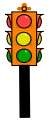
Recommendations from the Lothian Formulary Committee (FC) following Scottish Medicines Consortium (SMC) advice, NICE MTA advice, (FAF3) unlicensed and off-label medicines and (FAF2) medicines not considered by SMC

1 – Gastro-intestinal system

In alphabetical order

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
adalimumab 40mg injection in pre-filled pen and syringe (Humira®) *Abbott Laboratories Ltd* May 2009 *NICE MTA 187* *Superseeds SMC Report No. 417/07*	Adalimumab within its licensed indications, is recommended as treatment option 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. Adalimumab 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. People should then have their disease reassessed to determine whether ongoing treatment is still clinically appropriate.	Included on the Additional List, Specialist Use only.	September 2010
adalimumab (Humira®) Pre-filled Pen, Pre-filled Syringe and Vial *Abbott Laboratories Limited* February 2015 *NICE MTA329* Supersedes SMC Report No. 800/12	Adalimumab is recommended, within its marketing authorisations, as options for treating moderately to severely active ulcerative colitis in adults whose disease has responded inadequately to conventional therapy including corticosteroids and mercaptopurine or azathioprine, or who cannot tolerate, or have medical contraindications for, such therapies. Infliximab, adalimumab or golimumab should be given as a planned course of treatment until treatment fails (including the need for surgery) or until 12 months after starting treatment, whichever is shorter. Specialists should then discuss the risks and benefits of continued treatment with the patient, and their parent or carer if appropriate: They should continue treatment only if there is clear evidence of response as determined by clinical symptoms, biological markers and investigation, including endoscopy if necessary. People who continue treatment should be reassessed at least every 12 months to determine whether ongoing treatment is still clinically appropriate. They should consider a trial withdrawal from treatment for all patients who are in stable clinical remission. People whose disease relapses after treatment is stopped should have the option to start treatment again.	Included on the Additional List, adults only, specialist use only.	September 2015
adalimumab (Humira®) *Abbott Laboratories* 12.11.12 *SMC Report No. 824/12* NON SUBMISSION	NOT RECOMMENDED: adalimumab (Humira®) is not recommended for use within NHS Scotland for the treatment of moderately active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland. Adalimumab remains a treatment option 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, in line with the NICE (Multiple) Technology Appraisal Guidance No 187. Healthcare Improvement Scotland advises that the recommendations are as valid for Scotland as for England and Wales.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
adalimumab 40mg solution for injection in a single-use pre-filled syringe, pre-filled pen and a 40mg/0.8mL paediatric vial (Humira®) *AbbVie Limited* 08.07.13 *SMC Report No. 880/13* PRODUCT UPDATE (abbreviated submission)	Restricted use: adalimumab (Humira®) is accepted for restricted use within NHS Scotland for the treatment of severe active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and an immunomodulator, or who are intolerant to or have contraindications for such therapies. SMC restriction: prescribing by specialists in paediatric gastroenterology. Treatment of paediatric patients with adalimumab resulted in similar clinical remission and response rates at weeks 26 and 52 to that achieved with adalimumab in severe active Crohn's disease in adults. Adalimumab has previously been accepted for use for this indication in adults with severe active Crohn's disease in NHS Scotland as NHS Healthcare Improvement Scotland advised that NICE Multiple Technology Appraisal No 187 was valid for Scotland.	Included on the Additional List, Specialist Use only, for the indication in question.	July 2013
adalimumab (Humira®) 40mg/0.4mL pre-filled syringe and pre-filled pen adalimumab (Humira®) 40mg/0.8mL pre-filled syringe and pre-filled pen adalimumab (Humira®) 40mg/0.8mL vial for paediatric use *AbbVie Limited* 07.11.16 *SMC Report No. 1208/16* NON SUBMISSION	NOT RECOMMENDED: adalimumab (Humira®) is not recommended for use within NHS Scotland for the treatment of moderately active Crohn's disease in paediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy and a corticosteroid and/or an immunomodulator, or who are intolerant to or have contraindications for such therapies The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland. SMC has previously accepted adalimumab for restricted use for the treatment of severe active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and an immunomodulator, or who are intolerant to or have contraindications for such therapies (SMC 880/13). This advice remains valid.	NOT RECOMMENDED	
antacid and oxetacaine oral suspension *Rosemount Pharmaceuticals Ltd*	For short term management of odynophagia/pain post-endoscopic radiofrequency ablation. 	Added to the Additional List, for Specialist Use only. Antacid and oxetacaine oral suspension has been categorised **RED** under the ADTC 'Policy and procedures for the use of unlicensed medicines'.	August 2014
beclometasone dipropionate 5mg tablets (Clipper®) *Trinity-Chiesi Pharmaceuticals* 10.09.07 *SMC Report No. 166/05*	NOT RECOMMENDED: Beclometasone dipropionate (Clipper®) is not recommended for use within NHS Scotland for the treatment of mild to moderate ulcerative colitis in active phase as add-on therapy to 5-ASA containing drugs. The clinical and cost effectiveness against standard practice have not been demonstrated. This advice is based on an assessment carried out in April 2005. The licence holder has indicated their intention to resubmit.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
budesonide 2mg rectal foam (Budenofalk®) *Dr Falk Pharma UK Ltd* 08.10.07 *SMC Report No. 409/07* PRODUCT UPDATE (abbreviated submission)	Accepted for use: budesonide rectal foam (Budenofalk®) is accepted for use within NHS Scotland for the treatment of active ulcerative colitis that is limited to the rectum and the sigmoid colon. It should be used in patients for whom rectally administered budesonide is an appropriate choice of treatment. It costs less than equivalent doses of the other rectal formulation of budesonide.	'Not preferred' as suitable alternatives exist.	October 2007
budesonide 3mg gastro-resistant capsule (Budenofalk®) *Dr Falk Pharma* 14.01.13 *SMC Report No. 828/12*	Accepted for use: budesonide gastro-resistant capsule (Budenofalk®) is accepted for use within NHS Scotland for symptomatic relief of chronic diarrhoea due to collagenous colitis. budesonide (Budenofalk®) provides symptomatic improvement of diarrhoea associated with collagenous colitis compared with placebo.	Included on the LJF as a first choice drug, for the indication in question.	August 2013
budesonide 9mg gastro-resistant granules (Budenofalk®) *Dr Falk Pharma UK Ltd* *Induction of remission in patients with active collagenous colitis.* 14.01.13 *SMC Report No. 831/12* PRODUCT UPDATE (abbreviated submission)	Accepted for use: budesonide 9mg gastro-resistant granules (Budenofalk®) is accepted for use within NHS Scotland for the induction of remission in patients with active collagenous colitis. Budesonide gastro-resistant granules provides a once daily alternative to budesonide gastro-resistant 3mg capsules (which are given three times daily) at no additional cost. The granules may have advantages for patients who have difficulty swallowing.	**Included** on the LJF as a first choice drug, for the indication in question.	August 2013
budesonide 9mg gastro-resistant granules (Budenofalk®) *Dr Falk Pharma UK Limited* 09.06.14 *SMC Report No. 970/14* PRODUCT UPDATE (abbreviated	Accepted for use: budesonide gastro-resistant granules (Budenofalk®) is accepted for use within NHS Scotland for induction of remission in patients with mild to moderate active Crohn's disease affecting the ileum and/or ascending colon. Budesonide gastro-resistant granules provide a once daily alternative to budesonide gastro-resistant 3mg capsules three times daily at no additional cost. The granules may have advantages for patients who have difficulty swallowing.	Included on the Additional List, for Specialist Initiation only, for the indication in question.	May 2014
budesonide 9mg prolonged release tablet (Cortiment®) *Ferring Pharmaceuticals Ltd* 10.10.16 *SMC Report No. 1093/15* RESUBMISSION	Restricted use: budesonide (Cortiment®) is accepted for restricted use within NHS Scotland in adults for induction of remission in patients with mild to moderate active ulcerative colitis (UC) where aminosalicylate (5-ASA) treatment is not sufficient. SMC restriction: for use in patients with UC who present with active left-sided disease and/or proctosigmoiditis who are not suitable for oral prednisolone, as an alternative to budesonide rectal formulations or off-label oral budesonide. In two phase III studies, budesonide (Cortiment®) significantly increased combined clinical and endoscopic remission at eight weeks compared with placebo. However, there are no comparative data with other oral or rectal preparations.	Not included on the LJF, because clinicians hae not responded to an invitation to apply for formulary inclusion for this medicine.	November 2016

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
creon micro (Creon®) *Solvay Healthcare* 13.12.04 *SMC Report No. 141/04* PRODUCT UPDATE (abbreviated submission)	Restricted use: creon micro granule formulation (Creon®) is accepted for restricted use in NHS Scotland for the treatment of pancreatic exocrine insufficiency. It provides a formulation suitable for use in young infants and is expected to be used for young cystic fibrosis sufferers who are unable to swallow capsules. The associated resource implications are expected to be small.	New formulation of a drug already included in the Formulary.	October 2007
esomeprazole intravenous formulation (Nexium IV®) *AstraZeneca* 11.10.04 *SMC Report No. 124/04*	Accepted for use: Intravenous esomeprazole (Nexium IV®) is accepted for use within NHS Scotland for the treatment of gastroesophageal reflux disease in patients with oesophagitis and/or severe symptoms of reflux as an alternative to oral therapy when oral intake is not appropriate. Intravenous esomeprazole seems to be as effective as oral esomeprazole in terms of gastric acid suppression and healing of erosive oesophagitis. However comparisons with other IV proton pump inhibitors are restricted to pre-clinical studies. Esomeprazole has similar acquisition costs to other IV proton pump inhibitors.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	May 2007
esomeprazole 20mg tablets (Nexium®) *AstraZeneca UK Ltd* 12.06.06 *SMC Report No. 257/06*	NOT RECOMMENDED: esomeprazole (Nexium®) is not recommended for use within NHS Scotland for the prevention of gastric and duodenal ulcers associated with non-steroidal anti-inflammatory (NSAID) therapy in patients at risk. When compared to placebo, esomeprazole reduces the rate of gastro-duodenal ulcers associated with NSAID therapy in at-risk patients. There are no comparisons of esomeprazole with other proton pump inhibitors for this indication. The economic case has not been demonstrated.	NOT RECOMMENDED	
esomeprazole 20mg tablets (Nexium®) *AstraZeneca UK Ltd* 12.06.06 *SMC Report No. 274/06*	NOT RECOMMENDED: esomeprazole (Nexium®) is not recommended for use within NHS Scotland for the healing of gastric ulcers associated with non-steroidal anti-inflammatory drug (NSAID) therapy. In the treatment of gastric ulcers associated with NSAID therapy, esomeprazole produced greater healing rates than a histamine-H2 antagonist. However, there are no comparisons of esomeprazole with other proton pump inhibitors for this indication. The economic case has not been demonstrated.	NOT RECOMMENDED	
esomeprazole 20mg and 40mg tablets (Nexium®) *AstraZeneca UK Ltd* 11.06.07 *SMC Report No. 368/07*	Restricted use: esomeprazole (Nexium®) is accepted for restricted use within NHS Scotland, for patients in the age group 12-17 years inclusive, for the treatment of erosive reflux oesophagitis, the long-term management of patients with healed oesophagitis to prevent relapse, and the symptomatic treatment of gastro-oesophageal reflux disease. The use of esomeprazole for this indication and age group should be restricted to patients in whom maximum licensed doses of generic proton pump inhibitors have been ineffective. The pharmacokinetics of esomeprazole in adolescents have been shown to be similar to those seen in adults; there is no evidence of comparative efficacy in adolescents in this indication.	'Not preferred' in Lothian.	July 2007
esomeprazole, 20mg and 40mg tablets (Nexium®) *AstraZeneca UK Ltd* 10.12.07 *SMC Report No. 422/07*	Accepted for use: esomeprazole (Nexium®) is accepted for use within NHS Scotland for the treatment of Zollinger-Ellison Syndrome. Other proton pump inhibitors are available for this indication at a lower cost per treatment period.	Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	May 2009

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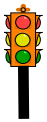
esomeprazole, 40mg vial of powder for solution for intravenous injection or infusion (Nexium I.V.®) *AstraZeneca* 09.11.09 *SMC Report No 578/09*	Accepted for use: esomeprazole (Nexium I.V.®) is accepted for use within NHS Scotland for prevention of rebleeding following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers. In patients with high-risk peptic ulcer bleeding, high-dose intravenous esomeprazole significantly reduced recurrent bleeding at 72 hours compared to placebo.	Included on the LJF as a prescribing note.	August 2010
esomeprazole 10mg gastro-resistant granules for oral solution, sachet (Nexium®) *AstraZeneca UK Ltd* 13.09.10 *SMC Report No 639/10* PRODUCT UPDATE (abbreviated submission)	esomeprazole 10mg gastro-resistant granules for oral solution, sachet (Nexium®): is accepted for restricted use within NHS Scotland. Indication under review: primarily indicated for treatment of gastro-oesophageal reflux disease in children 1 to 11 years old. Gastro-oesophageal reflux disease (GORD) • Treatment of endoscopically proven erosive reflux oesophagitis • Symptomatic treatment of gastro-oesophageal reflux disease Oral suspension may also be used by patients having difficulty swallowing dispersed esomeprazole gastro-resistant tablets. Restricted Advice: the use of esomeprazole for this indication and age group should be restricted to patients in whom licensed doses of a generic proton pump inhibitor have been ineffective. The gastro-resistant granules for oral solution have demonstrated bioequivalence to the tablet and capsule formulations. Doses of 10mg esomeprazole in children aged 1 to 11 resulted in the same exposure to drug as seen with the 20mg dose in adolescents and adults. There is no evidence of comparative efficacy in this population. The Scottish Medicines Consortium has previously accepted this product for use in patients in the 12-17 years age group, for the treatment of erosive reflux oesophagitis, the long-term management of patients with healed oesophagitis to prevent relapse, and the symptomatic treatment of gastro-oesophageal reflux disease.	Included on the LJF as a prescribing note, for in the indication in question. As an alternative to omeprazole suspension (unlicensed medicine)	January 2015
fidaxomicin 200mg film-coated tablets (Dificlir®) *Astellas Pharma Ltd* 09.07.12 *SMC Report No: 791/12*	Restricted use: fidaxomicin (Dificlir®) is accepted for restricted use within NHS Scotland for the treatment of adults with Clostridium difficile infections (CDI) also known as C. difficile-associated diarrhoea (CDAD). SMC restriction: Treatment of adults with a first CDI recurrence on the advice of local microbiologists or specialists in infectious diseases. Fidaxomicin demonstrated non-inferiority to another antibiotic in the clinical cure of Clostridium difficile infection and superiority in reducing recurrence. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC for first-line use in adults with severe CDI.	Included on the LJF, Specialist Use only, for the incidation in question.	October 2012

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
Forceval® capsules and soluble tablets *Alliance Pharmaceuticals Ltd.*	Vitamin and trace element supplementation for patients at risk of refeeding syndrome. 	Forceval® capsules: Included on the Additional List, for Specialist Use only, for use in accordance with the local guidelines. Forceval® soluble tablets: Included on the Additional List, Specialist Use only, classified as **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian', for use in accordance with the local guidelines.	July 2016
glyceryl trinitrate 0.4% rectal ointment (Rectogesic®) *ProStrakan* 11.02.08 *SMC Report No. 200/05* 3rd RESUBMISSION	NOT RECOMMENDED: glyceryl trinitrate 0.4% ointment (Rectogesic®) is not recommended for use within NHS Scotland for relief of pain associated with chronic anal fissure. It was associated with very small improvements in pain scores compared with vehicle, and therefore little clinically significant effect. The manufacturer did not present a sufficiently robust economic case to gain acceptance by SMC.	NOT RECOMMENDED	
golimumab, 50mg and 100mg solution for injection (Simponi®) *Merck Sharp & Dohme Ltd* February 2015 *NICE MTA329* Supersedes SMC Report No. 946/13	Golimumab is recommended, within its marketing authorisations, as an option for treating moderately to severely active ulcerative colitis in adults whose disease has responded inadequately to conventional therapy including corticosteroids and mercaptopurine or azathioprine, or who cannot tolerate, or have medical contraindications for, such therapies. Golimumab is recommended only if the company provides the 100 mg dose of golimumab at the same cost as the 50 mg dose, as agreed in the patient access scheme. The choice of treatment between infliximab, adalimumab or golimumab should be made on an individual basis after discussion between the responsible clinician and the patient about the advantages and disadvantages of the treatments available. This should take into consideration therapeutic need and whether or not the patient is likely to adhere to treatment. If more than 1 treatment is suitable, the least expensive should be chosen (taking into account administration costs, dosage and price per dose). Infliximab, adalimumab or golimumab should be given as a planned course of treatment until treatment fails (including the need for surgery) or until 12 months after starting treatment, whichever is shorter. Specialists should then discuss the risks and benefits of continued treatment with the patient, and their parent or carer if appropriate: They should continue treatment only if there is clear evidence of response as determined by clinical symptoms, biological markers and investigation, including endoscopy if necessary. People who continue treatment should be reassessed at least every 12 months to determine whether ongoing treatment is still clinically appropriate. They should consider a trial withdrawal from treatment for all patients who are in stable clinical remission. People whose disease relapses after treatment is stopped should have the option to start treatment again.	Included on the Additional List, adults only, specialist use only.	September 2015

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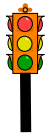
infliximab (Remicade®) 100mg vial (powder for reconstitution for intravenous infusion) *Schering-Plough*	Paediatric inflammatory bowel disease - induction of remission of severe abdominal or complex perianal Crohn's disease, induction of remission in severe acute ulcerative colitis, and maintenance of remission in severe abdominal or complex perianal Crohn's disease. 	Added to the Additional List for use in paediatric inflammatory bowel disease. For specialist use only. Infliximab (Remicade®) has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	May 2007
infliximab 100mg powder for concentrate for solution for infusion. (Remicade®) *Schering-Plough* 10.03.08 *SMC Report No. 448/08*	Accepted for use: infliximab (Remicade®) is accepted for use within NHS Scotland for the treatment of severe, active Crohn's disease, in paediatric patients aged 6 to 17 years, who have not responded to conventional therapy including a corticosteroid, an immunomodulator and primary nutrition therapy; or who are intolerant to or have contraindications for such therapies. In an open label study 88% of patients had a clinical response following the induction regimen and this was maintained at one year in significantly more patients receiving infliiximab every 8 weeks compared with every 12 weeks.	Previously approved as an 'off label medicine' for this indication in May 2007. Added to the Additional List, for use in paediatrics.	May 2009
infliximab 100mg powder for intravenous infusion (Remicade®) *Schering-Plough UK Ltd* May 2009 *NICE MTA 187* *Supersedes SMC Report No. 363/07*	Infliximab within its licensed indications is recommended as maintenance treatment of severe, active Crohn's disease, in patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.	Added to the Additional List for Specialist Use only.	September 2010
infliximab 100mg powder for intravenous infusion (Remicade®) *Schering-Plough UK Ltd* May 2009 *NICE MTA 187* *Supersedes SMC Report No. 364/07*	Infliximab within its licensed indications is recommended as maintenance treatment of fistulising, active Crohn's disease, in patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy).	Added to the Additional List for Specialist Use only.	September 2010
infliximab (Remicade®) 100 mg powder for concentrate for solution for infusion *Merck Sharp & Dohme Ltd* 10.10.11 *SMC Report No. 739/11* NON SUBMISSION	NOT RECOMMENDED: infliximab (Remicade®) is not recommended for use within NHS Scotland. Treatment of moderately active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland. Following NHS Quality Improvement Scotland's endorsement of the National Institute for Health and Clinical Excellence (NICE) multiple technology appraisal guidance No 187, infliximab is recommended as a treatment option in severe active Crohn's disease.	NOT RECOMMENDED	

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infliximab 100mg powder for concentrate for solution for infusion (Remicade®) *Merck Sharp & Dohme Limited* 11.03.13 *SMC Report No. 854/13*	Restricted use: infliximab (Remicade®) is accepted for restricted use within NHS Scotland for the treatment of severely active ulcerative colitis in children and adolescents aged 6 to 17 years who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies SMC restriction: as an alternative to ciclosporin in patients with acute, severe paediatric ulcerative colitis (rescue therapy) who are steroid refractory. Open-label, uncontrolled data indicate that infliximab induces remission of moderate to severe active ulcerative colitis in paediatric patients.	Not included on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine.	April 2013
infliximab 100mg powder for concentrate solution for infusion (Remicade®) *Merck, Sharp & Dohme Ltd* February 2015 *NICE MTA329* Supersedes SMC Report No. 374/07	Infliximab is recommended, within its marketing authorisation, as an option for treating severely active ulcerative colitis in children and young people aged 6–17 years whose disease has responded inadequately to conventional therapy including corticosteroids and mercaptopurine or azathioprine, or who cannot tolerate, or have medical contraindications for, such therapies. Infliximab, adalimumab or golimumab should be given as a planned course of treatment until treatment fails (including the need for surgery) or until 12 months after starting treatment, whichever is shorter. Specialists should then discuss the risks and benefits of continued treatment with the patient, and their parent or carer if appropriate: They should continue treatment only if there is clear evidence of response as determined by clinical symptoms, biological markers and investigation, including endoscopy if necessary. People who continue treatment should be reassessed at least every 12 months to determine whether ongoing treatment is still clinically appropriate. They should consider a trial withdrawal from treatment for all patients who are in stable clinical remission. People whose disease relapses after treatment is stopped should have the option to start treatment again.	Included on the Additional List, adults only, specialist use only.	September 2015
linaclotide hard capsules, 290 micrograms (Constella®) *Almirall SA* 10.06.13 *SMC Report No. 869/13*	Restricted use: linaclotide (Constella®) is accepted for restricted use within NHS Scotlandfor symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults. SMC restriction: linaclotide is restricted for use in patients with moderate to severe IBS-C who have not responded adequately to or cannot tolerate all other suitable treatment options. In two pivotal phase III studies linaclotide was superior to placebo for the co-primary endpoints of abdominal pain/discomfort responders and IBS degree-of-relief responders at 12 weeks. There are no comparative efficacy data versus first- or second-line treatments.	Included on the Additional List, for General Use on specialist's advice, for the indication in question.	May 2014
lubiprostone, 24 micrograms soft capsules (Amitiza®) *Sucampo Pharma Europe Ltd* 11.08.14 *SMC Report No. 977/14*	NOT RECOMMENDED: lubiprostone (Amitiza®) is not recommended for use within NHS Scotland the treatment of chronic idiopathic constipation and associated symptoms in adults, when response to diet and other non-pharmacological measures (e.g. educational measures, physical activity) are inappropriate. In patients with chronic idiopathic constipation, lubiprostone increased the weekly frequency of spontaneous bowel movements when compared with placebo. Patients treated with lubiprostone reported improved symptom scores for stool consistency, straining and constipation severity compared with patients who received placebo. The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	

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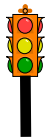
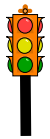
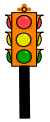
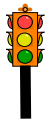
macrogol 4000 (Idrolax®) *Schwarz Pharma Ltd* 13.04.04 *SMC Report No. 94/04*	NOT RECOMMENDED: macrogol 4000 (Idrolax®) is not recommended for use within NHS Scotland for the treatment of constipation in adults and children aged 8 years and above. Macrogol 4000 is as effective as lactulose, but the available evidence does not justify the additional cost of this product. The licence holder has indicated their intention to resubmit.	NOT RECOMMENDED	
macrogol '3350', sodium bicarbonate, sodium chloride, potassium chloride (Movicol® Paediatric Plain) *Norgine Ltd* 12.07.04 *SMC Report No. 103/04* PRODUCT UPDATE (abbreviated submission)	Accepted for use: Movicol® Paediatric Plain is accepted for use in Scotland as an alternative to Movicol®-Half for the treatment of paediatric faecal impaction. The new product is a reformulation of an existing paediatric presentation of macrogol to remove flavour and sweetener, and no clinical data have been considered in drafting this recommendation.	Included on the LJF for Children as a Prescribing Note.	April 2005
macrogol 3350 and ascorbic acid (Moviprep®) *Norgine Pharmaceuticals Ltd*	Bowel preparation prior to colonoscopy.	Added to the Additional List.	August 2007
mesalazine modified release tablet 800mg (Asacol®) *Procter and Gamble Pharmaceuticals UK Ltd* 11.02.08 *SMC Report No. 222/05* PRODUCT UPDATE (abbreviated submission)	Accepted for use: mesalazine 800mg modified release tablet (Asacol®) is accepted for use in NHS Scotland for the treatment of moderate acute exacerbations of ulcerative colitis up to a maximum dose of 4.8g daily. The maximum recommended dose has been increased from 2.4g daily, and at the revised dose, the 800mg strength allows halving of the pill burden compared with the 400mg formulation. There will be a pro-rata increase in cost associated with the new maximum dose but no extra costs arise from the change in formulation.	New strength of a product already in the formulary.	January 2008
mesalazine modified release tablets 800mg (Asacol®) *Procter and Gamble Pharmaceuticals UK Ltd* 11.02.08 *SMC Report No. 223/05* PRODUCT UPDATE (abbreviated submission)	Accepted for use: Mesalazine 800 mg modified release tablet (Asacol®) is accepted for use in NHS Scotland for the treatment of mild acute exacerbations of ulcerative colitis. At the recommended dose of up to 2.4g daily, the 800mg strength allows halving of the pill burden compared with the 400mg formulation at no extra cost.	New strength of a product already in the formulary.	January 2008
mesalazine modified release tablet 800mg (Asacol®) *Procter and Gamble Pharmaceuticals UK Ltd* 11.02.08 *SMC Report No. 224/05* PRODUCT UPDATE (abbreviated submission)	Accepted for use: Mesalazine 800mg modified release tablet (Asacol®) is accepted for use in NHS Scotland for the maintenance of remission in ulcerative colitis and Crohn's ileo-colitis. At the recommended dose of up to 2.4g daily, the 800mg strength allows halving of the pill burden compared with the 400mg formulation at no extra cost.	New strength of a product already in the formulary.	January 2008

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
mesalazine 1200mg gastro-resistant, prolonged release tablet (Mezavant XL®) *Shire Pharmaceuticals Limited* 10.03.08 *SMC Report No. 445/08* PRODUCT UPDATE (abbreviated submission)	Accepted for use: mesalazine 1200mg gastro-resistant prolonged release tablet (Mezavant XL®) is accepted for use within NHS Scotland for the induction of clinical and endoscopic remission in patients with mild to moderate, active ulcerative colitis, and for maintenance of remission. It may be used in cases where mesalazine is an appropriate choice of treatment and offers the possible advantage of once-daily administration.	Added to the Formulary as a prescribing note.	November 2008
methotrexate 50mg/ml pre-filled syringe (Metoject®) *Medac*	Crohn's disease in paediatrics 	Added to the Additional List. Methotrexate has been categorised **AMBER** for **paediatrics** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian' – specialist use only.	May 2010
methotrexate 50mg/ml pre-filled syringe (Metoject®) *Medac*	Crohn's disease in adults 	Added to the Additional List and prescribed in accordance with Shared Care Protocol. Methotrexate has been categorised **AMBER** for **adults** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian' - General use with restrictions.	April 2010
methylnaltrexone 12mg in 0.6ml solution for injection (Relistor®) *Wyeth Europa Limited* 08.12.08 *SMC Report No. 518/08*	Restricted use: methylnaltrexone (Relistor®) is accepted for restricted use within NHS Scotland for treatment of opioid induced constipation in advanced illness patients who are receiving palliative care when response to usual laxative therapy has not been sufficient. It is restricted to use by physicians with expertise in palliative care. Methylnaltrexone has been shown to be superior to placebo in achieving bowel movement in terminally ill patients with opioid-induced constipation already receiving a stable laxative regimen.	'Not preferred' in Lothian, as suitable alternatives exist.	September 2009
naloxegol 12.mg and 25mg film-coated tablets (Moventig®) *AstraZeneca UK Ltd* 07.12.15 *SMC Report No. 1106/15*	Accepted: naloxegol (Moventig®) is accepted for use within NHS Scotland. Indication under review: the treatment of opioid-induced constipation in adult patients who have had an inadequate response to laxative(s). Naloxegol compared to placebo significantly improved the response rate in patients with opioid-induced constipation including patients who had previously had an inadequate response to at least four days of treatment with at least one class of laxative.	Routinely available in line with national guidance. Included on the Additional List, for Specialist initiation. Included on the Additional List, for Specialist initiation, for the indication in question.	March 2017

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
obeticholic acid, 5mg and 10mg film-coated tablets (Ocaliva®) *Intercept Pharma UK & Ireland* 12.06.17 *SMC Report No. 1232/17* Patient Access Scheme	Primary biliary cholangitis (also known as primary biliary 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.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.	August 2017
omeprazole suspension (various strengths) Unlicensed manufacturers	Any indication. 	Not recommended for use in Lothian. Omeprazole suspension has been categorised **BLACK** under the ADTC 'Policy and procedures for the use of unlicensed medicines'	January 2015
prucalopride 1mg and 2mg tablet (Resolor®) *Movetis UK* 11.07.11 *SMC Report No. 653/10* RESUBMISSION	NOT RECOMMENDED: prucalopride (Resolor) is not recommended for use within NHS Scotland. Indication under review: for symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief. Overall the manufacturer did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
rabeprazole (Pariet®) *Janssen Cilag* 13.09.04 *SMC Report No. 118/04*	Accepted for use: rabeprazole is accepted for use within NHS Scotland for on-demand symptomatic treatment of moderate to severe gastro-oesophageal reflux disease (GORD) in patients without oesophagitis. It is the second proton-pump inhibitor (PPI) with a specific licence for on-demand therapy. Provided that there is a clearly defined need for maintenance therapy following acute treatment of GORD and that rabeprazole is considered to be the most appropriate PPI, on-demand use of rabeprazole is an effective treatment option in patients without oesophagitis.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	May 2007
rabeprazole 10mg and 20mg tablet (Pariet®) *Eisai Ltd* 13.02.06 *SMC Report No. 232/06* PRODUCT UPDATE (abbreviated submission)	Accepted for use: rabeprazole 10mg and 20mg tablet (Pariet®) is accepted for use within NHS Scotland for the treatment of Zollinger-Ellison syndrome. Other proton pump inhibitors are available for this indication at a lower cost per treatment period.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	May 2007

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
racecadotril 10mg, 30mg granules for oral suspension (Hidrasec Infants®, Hidrasec Children®) *Abbott Healthcare Products Ltd* 11.08.14 *SMC Report No. 818/12* RESUBMISSION	NOT RECOMMENDED: racecadotril (Hidrasec Infants®, Hidrasec Children®) is not recommended for use within NHS Scotland for complementary symptomatic treatment of acute diarrhoea in infants older than three months and in children, together with oral rehydration and the usual support measures, when these measures alone are insufficient to control the clinical condition and when causal treatment is not possible. If causal treatment is possible racecadotril can be administered as a complementary treatment. In a meta-analysis, racecadotril was significantly better than placebo in reducing the duration of diarrhoea and stool output in children with acute diarrhoea. There is insufficient evidence that it improves recovery rate. The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
racecadotril (Hidrasec®) 100mg capsules *Abbott Healthcare Products Ltd* 10.12.12 *SMC Report No. 832/12* NON SUBMISSION	NOT RECOMMENDED: racecadotril (Hidrasec®) is not recommended for use within NHS Scotland for symptomatic treatment of acute diarrhoea in adults when causal treatment is not possible. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	
rifaximin 550mg film-coated tablets (Targaxan®) *Norgine Pharmaceuticals Ltd* 09.09.13 *SMC Report No. 893/13*	Accepted for use: rifaximin (Targaxan®) is accepted for use within NHS Scotland for reduction in recurrence of episodes of overt hepatic encephalopathy (HE) in patients ≥18 years of age. In a double-blind randomised controlled study of six months duration, rifaximin was superior to placebo for the primary outcome of time to first overt breakthrough episode of HE.	Included on the Additional List, Specialist Initiation, for the indication in question.	October 2013
rifaximin 200 mg film-coated tablets (Xifaxanta®) *Norgine Limited* 13.08.12 *SMC Report No. 808/12* NON SUBMISSION	NOT RECOMMENDED: rifaximin 200 mg film coated tablets (Xifaxanta®) is not recommended for use within NHS Scotland for the treatment of travellers' diarrhoea that is not associated with any of: • Fever • Bloody diarrhoea • Eight or more unformed stools in the previous 24 h • Occult blood or leucocytes in the stool. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	
senna 7.5mg in combination with macrogol oral powder '3350' Local formulary process	For pharmacological management of opioid-induced constipation.	Routinely available in line with local or regional guidance. Included on the LJF for General Use. Included on the LJF for General Use, for the indication in question.	March 2017

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
teduglutide (Revestive®) 5mg power and solvent for solution for injection *NPS Pharma UK Ltd* 08.02.16 *SMC Report No. 1139/16* NON SUBMISSION	NOT RECOMMENDED: teduglutide (Revestive®) is not recommended for use within NHS Scotland. Indication under review: For the treatment of adult patients with Short Bowel Syndrome. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	
terlipressin acetate 0.12mg/ml solution for injection (Glypressin® Solution) *Ferring Pharmaceuticals Ltd* 13.07.09 *SMC Report No: 555/09* PRODUCT UPDATE (abbreviated submission)	Accepted for use: terlipressin acetate 0.12mg/ml solution for injection (Glypressin® Solution) is accepted for use in NHS Scotland for the treatment of bleeding oesophageal varices in patients for whom terlipressin is an appropriate choice of therapy. It replaces a formulation that requires reconstitution and is associated with only a modest cost increase.	New formulation of a drug already included in the Formulary.	December 2009
thrombin (Floseal®) injection *Baxter*	For bleeding gastric and ectopic varices. 	Included on the Additional List, for Specialist Use only. Classified as **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	August 2016
ursodeoxycholic acid 500mg film-coated tablets (Ursofalk®) *Dr Falk Pharma UK Ltd.* 12.08.13 *SMC Report No. 889/13* PRODUCT UPDATE (abbreviated submission)	Accepted for use: ursodeoxycholic acid 500mg film-coated tablets (Ursofalk®) is accepted for use within NHS Scotland for the dissolution of cholesterol gallstones in the gall bladder. The gallstones must not show as shadows on X-ray images and should not exceed 15mm in diameter. The gall bladder must be functioning despite the gallstone(s). For the treatment of primary biliary cirrhosis (PBC), provided there is no decompensated hepatic cirrhosis. Ursodeoxycholic acid 500mg film-coated tablets have demonstrated bioequivalence to ursodeoxycholic acid capsules at the same dose. Relative costs may vary slightly depending on the pack size used.	Included on the Additional List for the indication in question.	August 2013
ustekinumab 130mg concentrate for solution for infusion and 90mg solution for injection (Stelara®) *Janssen-Cilag Ltd* 10.07.17 *SMC Report No. 1250/17* Patient Access Scheme	ustekinumab (Stelara®) is accepted for use within NHS Scotland for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist or have medical contraindications to such therapies.	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (link to local guidance)	October 2017

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
vedolizumab 300mg powder for concentrate for solution for infusion (Entyvio®) *Takeda UK Ltd.* 11.04.15 *SMC Report No. 1045/15* Patient Access Scheme	Accepted for use: vedolizumab (Entyvio®) is accepted for use within NHS Scotland as treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist. A higher proportion of patients treated with vedolizumab achieved a clinical response at week six and clinical remission at week 52 compared with placebo in a controlled phase III study. Patients who continue treatment should be reassessed at least every 12 months to determine whether ongoing treatment is still clinically appropriate. For people in complete remission at 12 months, consider stopping vedolizumab, resuming treatment if there is a relapse. This advice takes account of the benefits of a patient access scheme (PAS) that improves the cost-effectiveness of vedolizumab. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower. Vedolizumab is also indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist. A submission for this indication is currently undergoing SMC assessment.	Included on the Additional List, specialist use only.	September 2015
vedolizumab 300mg powder for concentrate for solution for infusion (Entyvio®) *Takeda UK Ltd* 13.07.15 *SMC Report No. 1064/15* Patient Access Scheme	Restricted: vedolizumab (Entyvio®) is accepted for restricted use for use within NHS Scotland. Indication under review: for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist. SMC restriction: for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to a TNFα antagonist. In two clinical studies, more patients treated with vedolizumab achieved clinical remission at week 6 compared with placebo but the difference was only statistically significant in one study. One study included a maintenance phase, and significantly more patients treated with vedolizumab were in clinical remission at week 52 compared with placebo. Patients who continue treatment should be reassessed at least every 12 months to determine whether ongoing treatment is still clinically appropriate. For people in complete remission at 12 months, consider stopping vedolizumab, resuming treatment if there is a relapse. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of vedolizumab. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	Included on the Additional List, specialist use only.	October 2015
VSL#3® (Lactic acid bacteria probiotic food supplement) 3g sachet *Ferring Pharmaceuticals* (VSL#3® is a probiotic food supplement.)	Maintenance of remission in chronic or relapsing inflammation of ileoanal pouch anastomosis (pouchitis) 	Added to the Additional List - Categorised **AMBER** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian' - General use with restrictions. Only prescribable under ACBS conditions "for the maintenance of remission of ileoanal pouchitis only in adults as induced by antibiotics."	December 2008