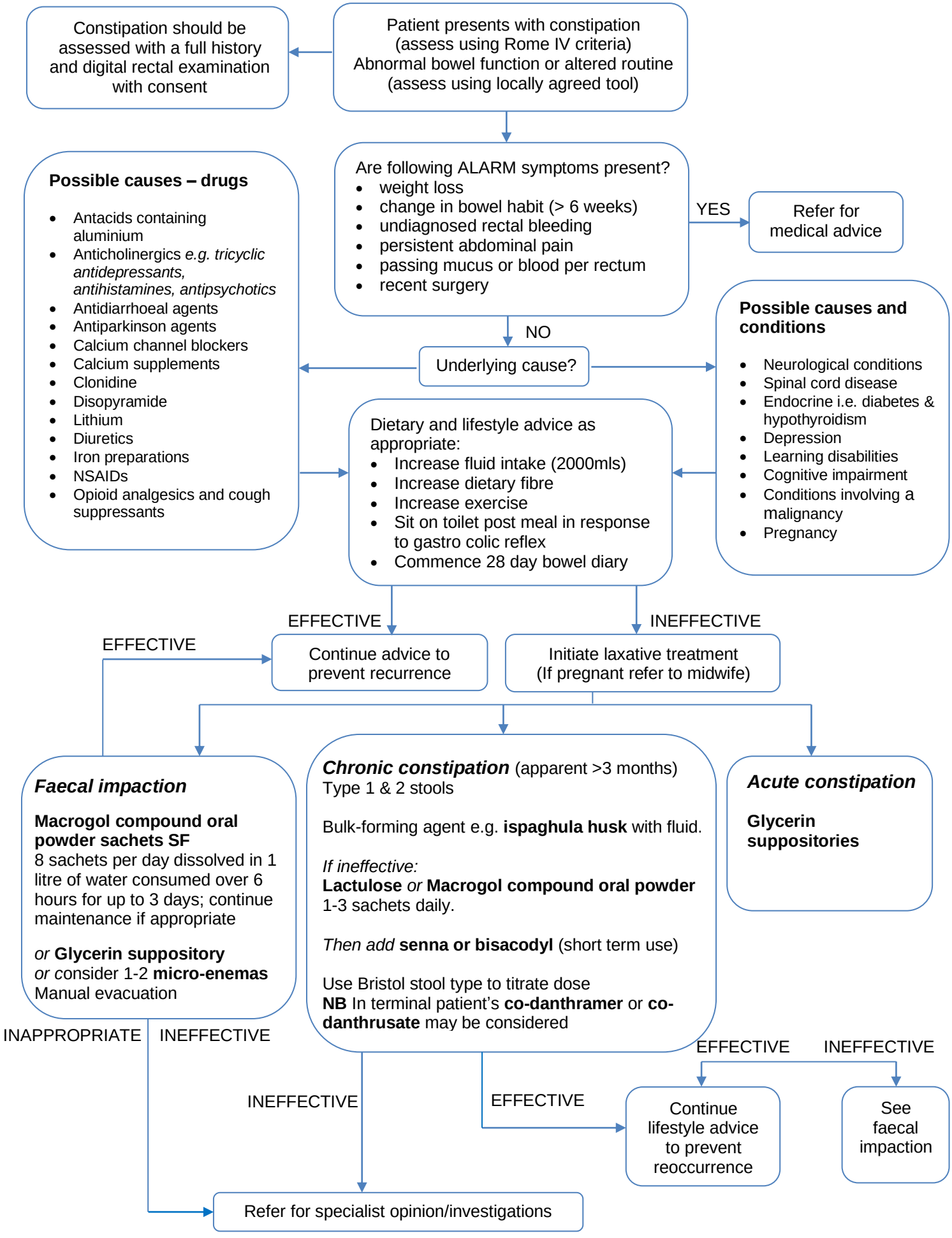
1. Colestyramine and colesevelam are **GREY** after gastroenterology consultant initiation and assessment for chronic diarrhoea secondary to bile salt malabsorption. See JAPC advice position statement.

1.9.4 Pancreatin

Creon
Pancrex and **Pancrex V**

1. It is important to ensure adequate hydration at all times in patients receiving high strength pancreatin preparations.

Appendix 1- Assessment and management of constipation in adults



Definition of constipation

The Rome IV Criteria for chronic constipation requires the presence of two or more of the following:

- Straining during at least 25% of bowel movement
- Lumpy or hard stool in at least a 25% of bowel movements
- A sensation of incomplete evacuation for at least 25% of bowel movements
- Sensation of anorectal blockage for at least 25% of bowel movements
- Manual manoeuvres to facilitate at least 25% of bowel movements
- Fewer than three bowel movements per week

Bristol stool chart

	Type 1	Separate hard lumps like nuts (hard to pass)	**Types 1 and 2** Consider chronic or acute constipation and faecal impaction
	Type 2	Sausage shaped but also lumpy	
	Type 3	Like a sausage but with cracks on the surface	**Types 3, 4 and 5** Considered as “normal” consistency
	Type 4	Like a sausage or snake smooth and soft	
	Type 5	Soft blobs with clear-cut edges	
	Type 6	Fluffy pieces with ragged edges, a mushy stool	**Types 6 and 7** Consider faecal impaction with overflow
	Type 7	Watery, no solid pieces ENTIRELY LIQUID	

First published: Lewis SJ, Heaton KW (1997) Stool form scale as a useful guide to intestinal transit time. Scandinavian Journal of Gastroenterology 32: 920–4

Laxatives

Classification	Contra-indications	Cautions/ precautions	Preparation	Recommended dose range	Cost* (28 days)	Time to effect
Bulk forming	Difficulty swallowing Intestinal obstruction Atonic colon Faecal impaction	Full effect may take some days Maintain adequate fluid	**Ispaghula husk** (Ispagel®)	1 sachet BD	£4.57	2 – 3 days
Osmotic laxatives	Intestinal obstruction Galactosaemia	Lactulose intolerance	**Lactulose**	15mL BD	£5.07	2 – 3 days
	Perforation or obstruction Paralytic ileus Crohn's disease		**Macrogols compound oral powder sachets SF**	1-2 sachets daily	£4.66-£9.31	2 – 3 days
	Acute gastrointestinal conditions	Caution in elderly and debilitated	**Sodium citrate micro-enema (Relaxit®)**	5mL stat	43p (one)	5 – 15 minutes
Stimulant	Intestinal obstruction **Dantron is only indicated for terminal care**	Avoid long-term use – risk of atonic colon and hypokalaemia Often cause abdominal cramp	**Bisacodyl**	5 - 10mg ON	£1.90 – £3.80	6 – 12 hours
			Senna	2 - 4 tablets ON	£1.48 – £2.97	8 – 12 hours
			Docusate	100 - 500mg daily	£1.95 - £9.75	12 – 72 hours
			Glycerol suppositories (PR)	4g **stat**	27p (one)	15 – 30 minutes
			Dantron • Co-danthramer suspension • Co-danthramer strong suspension • Co-danthrusate suspension	5 - 10ml ON 5ml ON 5 - 15ml ON	£114.47 - £228.94 £235.19 £165.38 - £496.14	6 – 12 hours
Faecal softener		Bulk laxatives and docusate also have softening properties	Arachis oil enema (PR)	130mL **stat**	£52.06 (one)	

***Drug tariff online & MIMS online accessed January 2024**