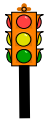
Recommendations from the Lothian Formulary Committee (FC) following Scottish Medicines Consortium (SMC) advice, NICE MTA advice, (FAF3) unlicensed and off-label medicines and (FAF2) medicines not considered by SMC

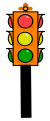
9 – Nutrition and Blood

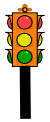
In alphabetical order

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**
ADEKplus tablets Local formulary process	As fat soluble vitamin supplementation in adult and paediatric patients with cystic fibrosis. 	Routinely available in line with local or regional guidance. Included on the LJF as first choice, for General Use, categorised as **GREEN** under the ADTC 'Policy for the use of unlicensed (and off-label use) medicines in NHS Lothian'.	January 2017 – approved for use in paediatric patients. July 2017 – approved for use in adult patients.
alglucosidase alfa 50mg powder for concentrate for solution for infusion (Myozyme®) *Genzyme* . 12.03.07 *SMC Report No. 352/07*	NOT RECOMMENDED: alglucosidase alfa (Myozyme®) is not recommended for use within NHS Scotland for the treatment of Pompe disease (acid α-glucosidase deficiency). Treatment in patients with the infantile-form of Pompe disease significantly improved survival compared with historical controls. The evidence is less clear for patients who are already receiving ventilatory support or who have the late-onset form of the disease. The economic case has not been demonstrated. The SMC orphan drug policy requires manufacturers to make complete submissions to allow a comprehensive product assessment similar to all other drug submissions. However, in addition to the usual assessment of clinical and cost effectiveness, SMC may consider additional factors specific to orphan products. Within this context the particular features of the condition and population receiving the technology and whether a drug can reverse (rather than stabilise) the condition or bridge a gap to a definitive therapy may also be considered. SMC considered the submission in the context of its orphan drug policy.	NOT RECOMMENDED	
anagrelide 0.5mg capsule (Xagrid®) *Shire* 10.10.05 *SMC Report No. 163/05* RESUBMISSION	Accepted for use: anagrelide (Xagrid®) is accepted for use within NHS Scotland for the reduction of elevated platelet counts in at-risk patients with essential thrombocythaemia who are intolerant of their current therapy or whose elevated platelet counts are not reduced to an acceptable level by their current therapy. Anagrelide reduces platelet counts in patients with essential thrombocythaemia who were intolerant of another cytoreductive therapy or whose platelet count could not be controlled by it.	Added to the Additional List, for Specialist Use only.	November 2005
AquADEKs softgel capsules	Supplementation of fat soluble vitamins for adults with cystic fibrosis. 	Included on the LJF for General Use. AquADEKs softgel capsules have been categorised as **GREEN** under the ADTC 'Policy for the use of unlicensed (and off-label use) medicines in NHS Lothian'.	December 2016 Product has been discontinued. 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**
betaine anhydrous oral powder (Cystadane®) *Orphan Europe (UK) Limited* 09.08.10 *SMC Report No. 407/07* 2nd RESUBMISSION	Restricted use; betaine anhydrous (Cystadane®) is accepted for restricted use within NHS Scotland. Indication under review: adjunctive treatment of homocystinuria involving deficiencies or defects in cystathionine beta-synthase (CBS), 5,10-methylene-tetrahydrofolate reductase (MTHFR) or cobalamin cofactor metabolism (cbl). SMC restriction: patients who are not responsive to vitamin B6 treatment. Limited clinical data confirmed the effectiveness of betaine anhydrous in homocystinuria, There remains some uncertainty about the cost-effectiveness of betaine anhydrous even in the restricted patient group described above, but given the orphan nature of the condition the economic case for use was accepted.	Added to the Additional List.	August 2011
calcium carbonate equivalent to 500mg calcium, cholecalciferol (vitamin D3) 800 IU (20 microgram) tablets (Kalcipos-D 500mg/800 IU chewable tablets®) *Meda Pharmaceuticals Ltd* 08.08.11 *SMC Report No: 718/11* PRODUCT UPDATE (abbreviated submission)	Accepted for use: calcium carbonate and cholecalciferol (Kalcipos-D®) is accepted for use within NHS Scotland. Indications under review: •Prevention and treatment of calcium and vitamin D deficiency in the elderly. •Vitamin D and calcium supplement in addition to specific osteoporosis treatment of patients who are at risk of vitamin D and calcium deficiency. This is a new combination product with a different ratio of calcium to cholecalciferol than alternative combination preparations. It is a similar price to an alternative product containing 800IU of cholecalciferol per tablet but is more expensive than some other calcium and cholecalciferol combinations. Any overall budget impact is likely to be small.	'Not preferred' as suitable alternatives exist.	August 2011
calcium acetate 667mg hard capsules (PhosLo®) *Fresenius Medical Care (UK) Ltd* 08.02.10 *SMC Report No. 601/10* PRODUCT UPDATE (abbreviated submission)	Accepted for use: calcium acetate (PhosLo®) is accepted for use in NHS Scotland for prevention/treatment of hyperphosphataemia in patients with advanced renal failure on dialysis. For patients in whom calcium acetate is an appropriate phosphate binding agent this product is available at a cost per unit of calcium equivalent to that of an existing preparation.	Added to the Formulary.	March 2010
calcium acetate 435mg/magnesium carbonate 235mg tablet (Osvaren®) *Fresenius Medical Care* . 11.04.11 *SMC Report No 693/11*	NOT RECOMMENDED: calcium acetate 435mg/magnesium carbonate 235mg tablet (Osvaren®) is not recommended for use within NHS Scotland. Indication under review: treatment of hyperphosphataemia associated with chronic renal insufficiency in patients undergoing dialysis (haemodialysis, peritoneal dialysis). The combined preparation of calcium acetate/magnesium carbonate has been shown to reduce hyperphosphataemia associated with chronic renal disease. However, the manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
Calcium and vitamin D supplement (theiCal-D3®) *Stirling Pharmaceuticals*	Prevention and treatment of calcium and vitamin D deficiency.	Not Included on the LJF because the NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question.	December 2015

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**
calcium phosphate, colecalciferol (Calfovit D3®) *Trinity Pharmaceuticals* 13.10.03 *SMC Report No. 72/03* PRODUCT UPDATE (abbreviated submission)	Accepted for use: New combination product for correction of calcium and Vitamin D deficiency in the elderly. This product is a once-daily formulation of calcium phosphate and colecalciferol and is an appropriate less expensive alternative to existing treatments.	Approved for use - added to the Formulary as second choice after Adcal-D_3®. Calfovit D3® is available as powder sachets and it may be useful for patients who have difficulty chewing tablets.	April 2005
calcium polystyrene sulphonate powder for oral/rectal suspension (Sorbisterit®) *Stanningley Pharma Ltd* 12.08.13 *SMC Report No. 890/13* PRODUCT UPDATE (abbreviated submission)	Accepted for use: calcium polystyrene sulphonate powder (Sorbisterit®) is accepted for use within NHS Scotland for the treatment of hyperkalaemia, in patients with acute and chronic renal insufficiency, including patients undergoing dialysis treatment. Sorbisterit® provides an alternative to the existing proprietary product at a lower cost. The dose of Sorbisterit® and the existing proprietary product differ as the strength of the active ingredient varies slightly.	Included on the Additional List, Specialist Use only for the indication in question.	August 2013
calci-D chewable tablets	Correction of calcium and vitamin D deficiency in the elderly and as an adjunct to specific therapy for osteoporosis	Not routinely available as local implementation plans are bring developed or the FC is waiting for further advice from local clinical experts – decision expected by 8 November 2017	August 2017
Accrete D3 film-coated tablets	Correction of calcium and vitamin D deficiency in the elderly and as an adjunct to specific therapy for osteoporosis	Not routinely available as local implementation plans are bring developed or the FC is waiting for further advice from local clinical experts – decision expected by 8 November 2017	August 2017
carglumic acid 200mg dispersible tablets (Carbaglu®) *Orphan Europe* 09.10.06 *SMC Report No. 299/06.*	Restricted use: carglumic acid (Carbaglu®) is accepted for restricted use within NHS Scotland for the treatment of hyperammonaemia due to N-acetylglutamate synthase deficiency. Limited data from retrospective case analysis indicate that carglumic acid generally allowed patients to maintain normal ammonia levels, growth and psychomotor development. Carglumic acid is restricted to use by experts providing the supraregional specialist service for this disease.	Added to the Additional List, only if initiated by specialists working in the supraregional service for this disease.	April 2008
carglumic acid 200mg dispersible tablets (Carbaglu®) *Orphan Europe (UK) Limited* 07.10.13 *SMC Report No. 899/13*	Accepted for use: carglumic acid (Carbaglu®) is accepted for use within NHS Scotland for hyperammonaemia due to isovaleric acidaemia, methylmalonic acidaemia and propionic acidaemia. The available clinical evidence for carglumic acid, although limited, suggests that plasma ammonia is reduced rapidly to non-toxic levels in life-threatening situations where rapid initiation of treatment is essential.	Not included on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion.	November 2013

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**
cholecalciferol 25,000 international units oral solution (InVita D3®) *Consilient Health Limited* 08.12.14 *SMC Report No. 1011/14* PRODUCT UPDATE (abbreviated submission)	Accepted for use: cholecalciferol oral solution (InVita D3®) is accepted for use within NHS Scotland for the prevention and treatment of vitamin D deficiency. As an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency. The therapeutic use and safety profile of cholecalciferol as a treatment for vitamin D deficiency and as an adjunctive treatment in osteoporosis is well established. InVita D3® provides a higher strength preparation than some other licensed vitamin D preparations and is licensed for use in both children and adults. At equivalent doses, it is a similar cost to other vitamin D preparations.	Included on the LJF, for the indication in question.	December 2014
colecalciferol (Dekristol®) *Jenapharm/ IDIS*	Treatment of Vitamin D deficiency and osteomalacia 	Added to the Additional List **for use in rheumatology patients**. Colecalciferol has been categorised **AMBER** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian' - General use with restrictions. Prescribing should be initiated by or on the advice of specialists.	January 2011
colecalciferol (Dekristol®) *Jenapharm/ IDIS*	Treatment of Vitamin D deficiency 	Added to the Additional List **for use in patients with HIV and Hepatitis C infection**. Colecalciferol has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian' – Specialist use only.	May 2011
colecalciferol 800 international units (equivalent to 20 micrograms vitamin D_3) capsules (Fultium-D_3®) *Internis Pharmaceuticals Limited* 10.09.12 *SMC Report No. 801/12*	Accepted for use: colecalciferol (Fultium-D3®) is accepted for use within NHS Scotland in adults, the elderly and adolescents for the prevention and treatment of vitamin D deficiency and as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency. The therapeutic use and safety profile of colecalciferol as a treatment for vitamin D deficiency and as an adjunctive treatment in osteoporosis is well established. There are no comparative data for Fultium-D3® as it is the first licensed oral vitamin D monotherapy formulation.	Included on the LJF for the indication in question.	October 2012
colecalciferol (Dekristol®) *mibe GmbH Arneimittel/IDIS*	Treatment of Vitamin D deficiency 	Added to the LJF for General Use, in line with Adult Vitamin D guidelines Colecalciferol has been categorised **GREEN** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	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**
colecalciferol (Dekristol®)	For vitamin D deficiency (vit D < 25nmol/L) in children and adolescents aged 12 to 18 years. 	Added to the LJF (Children) as a joint first choice preparation. Colecalciferol for vitamin D deficiency in children and adolescents aged 12 to 18 years has been categorised **GREEN** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	April 2014
colecalciferol 800 international units (equivalent to 20 micrograms vitamin D_3) tablets (Desunin 800 IU®) *Meda* 11.02.13 *SMC Report No. 840/13* PRODUCT UPDATE (abbreviated submission)	Accepted for use: colecalciferol tablets (Desunin 800 IU®) is accepted for use within NHS Scotland for the prevention and treatment of vitamin D deficiency in adults and adolescents. In addition to specific osteoporosis treatment of patients who are at risk of vitamin D deficiency, supplemental calcium should be considered. The therapeutic use and safety profile of colecalciferol as a treatment for vitamin D deficiency and as an adjunctive treatment in osteoporosis is well established. There are no comparative data for colecalciferol (Desunin®). It is the same cost as another vitamin D preparation.	Included on the LJF for the indication in question. Included on the LJF Child as a joint first choice drug, for the indication in question.	January 2013 May 2014
colecalciferol (Fultium D3®) 3200units *Internis* .	For the treatment of vitamin D deficiency	Added to the LJF as an alternative first choice preparation for patients who require higher dose of colecalciferol.	December 2014
colecalciferol (Desunin®) 800units (tablet)	Vitamin D supplement in Vitamin D deficient patient aged 12-18 years.	Not included on the LJF, as the LJF section includes generic colecalciferol 800units (tablets).	October 2015
colecalciferol tablets 4000units (Desunin®) Local formulary process	Treatment of vitamin D deficiency in paediatric patients with cystic fibrosis.	Routinely available in line with local or regional guidance. Included on the LJF as second choice, for Specialist initiation. Included on the LJF as second choice, for Specialist initiation, for the indication in question.	January 2017
colecalciferol (InVita®) 2,400units/ml (liquid)	Vitamin D supplement in patients aged 0-18 years who prefer a liquid daily dose.	Included on the LJF for the indication in question.	October 2015
colecalciferol (Aviticol) 20,000unit (capsule)	Treatment and supplementation of vitamin D in patient with vitamin D deficiency.	Included on the LJF for the indication in question, as generic colecalciferil 20000units capsules.	October 2015

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Complan® Shake *Complan Foods*	Oral Nutritional Supplement	Added to section 9.4 (Oral Nutritional Supplements) of the Formulary as First Choice.	April 2011
colestilan 1g film-coated tablets, 2g and 3g granules sachets (BindRen®) *Mitsubishi Tanabe Pharma Europe Ltd* 09.02.15 *SMC Report No. 939/14* INDEPENDENT REVIEW PANEL	NOT RECOMMENDED: colestilan (BindRen®) is not recommended for use within NHS Scotland for the treatment of hyperphosphataemia in adult patients with chronic kidney disease (CKD) stage 5 receiving haemodialysis or peritoneal dialysis. Colestilan, compared with placebo, reduced serum phosphorus in dialysis patients with CKD and hyperphosphataemia. Comparative data with another non-calcium-based, non-absorbed phosphate binder suggested comparable phosphorus lowering effects but non-inferiority was not demonstrated conclusively. The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by the IRP.	NOT RECOMMENDED	
DEKAs® PLUS liquid Local formulary process	As vitamin supplementation for pancreatic insufficient cystic fibrosis in paediatric patients. 	Routinely available in line with local or regional guidance. Included on the LJF as first choice, for General Use. Classified as **GREEN** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. **Included** on the LJF as first choice, General Use. Classified as **GREEN** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	March 2017
deferasirox, 125, 250, 500mg dispersible tablets (Exjade®) *Novartis Pharmaceuticals UK Limited* 12.02.07 *SMC Report No. 347/07*	Restricted use: deferasirox (Exjade®) is accepted for restricted use within NHS Scotland for the treatment of chronic iron overload associated with the treatment of rare acquired or inherited anaemias requiring recurrent blood transfusions. It is not recommended for patients with myelodysplastic syndromes. Patients with myelodysplastic syndromes, the commonest cause of transfusion-dependent anaemia, were poorly represented in the clinical trial population and the economic case was not demonstrated in this group.	Added to the LJF as a prescribing note, for Specialist Use only.	July 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**
deferasirox, 125, 250, 500mg dispersible tablets (Exjade®) *Novartis Pharmaceuticals UK Limited* 16.01.17 *SMC Report No. 347/07* RESUBMISSION	Restricted use: deferasirox (Exjade®) is accepted for restricted use within NHS Scotland for the treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate, in adult and paediatric patients aged 2 years and older with rare acquired or inherited anaemias. The current advice relates only to use in the myelodysplastic syndrome (MDS) population. SMC restriction: use in patients with MDS with an International Prognostic Scoring System (IPSS) score of low or intermediate -1 risk. Plasma ferritin levels were statistically significantly reduced from baseline to end of study in two phase II/III open-label, single-arm studies of patients with MDS with an IPSS score of low or intermediate -1 risk. SMC has previously accepted deferasirox for restricted use for the treatment of chronic iron overload associated with the treatment of rare acquired or inherited anaemias requiring recurrent blood transfusions. This advice remains valid. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.	May 2017
deferasirox (Exjade®) 125mg, 250mg and 500mg dispersible tablets *Novartis Pharmaceuticals UK Ltd* 08.04.13 *SMC Report No. 866/13* NON SUBMISSION	NOT RECOMMENDED: deferasirox (Exjade®) is not recommended for use within NHS Scotland for the treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients with non-transfusion-dependent thalassaemia syndromes aged 10 years and older. 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	
deferasirox 90mg, 180mg and 360mg film-coated tablets (Exjade®) *Novartis Pharmaceuticals UK Limited* 12.06.17 *SMC Report No. 1246/17* PRODUCT UPDATE (abbreviated submission)	• Treatment of chronic iron overload due to frequent blood transfusions (≥7mL/kg/month of packed red blood cells) in patients with beta thalassaemia major aged 6 years and older. • Treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate in the following patient groups: o in paediatric patients with beta thalassaemia major with iron overload due to frequent blood transfusions (≥7mL/kg/month of packed red blood cells) aged 2 to 5 years, o in adult and paediatric patients with beta thalassaemia major with iron overload due to infrequent blood transfusions (<7mL/kg/month of packed red blood cells) aged 2 years and older, o in adult and paediatric patients with other anaemias aged 2 years and older. SMC restriction: deferasirox film-coated tablets are restricted to use as for the SMC advice issued for deferasirox dispersible tablets (No.347/07).	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.	May 2017

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eculizumab 300mg concentrate for solution for infusion (Soliris®) *Alexion Pharma UK Ltd* 08.11.10 *SMC Report No. 436/07*	NOT RECOMMENDED: eculizumab (Soliris®) is not recommended for use within NHS Scotland. Indication under review: for the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH). Evidence of clinical benefit of eculizumab in the treatment of patients with PNH is limited to patients with a history of transfusions. In a controlled study in patients with transfusion-dependent PNH, eculizumab reduced the rate of haemolysis and improved anaemia compared to placebo. Uncontrolled data suggest that eculizumab reduces the incidence of thrombosis in patients with PNH. The manufacturer did not supply any health economic analysis and cost-effectiveness was not demonstrated in an independent economic analysis therefore eculizumab cannot be recommended for use within NHS Scotland.	NOT RECOMMENDED	
eculizumab (Soliris®) 300 mg concentrate for solution for infusion *Alexion Pharma UK Ltd* 08.02.16 *SMC Report No. 767/12*	NOT RECOMMENDED: eculizumab (Soliris®) is not recommended for use within NHS Scotland. Indication under review: in adults and children for the treatment of patients with atypical haemolytic uraemic syndrome (aHUS). Four phase II, open-label, single-arm studies demonstrated the beneficial treatment effect of eculizumab on haematological parameters, renal function and thrombotic microangiopathy events. The submitting company did not present a sufficiently robust economic analysis and in addition their justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	NOT RECOMMENDED	
eculizumab (Soliris®) 300 mg concentrate for solution for infusion *Alexion Pharma UK Ltd* 09.09.13 *SMC Report No. 915/13* NON SUBMISSION	NOT RECOMMENDED: eculizumab (Soliris®) is not recommended for use within NHS Scotland in children for the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH). Evidence of clinical benefit of Soliris in the treatment of patients with PNH is limited to patients with history of transfusions. 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	

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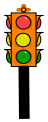
eculizumab 300mg/30mL vial concentrate for solution for infusion (Soliris®) *Alexion Pharma UK* 11.04.16 *SMC Report No. 1130/16*	NOT RECOMMENDED: eculizumab (Soliris®) is not recommended for use within NHS Scotland. Indication under review: In adults and children, for the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH). Evidence of clinical benefit is demonstrated in patients with haemolysis with clinical symptom(s) indicative of high disease activity, regardless of transfusion history. In a controlled study in patients with transfusion-dependent PNH, eculizumab reduced the rate of haemolysis and improved anaemia compared with placebo. Observational data from a subset of the PNH registry suggest that these benefits may also be achieved in patients with no history of transfusions. Uncontrolled data suggest that eculizumab reduces the incidence of thrombosis in patients with PNH. The submitting company did not present a sufficiently robust economic analysis and in addition their justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	NOT RECOMMENDED	
elosulfase alfa, 1mg/mL concentrate for solution for infusion (Vimizim®) *Biomarin Europe Limited* 07.09.15 *SMC Report No. 1072/15*	NOT RECOMMENDED: elosulfase alfa (Vimizim®) is not recommended for use within NHS Scotland. Indication under review: treatment of mucopolysaccharidosis, type IVA (Morquio A Syndrome, MPS IVA) in patients of all ages. In a double-blind placebo-controlled study the difference from baseline in the mean distance walked in the 6-minute walking test was significantly longer for elosulfase alfa, given weekly, than placebo at week 24. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition the company did not present a sufficiently robust economic analysis to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician and Engagement (PACE) meeting.	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**
eltrombopag, 25mg and 50mg film-coated tablets (Revolade®) *GlaxoSmithKline UK* 09.08.10 *SMC Report No. 625/10*	Restricted use: eltrombopag (Revolade®) is accepted for restricted use within NHS Scotland. Indication under review: Eltrombopag is indicated for adult chronic immune (idiopathic) thrombocytopenic purpura (ITP) splenectomised patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Eltrombopag may be considered as second-line treatment for adult non splenectomised patients where surgery is contraindicated. SMC restriction: in both the splenectomised and non-splenectomised patient populations, restricted to use in patients with severe symptomatic ITP or a high risk of bleeding. Eltrombopag has been shown to be significantly more effective than placebo in raising and maintaining platelet counts at (or above) a minimum target level in previously treated patients with ITP.	Added to the Additional List, for Specialist Use only.	November 2011
eltrombopag (Revolade®) *GlaxoSmithKline UK*	For peri-operative bridging in non-splenectomised patients with a diagnosis of immune thrombocytopenic purpura. 	Added to the Additional List, for Specialist Use only. Eltrombopag (Revolade®) has been categorised **RED** under the ADTC 'Policy and procedures for the use of unlicensed medicines'.	November 2014
eltrombopag olamine (Revolade®) 25 mg / 50 mg film-coated tablets *Novartis Pharmaceuticals UK Ltd* 13.06.16 *SMC Report No. 1164/16* NON SUBMISSION	NOT RECOMMENDED: eltrombopag olamine (Revolade®) is not recommended for use within NHS Scotland for the treatment in adult patients with acquired severe aplastic anaemia (SAA) who were either refractory to prior immunosuppressive therapy or heavily pretreated and are unsuitable for haematopoietic stem cell transplantation. 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	

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**
epoetin alfa 1,000 IU/0.5mL, 2,000 IU/1mL, 3,000 IU/0.3mL, 4,000 IU/0.4mL, 5,000 IU/0.5mL, 6,000 IU/0.6mL, 7,000 IU/0.7mL, 8,000 IU/0.8mL, 9,000 IU/0.9mL, 10,000 IU/1mL, solution for injection in prefilled syringe (Binocrit®) *Sandoz Ltd* 08.02.10 *SMC Report No. 597/10*	Accepted for use: epoetin alfa (Binocrit®) is accepted for use within NHS Scotland for: • treatment of symptomatic anaemia associated with chronic renal failure in adult and paediatric patients: • treatment of anaemia associated with chronic renal failure in paediatric and adult patients on haemodialysis and adult patients on peritoneal dialysis; • treatment of severe anaemia of renal origin accompanied by clinical symptoms in adult patients with renal insufficiency not yet undergoing dialysis. Binocrit® can be used to increase the yield of autologous blood from patients in a predonation programme. Its use in this indication must be balanced against the reported risk of thromboembolic events. Treatment should only be given to patients with moderate anaemia (haemoglobin 10 to 13g/dL [6.2 to 8.1 mmol/L], no iron deficiency), if blood saving procedures are not available or insufficient when the scheduled major elective surgery requires a large volume of blood (4 or more units of blood for females or 5 or more for males). Epoetin alfa (Binocrit®) is a biosimilar product and has demonstrated equivalency in terms of efficacy and safety to a reference product (epoetin alfa (Eprex®)). Unlike some other erythropoiesis stimulating agents, Binocrit® is only licensed for administration by the intravenous route in the indications under review. The British National Formulary advises that it is good practice to prescribe biological medicinal products by brand name.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	May 2011
epoetin delta, for injection (Dynepo®) *Shire Pharmaceuticals Ltd* 12.11.07 *SMC Report No. 418/07*	Accepted for use: epoetin delta (Dynepo®) is accepted for use within NHS Scotland for the treatment of anaemia in patients with chronic renal failure. It may be used in patients on dialysis and in patients not on dialysis. Clinical studies have demonstrated epoetin delta's efficacy and safety profile in correcting and maintaining haemoglobin levels for up to a year in predialysis, haemodialysis and peritoneal dialysis patients, when administered via both the subcutaneous and intravenous routes.	'Not preferred' as suitable alternatives exist.	May 2009 PRODUCT WITHDRAWN FROM THE MARKET
epoetin theta, 1,000 IU/0.5mL, 2,000 IU/0.5mL, 3,000 IU/0.5mL, 4,000 IU/0.5mL, 5,000 IU/0.5mL, 10,000 IU/1mL, 20,000 IU/1mL, 30,000 IU/1mL solution for injection in pre filled syringe (Eporatio®) *Ratiopharm UK Limited* 12.07.10 *SMC Report No. 620/10*	Accepted for use within NHS Scotland for the treatment of symptomatic anaemia associated with chronic renal failure in adult patients. Epoetin theta demonstrated non-inferiority to another erythropoietin analogue in maintaining stable haemoglobin levels in renal failure associated anaemia both in patients not yet receiving dialysis (subcutaneous route) and in those receiving haemodialysis (intravenous route). The British National Formulary advises that it is good practice to prescribe biological medicinal products by brand name. Other erythropoietin stimulating agents are available at lower cost.	'Not Preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	March 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**
epoetin zeta, 1000 IU/0.3ml, 2000 IU/0.6ml, 3000 IU/0.9ml, 4000 IU/0.4ml, 5000 IU/0.5ml, 6000 IU/0.6ml, 8000 IU/0.8ml, 10,000 IU/1.0ml, 20,000 IU/0.5ml, 30,000 IU/0.75ml and 40,000 IU/1ml solution for injection in pre-filled syringe (Retacrit®) *Hospira UK Limited* 09.06.08 *SMC Report No. 467/08*	Accepted for use: epoetin zeta (Retacrit®) is accepted for use within NHS Scotland for treatment of anaemia associated with chronic renal failure in adult and paediatric patients on haemodialysis and adult patients on peritoneal dialysis and for treatment of severe anaemia of renal origin accompanied by clinical symptoms in adult patients with renal insufficiency not yet undergoing dialysis. Clinical studies in adult haemodialysis patients have demonstrated equivalence in correcting and maintaining haemoglobin levels when compared to another erythropoiesis stimulating agent (ESA). Unlike other ESAs, epoetin zeta is only licensed for administration by the intravenous route.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	November 2009
ergocalciferol (Sterogyl®) *Desma Pharma*	For vitamin D deficiency (vit D < 25nmol/L) in children and adolescents aged 12 to 18 years. 	Added to the LJF (Children) as a joint first choice preparation. Ergocalciferol for vitamin D deficiency in children and adolescents aged 12 to 18 years has been categorised **GREEN** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	April 2014
febuxostat 80mg and 120mg tablets (Adenuric®) *Menarini Pharma UK SRL* 13.09.10 *SMC Report No. 637/10*	Restricted use: febuxostat (Adenuric®) is accepted for restricted use within NHS Scotland. Indication under review: Treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history, or presence, of tophus and/or gouty arthritis). SMC restriction: when treatment with allopurinol is inadequate, not tolerated or contra-indicated. Febuxostat is superior to allopurinol 300mg daily in reducing serum uric acid to <6mg/dL, (360micromol/L) in patients with hyperuricaemia and gout. (NB The maximum licensed daily dose of allopurinol is 900mg.) The economic case was demonstrated for second line use of febuxostat in patients who had an inadequate response to allopurinol, or when allopurinol is contraindicated or not tolerated.	Added to the Formulary as second choice. A prescribing note added for prescribing in relation to allopurinol.	December 2010

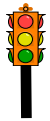
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
ferric carboxymaltose 50mg iron/mL solution for injection/infusion (Ferinject®) *Syner-Med (PP) Ltd* 13.06.11 *SMC Report No 463/08* 2nd RESUBMISSION	Restricted use: ferric carboxymaltose (Ferinject®) is accepted for restricted use within NHS Scotland. Indication under review: the treatment of iron deficiency when oral iron preparations are ineffective or cannot be used. The diagnosis must be based on laboratory tests. SMC restriction: use is restricted to administration by intravenous infusion within the licensed indication but excluding use in patients receiving haemodialysis. The manufacturer's economic case did not consider the cost-effectiveness of iv bolus administration or use in haemodialysis patients. Ferric carboxymaltose was superior to oral ferrous sulphate in raising haemoglobin levels in non-dialysis-dependent patients with chronic kidney disease and iron deficiency anaemia.	Included on the LJF as an equal first choice drug, for Specialist Use only, for the indication in question, for the use in GI and Haematology patients only. Included on the LJF for paediatrics in GI patients.	November 2013 March 2015
ferric maltol 30mg hard capsules (Feraccru®) *Shield TX UK Limited* 12.12.16 *SMC Report No 1202/16*	NOT RECOMMENDED: ferric maltol (Feraccru®) is not recommended for use within NHS Scotlandin adults for the treatment of iron deficiency anaemia (IDA) in patients with inflammatory bowel disease (IBD). In a pooled analysis of two phase III studies in IBD patients with IDA who had failed previous treatment with oral ferrous products, there was a significantly greater increase in haemoglobin concentrations after 12 weeks of ferric maltol treatment compared with placebo. The submitting company did not present sufficiently robust clinical and economic analyses to gain acceptance by SMC.	NOT RECOMMENDED	
ferumoxytol, 30mg/mL solution for injection (Rienso®) *Takeda UK Limited* 11.02.13 *SMC Report No 833/13*	Restricted use: ferumoxytol (Rienso®) is accepted for restricted use within NHS Scotland for intravenous treatment of iron deficiency anaemia in adult patients with chronic kidney disease. SMC restriction: treatment of iron deficiency anaemia in non-haemodialysis dependent adult patients with chronic kidney disease when oral iron preparations are ineffective or cannot be used. In two phase III studies the mean increase from baseline in haemoglobin was significantly higher for ferumoxytol than oral iron in non-haemodialysis dependent patients with chronic kidney disease. A mixed treatment comparison demonstrated equivalent efficacy outcomes for ferumoxytol versus a range of intravenous iron preparations.	Not included on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion.	March 2013 VOLUNTARILY WITHDRAWN FROM THE MARKET

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**
filgrastim, 30 million units (300 microgram)/0.5mL and 48 million units (480 microgram)/0.8mL, prefilled syringe containing solution for injection or infusion (Ratiograstim®) *Ratiopharm UK Ltd* 09.11.09 *SMC Report No: 577/09*	Accepted for use: filgrastim (Ratiograstim®) is accepted for use within NHS Scotland for: Reduction in the duration of neutropenia and the incidence of febrile neutropenia (FN) in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes). Reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia. Mobilisation of peripheral blood progenitor cells (PBPC). As long term administration, to increase neutrophil counts and to reduce the incidence and duration of infection-related events in children or adults with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of 0.5 x 109/L, and a history of severe or recurrent infections. For the treatment of persistent neutropenia (ANC less than or equal to 1.0 x 109/L) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate. Filgrastim (Ratiograstim®) is a biosimilar product and has demonstrated equivalency in terms of efficacy and safety to a reference granulocyte colony stimulating factor (filgrastim (Neupogen®)). The British National Formulary advises that it is good practice to prescribe biological medicinal products by brand name.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	May 2011
filgrastim, 30 million units (300 microgram)/0.5mL and 48 million units (480 microgram)/0.8mL, prefilled syringe containing solution for injection or infusion (TevaGrastim®) *Teva UK Limited* 09.08.10 *SMC Report No. 629/10* PRODUCT UPDATE (abbreviated submission)	Accepted for use: filgrastim (TevaGrastim®) is accepted for use within NHS Scotland. Indications under review: • Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes); • Reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia; • Mobilisation of peripheral blood progenitor cells (PBPC); • In patients, children or adults, with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of < 0.5 x 109/L, and a history of severe or recurrent infections, long term administration is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events; • For the treatment of persistent neutropenia (ANC less than or equal to 1.0 x 109/L) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate. Filgrastim (TevaGrastim®) is a follow on biosimilar product. It is manufactured at the same production site and is identical to the biosimilar product filgrastim (Ratiograstim®), previously accepted for use by SMC. The British National Formulary advises that it is good practice to prescribe biological medicinal products by brand name.	'Not preferred' in Lothian as suitable alternatives exist.	August 2010

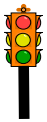
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
filgrastim 12 million units (120microgram) / 0.2mL, 30 million units (300microgram) / 0.5mL, 48 million units (480microgram) / 0.5mL solution for injection/infusion in pre-filled syringe (Nivestim®) *Hospira UK limited* 14.01.11 SMC Report No. 671/11	Accepted for use: filgrastim (Nivestim®) is accepted for use within NHS Scotland. Indications under review: The reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes); Reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia; The mobilisation of peripheral blood progenitor cells (PBPC); In patients, children or adults, with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of £ 0.5 x 109/l and a history of severe or recurrent infections, long term administration of filgrastim is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events; The treatment of persistent neutropenia (ANC less than or equal to 1.0 x 109/l) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other options to manage neutropenia are inappropriate. Filgrastim (Nivestim®) is a biosimilar product and has demonstrated equivalence in terms of efficacy and safety to a reference granulocyte colony stimulating factor, filgrastim (Neupogen®). The British National Formulary advises that it is good practice to prescribe biological medicinal products by brand name.	''Not preferred' in Lothian as suitable alternatives exist.	March 2012
filgrastim, 30 million units (300 micrograms)/0.5mL, 48 million units (480 micrograms)/0.5mL, solution for injection or infusion in pre-filled syringe (Zarzio®) *Sandoz Ltd* 13.06.11 *SMC Report No. 704/11*	Accepted for use: filgrastim (Zarzio®) is accepted for use within NHS Scotland. Indications under review: • Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia. The safety and efficacy of filgrastim are similar in adults and children receiving cytotoxic chemotherapy. • Mobilisation of peripheral blood progenitor cells (PBPC). • In children and adults with severe congenital, cyclic, or idiopathic neutropenia with an absolute neutrophil count (ANC) of≤ 0.5 x 109/l, and a history of severe or recurrent infections, long term administration of filgrastim is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events. • Treatment of persistent neutropenia (ANC≤ 1.0 x 109/l) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other therapeutic options are inappropriate. Filgrastim (Zarzio®) is a biosimilar product to a reference granulocyte colony stimulating factor, filgrastim (Neupogen®). The British National Formulary advises that it is good practice to prescribe biological medicinal products by brand name. Other granulocyte colony stimulating factor products are available at lower cost.	''Not preferred' in Lothian as suitable alternatives exist.	March 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**
hydroxycarbamide (Siklos®) *Nordic Pharma UK* 12.10.09 *SMC Report No. 582/09* NON SUBMISSION	NOT RECOMMENDED: hydroxycarbamide (Siklos®) is not recommended for use within NHSScotland for the prevention of recurrent painful vaso-occlusive crises including acute chest syndrome in paediatric and adult patients suffering from symptomatic Sickle Cell 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	
ibandronic acid (Bondronat®) HCM *Roche* 11.10.04 *SMC Report No. 122/04*	Accepted for use: ibandronic acid is accepted for use within NHS Scotland for the treatment of tumour-induced hypercalcaemia with or without metastases. It has been shown to be a cost effective option in reducing serum calcium in patients with hypercalcaemia of malignancy.	Added to the Formulary.	February 2005
idursulfase 2mg/mL concentrate for solution for infusion (Elaprase®) *Shire HGT UK Ltd* 13.08.07 *SMC Report No. 391/07*	NOT RECOMMENDED: idursulfase (Elaprase®) is not recommended for use within NHS Scotland for the long-term treatment of patients with Hunter syndrome (Mucopolysaccharidosis II, MPS II). Idursulfase was approved by the EMEA under exceptional circumstances and has been designated an orphan medicinal product. The manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC and, in addition, they did not present a sufficiently robust economic analysis.	NOT RECOMMENDED	
iron isomaltoside 1000, 100mg/mL solution for injection/infusion (Monofer®) *Pharmacosmos UK* 09.05.11 *SMC Report No. 697/11*	Restristed use: iron isomaltoside 1000 (Monofer®) is accepted for restricted use within NHS Scotland. Indication under review: Treatment of iron deficiency anaemia in the following conditions: • When oral iron preparations are ineffective or cannot be used; • Where there is a clinical need to deliver iron rapidly. SMC restriction: use is restricted to administration by high dose infusion within the licensed indication but excluding use in patients receiving haemodialysis. The manufacturer's economic case did not consider the cost-effectiveness of iv bolus administration or use in haemodialysis patients. Efficacy data are limited to two small open-label non comparative studies in patients with chronic kidney disease and chronic heart failure. Haemoglobin levels significantly increased from baseline in one study only.	Included on Lothian Joint Formulary for the indication in question. Added to the LJF as a first choice drug. Specialist Use only, Restricted to Renal and Reproductive Medicine patient groups only	May 2012 November 2013

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**
iron (III) isomaltoside 1000 (contains 50mg iron per mL) (Diafer®) solution for injection *Pharmacosmos UK Limited* 13.02.17 *SMC Report No. 1177/16* RESUBMISSION Patient Access Scheme	Accepted for use: iron III isomaltoside 1000 5% (Diafer®) is accepted for use within NHS Scotland for the treatment of iron deficiency in adults with chronic kidney disease (CKD) on dialysis, when oral iron preparations are ineffective or cannot be used. Iron III isomaltoside 1000 at a higher (10%) concentration has been shown to be non-inferior to another intravenous iron product in maintaining haemoglobin concentration in adult patients with CKD who are iron deficient and are receiving haemodialysis. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of iron III isomaltoside 1000 5%. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	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. Not included on the LJF because clinicians do not support the formulary inclusion.	March 2017
lanthanum carbonate 500, 750, 1000mg chewable tablets (Fosrenol®) *Shire Pharmaceuticals Contract Ltd* 07.05.07 *SMC Report No. 286/06*	Restricted use: Lanthanum carbonate (Fosrenol®) is accepted for restricted use within NHS Scotland as a phosphate-binding agent for use in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or continuous ambulatory peritoneal dialysis. Lanthanum carbonate is as effective as calcium carbonate in reducing phosphate to target levels. It is restricted to use as a second-line agent in patients where a non-aluminium, non-calcium phosphate binder is required.	Added to the Additional List for use in the control of hyperphosphataemia in chronic renal failure after calcium-based binders and sevelamer.	March 2008
lanthanum carbonate, 500mg, 750mg, 1,000mg, chewable tablets (Fosrenol®) *Shire Pharmaceuticals Ltd* 11.10.10 *SMC Report No. 640/10*	NOT RECOMMENDED: lanthanum carbonate (Fosrenol®) is not recommended for use within NHS Scotland. Indication under review: as a phosphate binding agent for use in the control of hyperphosphataemia in adult patients with chronic kidney disease not on dialysis with serum phosphate levels ≥1.78mmol/L in whom a low phosphate diet alone is insufficient to control serum phosphate levels. When compared with placebo, in patients with chronic kidney disease not yet on dialysis, more patients treated with lanthanum carbonate achieved a serum phosphate concentration ≤1.49mmol/L. The manufacturer did not present a sufficiently robust clinical or economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
lanthanum carbonate 750mg and 1000mg oral powder (Fosrenol®) *Shire Pharmaceuticals Contracts Ltd* 10.12.12 *SMC Report No. 821/12* PRODUCT UPDATE (abbreviated submission)	Restricted use: lanthanum carbonate oral powder (Fosrenol®) is accepted for restricted use in NHS Scotland as a phosphate binding agent for use in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or continuous ambulatory peritoneal dialysis (CAPD). Lanthanum is also indicated in adult patients with chronic kidney disease not on dialysis with serum phosphate levels ≥ 1.78 mmol/L in whom a low phosphate diet alone is insufficient to control serum phosphate levels. SMC restriction: as a second-line agent in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or CAPD where a non-aluminium, non-calcium phosphate binder is required. Lanthanum carbonate is as effective as calcium carbonate in reducing phosphate to target levels.	Included on the Additional List for the indication in question.	December 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**
laronidase (Aldurazyme®) *Genzyme* 13.12.04 *SMC Report No. 100/04* RESUBMISSION	NOT RECOMMENDED: laronidase is not recommended for use within NHS Scotland for the treatment of Mucopolysaccharidosis I. Laronidase was approved by the EMEA under exceptional circumstances and has been granted orphan drug status. No information is presented in the submission to support the therapy being cost effective.	NOT RECOMMENDED	
lenalidomide 2.5mg, 5mg, and , 10mg, hard capsules (Revlimid®) *Celgene Ltd* 10.03.14 *SMC Report No. 942/14*	Accepted for use: lenalidomide (Revlimid®) is accepted for use within NHS Scotland for the treatment of patients with transfusion-dependent anaemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate. Lenalidomide therapy significantly increased the proportion of patients achieving sustained red blood cell transfusion independence compared with best supportive care. However, there was no significant improvement in overall survival.	Included on the Additional List, for Specialist Use only, for the indication in question.	April 2014
magnesium aspartate 2.5mmol tablets	Suitable for use for children who cannot tolerate Magnaspartate sachets. 	Included on the additional list, as **RED** under the ADTC 'Policy and procedures for the use of unlicensed medicines' – specialist use only.	July 2015
magnesium aspartate dihydrate equivalent to 243mg (10mmol) of magnesium powder for oral solution (Magnaspartate®) *Kora Corporation Limited* 08.06.15 *SMC Report No. 1042/15* PRODUCT UPDATE (abbreviated submission)	Accepted for use: magnesium aspartate dihydrate (Magnaspartate®) is accepted for use within NHS Scotland. Indication under review: for the treatment and prevention of magnesium deficiency, as diagnosed by a doctor This is the first licensed oral magnesium product to be available in the UK for the treatment and prevention of magnesium deficiency. Magnesium supplementation has previously been available as a food supplement.	Included on the LJF for the indication in question.	July 2015
magnesium glycerophosphate 4mmol chewable tablet (Neomag®) *Neoceuticals Ltd* 11.09.17 *SMC Report No 1267/17* PRODUCT UPDATE (abbreviated submission)	Accepted for use within NHS Scotland. Indication under review: as an oral magnesium supplement for the treatment of patients with chronic magnesium loss or hypomagnesaemia as diagnosed by a doctor. Magnesium glycerophosphate is also indicated for adult patients with hypomagnesaemia due to the concomitant administration of loop and thiazide diuretics or other drugs which cause hypomagnesaemia. Unlicensed tablet formulations of magnesium glycerophosphate have been used in the NHS in Scotland. This product provides a licensed preparation at a similar cost.	Routinely available in line with national guidance. Included in the Lothian Joint Formulary.	August 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**
methoxy polyethylene glycol-epoetin beta, for injection (Mircera®) *Roche* 07.04.08 *SMC Report No. 455/08*	Accepted for use: methoxy polyethylene glycol-epoetin beta (Mircera®) is accepted for use within NHS Scotland for treatment of anaemia associated with chronic kidney disease. Clinical studies have demonstrated the efficacy of methoxy polyethylene glycol-epoetin beta in correcting and maintaining haemoglobin levels for up to a year in dialysis patients, when administered by either the subcutaneous or intravenous route. Non-inferiority to other erythropoiesis stimulating agents, with respect to achieving and maintaining haemoglobin levels, was demonstrated.	Added to LJF as a prescribing note.	March 2010
migalastat, 123mg hard capsules (Galafold®) *Amicus Therapeutics* 07.11.16 *SMC Report No. 1196/16* Patient Access Scheme	Restricted use: migalastat (Galafold®) is accepted for restricted use within NHS Scotland for long-term treatment of adults and adolescents aged 16 years and older with a confirmed diagnosis of Fabry disease (α-galactosidase A deficiency) and who have an amenable mutation. SMC restriction: in males with classic mutations (leucocyte enzyme activity <1%) treatment should commence at diagnosis; in females and those males with later onset mutations with higher levels of leucocyte enzyme activity, treatment should commence when patients experience uncontrolled pain, evidence of renal, cardiac or neurovascular disease, or gastrointestinal symptoms that significantly reduce quality of life. In an 18-month, randomised, phase III study, migalastat was comparable to enzyme replacement therapy, measured by mean annualised rate of change in glomerular filtration rate. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of migalastat. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	Not included on the LJF, pending protocol.	December 2016
miglustat (Zavesca®) *Actelion* 13.12.04 *SMC Report No. 133/04*	Accepted for use: miglustat is accepted for use within NHS Scotland for the treatment of mild to moderate type 1 Gaucher disease in patients for whom enzyme replacement therapy is unsuitable. Miglustat should only be initiated by physicians experienced in the management of Gaucher's disease.	Added to the Additional List, to be prescribed and dispensed by secondary care Specialists only.	January 2005
miglustat (Zavesca®)100 mg hard capsules *Actelion Pharmaceuticals UK Ltd* 13.07.10 *SMC Report No. 632/10* NON SUBMISSION	NOT RECOMMENDED: miglustat (Zavesca®) is not recommended for use within NHSScotland for the treatment of progressive neurological manifestations in adult patients and paediatric patients with Niemann-Pick type C disease. 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	

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**
multivitamin (vitamin A, D, E and K) supplement (AquADEKs) *Aptalis*	Supplement of fat-soluble vitamins for children with Cystic Fibrosis. 	Included on the LJF. Multivitamin (vitamin A, D, E and K) supplement (AquADEKs) has been categorised as **GREEN** – unrestricted general use – under the ADTC 'Policy for the use of unlicensed (and off label use) Medicines in NHS Lothian'.	November 2015
Nutilis Clear oral powder Local formulary process	Nutritional supplement.	Routinely available in line with local or regional guidance. Included on the LJF as a prescribing note, for Specialist initiation.	May 2017
paricalcitol 5micrograms/mL and 10micrograms/2mL solution for injection (Zemplar®) *Abbott Laboratories* 07.07.08 *SMC Report No. 288/06* RESUBMISSION	NOT RECOMMENDED: paricalcitol (Zemplar®) is not recommended for use within NHS Scotland for the prevention and treatment of secondary hyperparathyroidism in patients with chronic renal failure undergoing haemodialysis. The benefits and adverse effects of paricalcitol are similar to another vitamin D analogue with which it has been compared. The economic case has not been demonstrated.	NOT RECOMMENDED.	
paricalcitol, capsules 1,2 and 4 micrograms (Zemplar®) *Abbott Laboratories* 07.07.08 *SMC Report No. 478/08*	NOT RECOMMENDED: paricalcitol capsules 1, 2 and 4 micrograms (Zemplar®) are not recommended for use within NHS Scotland for the prevention and treatment of secondary hyperparathyroidism associated with chronic renal insufficiency (chronic kidney disease [CKD] Stages 3 and 4) patients and chronic renal failure (CKD Stage 5) patients on haemodialysis or peritoneal dialysis. The benefits and adverse effects of paricalcitol capsules compared to other vitamin D analogues have not directly been assessed. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
pegfilgrastim (Neulasta®) *Amgen Ltd* 13.10.03 *SMC Report No. 67/03*	Restricted use: This sustained release formulation of filgrastim can be used for reducing the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy within the context of current practice guidelines. For malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes). Pegfilgrastim is a pegylated form of colony stimulating factor (CSF), with a sustained duration of action allowing administration once per chemotherapy cycle. It has benefits of convenience for patients and staff.	Added to the Additional List, for Specialist Use only.	September 2004
rituximab (Mabthera®) *Roche*	Acquired Haemophilia. 	Added to the Additional List, for Specialist Use only. Rituximab (Mabthera®) for the treatment of acquired haemophilia has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	July 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**
rituximab (Mabthera®) *Roche*	Immune Thrombocytopenia. 	Added to the Additional List, for Specialist Use only. Rituximab (Mabthera®) for the treatment of immune thrombocytopenia has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	July 2012
romiplostim, 250 microgram vial of powder for solution for subcutaneous injection (Nplate®) *Amgen* 12.10.09 *SMC Report No. 553/09*	Restricted use: romiplostim (Nplate®) is accepted for restricted use within NHS Scotland for adult chronic immune (idiopathic) thrombocytopenic purpura (ITP) splenectomised patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Romiplostim is also accepted for restricted use as second line treatment for adult non-splenectomised patients where surgery is contra-indicated. Romiplostim is restricted to use in patients with severe symptomatic ITP or patients with a high risk of bleeding. Romiplostim was significantly better than placebo in maintaining platelets at (or above) a minimum target level in previously treated patients with ITP.	'Not preferred' in Lothian as suitable alternatives exist.	November 2011
sapropterin (Kuvan®) 100mg soluble tablets *Merck Serono* 08.06.09 *SMC Report No. 558/09* NON SUBMISSION	NOT RECOMMENDED: sapropterin (Kuvan®) is not recommended for use within NHSScotland for the treatment of hyperphenylalaninaemia (HPA) in adult and paediatric patients with phenylketonuria (PKU) and for the treatment of hyperphenylalaninaemia (HPA) in adult and paediatric patients with tetrahydrobiopterin (BH4) deficiency. 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	
sevelamer hydrochloride, 800mg tablets (Renagel®) *Genzyme Therapeutics Ltd* 10.12.07 *SMC Report No. 423/07*	NOT RECOMMENDED: sevelamer (Renagel®) is not recommended for use within NHS Scotland for control of hyperphosphataemia in adult patients receiving peritoneal dialysis. It was non-inferior to a calcium-based phosphate binder in reducing serum phosphate and was associated with a lower rate of hypercalcaemia. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	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**
sevelamer carbonate, 800mg film-coated tablets and 2.4g of anhydrous powder for oral suspension (Renvela®) *Genzyme Therapeutics Limited* 11.04.11 *SMC Report No. 641/10* RESUBMISSION PRODUCT UPDATE (abbreviated submission)	Restricted Use: sevelamer carbonate (Renvela®) is accepted for restricted use within NHS Scotland. Indication under review: for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis. SMC restriction: the second-line management of hyperphosphataemia in adult patients receiving haemodialysis. Sevelamer carbonate has been shown to be therapeutically equivalent to sevelamer hydrochloride in reducing serum phosphorus in patients with chronic kidney disease on haemodialysis. For patients in whom sevelamer hydrochloride is an appropriate choice of phosphate binder, the carbonate salt provides an alternative at no additional cost. Sevelamer carbonate is also indicated for the control of hyperphosphataemia in adult patients with chronic kidney disease not on dialysis with serum phosphorus ≥1.78 mmol/L. As the manufacturer's submission related only to the control of hyperphosphataemia in adult patients receiving haemodialysis SMC cannot recommend the use of sevelamer carbonate in pre-dialysis patients or in peritoneal dialysis patients.	Added to the Additional List, for Specialist Initiation in haemodialysis patients	April 2011
sodium bicarbonate 1mmol/ml	Treatment in chronic acidotic states.	Included on the childrens LJF as first choice for the indication in question.	October 2015
sodium Chloride 1mmol/mL oral solution	Sodium supplementation in infants with cystic fibrosis and in other paediatric specialities for sodium depletion	Included on the LJF as first choice, specialist initiation, for the indication in question	March 2016
sodium phenylbutyrate granules 483mg/g (Pheburane®) *Lucane Pharma* 11.11.13 *SMC Report No. 914/13* PRODUCT UPDATE (abbreviated submission)	Accepted for use: sodium phenylbutyrate granules (Pheburane®) are accepted for use within NHS Scotland as adjunctive therapy in the chronic management of urea cycle disorders, involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase. It is indicated in all patients with neonatal-onset presentation (complete enzyme deficiencies, presenting within the first 28 days of life). It is also indicated in patients with late-onset disease (partial enzyme deficiencies, presenting after the first month of life) who have a history of hyperammonaemic encephalopathy. Sodium phenylbutyrate granules (Pheburane®) provide an alternative to sodium phenylbutyrate tablets at no additional cost but are more expensive than an existing brand of sodium phenylbutyrate granules.	Included on the Additional List, for the indication in question.	November 2013
sucroferric oxyhydroxide 500mg chewable tablets (Velphoro®) *Fresenius Medical Care (UK) Ltd.* 13.04.15 *SMC Report No. 1035/15*	Accepted for use: sucroferric oxyhydroxide (Velphoro®) is accepted for use within NHS Scotland for the control of serum phosphorus levels in adult chronic kidney disease (CKD) patients on haemodialysis (HD) or peritoneal dialysis (PD). It should be used within the context of a multiple therapeutic approach, which could include calcium supplement, 1,25-dihydroxy vitamin D3 or one of its analogues, or calcimimetics to control the development of renal bone disease. After 12 weeks, sucroferric oxyhydroxide was non-inferior to a non-calcium, non-aluminium-based phosphate binder at lowering serum phosphorus levels in adults with CKD, receiving HD or PD.	Included on the Additional List, Specialist initiation, for the indication in question.	May 2015

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**
TachoSil® medicated sponge *Nycomed* 12.02.07 *SMC Report No. 344/07*	Accepted for use: TachoSil® medicated sponge is accepted for use within NHS Scotland for supportive treatment in surgery for improvement of haemostasis where standard techniques are insufficient. In addition to the previous SMC advice for TachoSil® use in liver surgery the economic case for renal surgery has also now been demonstrated.	New indication for a drug already included in Formulary.	April 2008
TachoSil® sponge (9.5cm x 4.8cm) containing fibrinogen 5.5mg and thrombin 2iu per cm^2 *Nycomed* 09.05.05 *SMC Report No. 168/05*	Accepted for use: TachoSil® is accepted for use within NHS Scotland for the improvement of haemostasis in liver surgery where standard techniques are insufficient.	Added to the Additional List, for Specialist Use only	August 2005
tocofersolan, 50mg/mL (corresponding to 74.5 IU tocopherol) oral solution (Vedrop®) *Orphan Europe UK* 08.10.12 *SMC Report No. 696/11* RESUBMISSION	NOT RECOMMENDED: tocofersolan oral solution (Vedrop®) is not recommended for use within NHS Scotland for vitamin E deficiency due to digestive malabsorption in paediatric patients suffering from congenital chronic cholestasis or hereditary chronic cholestasis, from birth (in term newborns) to 16 or 18 years of age, depending on the region. In an open-label, single-arm study, 96% of patients had an improved or stable neurological score after 2.5 years of treatment with tocofersolan. The submitting company did not present a sufficiently robust economic analysis and in addition their justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED	
velaglucerase alfa 400 units powder for solution for infusion (VPRIV®) *Shire Pharmaceuticals Limited* 08.10.12 *SMC Report No. 681/11* Patient Access Scheme	Accepted for use: velaglucerase alfa (Vpriv®) is accepted for use within NHS Scotland for Long-term enzyme replacement therapy in patients with type 1 Gaucher disease. Velaglucerase alfa has been shown to be non-inferior to another enzyme replacement treatment in patients with type 1 Gaucher disease. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of velaglucerase. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.	Not included on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion.	November 2012
Vitamin A oral solution 10,000 units/mL	For the treatment of low vitamin A levels in children. 	Included on the LJF as first choice, classified as GREEN under the ADTC 'Policy for the use of unlicensed (and off-label use) medicines in NHS Lothian.	October 2016
Vitamins A & D (5000iu/400iu) capsules	Malabsorption in adult cystic fibrosis	Added to the Additional List.	January 2011
Vitamin E 75iu capsules	Malabsorption in adult cystic fibrosis	Added to the Additional List.	January 2011