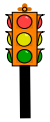
Recommendations from the Lothian Formulary Committee (FC) following Scottish Medicines Consortium (SMC) advice, NICE MTA advice, (FAF3) unlicensed and off-label medicines and (FAF2) medicines not considered by SMC

5 - Infections

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**
abacavir (Ziagen®) *GlaxoSmithKline* 09.05.05 *SMC Report No. 174/05* PRODUCT UPDATE (abbreviated submission)	Accepted for use: abacavir tablets 300mg are accepted for use in a once-daily dosing regimen in NHS Scotland for treatment of Human Immunodeficiency Virus Type 1 (HIV-1) infected adults and adolescents over 12 years, in combination with other antiretroviral medicinal products.	Added to the Additional List, for Specialist Use only.	June 2005
abacavir/lamivudine combination (Kivexa®) *GlaxoSmithKline* 09.05.05 *SMC Report No. 175/05* PRODUCT UPDATE (abbreviated submission)	Accepted for use: tablets delivering a fixed dose combination of abacavir 600mg and lamivudine 300mg are accepted for use in NHS Scotland for the treatment of Human Immunodeficiency Virus Type 1 (HIV-1) infected adults and adolescents over 12 years, in combination with other antiretroviral medicinal products. Both products are nucleoside reverse transcriptase inhibitors. In patients for whom this combination is appropriate, it offers a single tablet at a lower cost per dose compared with the individual components.	Added to the Additional List, for Specialist Use only.	June 2005
adefovir dipivoxil tablets 10mg (Hepsera®) *Gilead Sciences Ltd* 09.05.05 *SMC Report No. 54/03* RESUBMISSION	Restricted use: adefovir dipivoxil (Hepsera®) is accepted for restricted use within NHS Scotland for the treatment of chronic hepatitis B in adults with either compensated liver disease with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active liver inflammation and fibrosis, or decompensated liver disease. Its use is restricted to patients who demonstrate lamivudine resistance.	Added to the Additional List. Shared care. Shared care removed May 2012	May 2005
anidulafungin 100mg powder and solvent for concentrate for solution for infusion (Ecalta®) *Pfizer Ltd* 10.11.08 *SMC Report No. 465/08* RESUBMISSION	Restricted use: anidulafungin (Ecalta®) is accepted for restricted use within NHS Scotland for the treatment of invasive candidiasis in adult non-neutropenic patients. Anidulafungin has been shown to be at least as effective as an alternative antifungal in a study of patients, the majority of whom had candidaemia. Its use is restricted to patients who are unable to tolerate fluconazole or have invasive candidiasis that is resistant to fluconazole.	Added to the Additional List, for Specialist Use only.	August 2011

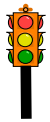
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
artesunate (Malacef®) *Guilin Pharmaceuticals*	Treatment of adults and children with severe P. Falciparum malaria. 	Added to the Additional List, for Specialist Use only. Artesunate for the treatment of adults and children with severe P. Falciparum malaria has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	April 2014
atazanavir (Reyataz®) *Bristol-Myers Squibb* 13.09.04 *SMC Report No. 120/04*	Restricted use: atazanavir (Reyataz®) is accepted for restricted use within NHS Scotland for the treatment of HIV-1 infected, antiretroviral treatment experienced adults, in combination with other antiretroviral medicinal products in those patients who do not require concomitant statin use. The combination of atazanavir and ritonavir was non-inferior to a standard boosted protease inhibitor (PI) regimen in patients with moderate previous exposure to PIs, however, it was inferior in patients with PI-resistant viruses. It was associated with lower incidences of diarrhoea and lipid adverse-effects and a higher incidence of hyperbilirubinaemia. The health economic case for use is acceptable when atazanavir is compared with a standard boosted protease inhibitor regime in patients receiving concomitant statins.	Added to the Additional List. Specialist Use only in line with recommendations for other antiretroviral therapy.	November 2004
atazanavir, 300mg capsules (Reyataz®) *Bristol-Myers Squibb Pharmaceuticals Ltd* 12.01.09 *SMC Report No. 520/08*	Accepted for use: atazanavir (Reyataz®) is accepted for use within NHS Scotland in antiretroviral treatment naïve HIV-1 infected adults in combination with other antiretroviral medicinal products. The combination of atazanavir and ritonavir was non-inferior to a standard boosted protease inhibitor regimen in treatment naïve HIV patients. The combined regimen was associated with lower incidences of diarrhoea and lipid adverse-effects and a higher incidence of hyperbilirubinaemia in this patient population.	Added to the Additional List, for Specialist Use only.	August 2010
atazanavir 150, 200 and 300mg capsules (Reyataz®) *Bristol Myers Squibb Pharmaceuticals* 13.12.10 *SMC Report No. 656/10* PRODUCT UPDATE (abbreviated submission)	Accepted for use: atazanavir (Reyataz®) is accepted for use within NHS Scotland. Indication under review: atazanavir, co-administered with low dose ritonavir, is indicated for the treatment of paediatric patients 6 years of age and older in combination with other antiretroviral medicinal products. Data available in children aged 6 to less than 18 years are very limited. Available data suggest that atazanavir in combination with ritonavir may not be effective in treatment experienced children even with very few (<3) protease inhibitor mutations. The choice of atazanavir in treatment experienced paediatric patients should be based on individual viral resistance testing and the patient's treatment history. The Scottish Medicines Consortium has previously accepted this product for use in HIV infection in adults. Atazanavir is listed in the British National Formulary for Children 2010 -11 for the treatment of HIV.	Added to the Additional List, for Specialist Use only.	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**
atazanavir/cobicistat 300mg/150mg film-coated tablets (Evotaz®) *Bristol-Myers Squibb Pharmaceuticals Ltd* 09.11.15 *SMC Report No. 1098/15* PRODUCT UPDATE (abbreviated submission)	Accepted: atazanavir/cobicistat (Evotaz®) is accepted for use within NHS Scotland. Indication under review: in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults without known mutations associated with resistance to atazanavir. Pharmacokinetic studies have demonstrated that atazanavir plus cobicistat is bioequivalent (in terms of atazanavir exposure) to ritonavir-boosted atazanavir. For patients in whom atazanavir is an appropriate treatment, atazanavir/cobicistat (Evotaz®) provides a combination product at a small cost premium compared to ritonavir-boosted atazanavir.	Included on the Additional list.	November 2015
azithromycin dihydrate (Azyter®) 15 mg/g, eye drops, solution in single-dose container *Spectrum Thea Pharmaceuticals Limited* 03.07.12 *SMC Report No. 804/12* NON SUBMISSION	NOT RECOMMENDED: azithromycin dihydrate (Azyter®) is not recommended for use within NHS Scotland as local antibacterial treatment of conjunctivitis caused by susceptible strains: - Purulent bacterial conjunctivitis, - Trachomatous conjunctivitis caused by Chlamydia trachomatis. 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	
azithromycin 500mg powder for solution for infusion (Zedbac®) *Aspire Pharma Limited* 07.04.14 *SMC Report No. 950/14* PRODUCT UPDATE (abbreviated submission)	Accepted for use: azithromycin (Zedbac®) is accepted for use within NHS Scotland for the treatment of community acquired pneumonia (CAP) and pelvic inflammatory disease (PID) due to susceptible organisms in adult patients where initial intravenous therapy is required. Consideration should be given to official guidance regarding the appropriate use of antibacterial agents. This is the first intravenous formulation of azithromycin to be made available in the UK. The intravenous formulation is significantly more expensive than the oral preparation of azithromycin, but it is intended only for short-term use and on the advice of local microbiologists or specialists in infectious diseases.	Included on the Additional List, for Specialist Use only, for the indication in question. Azithromycin has been classified as an alert antibiotic.	April 2014

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**
aztreonam lysine, 75mg, powder and solvent for nebuliser solution (Cayston®) *Gilead Life Sciences Limited* 12.01.15 *SMC Report No. 753/12* RESUBMISSION Patient Access Scheme	Restricted use: aztreonam lysine (Cayston®) is accepted for restricted use within NHS Scotland as suppressive therapy of chronic pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis aged six years and older. SMC restriction: When inhaled colistimethate sodium and inhaled tobramycin are not tolerated or not providing satisfactory therapeutic benefit (measured ~~a~~≥2% decline in forced expiratory volume in 1 second [FEV_1]). Aztreonam lysine has demonstrated superiority in improving lung function and respiratory symptoms in one active-controlled study and two 28-day placebo-controlled studies in patients with cystic fibrosis and chronic Pseudomonas aeruginosa infection. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of aztreonam lysine. It is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Included on the Additional List for Specialist Initiation.	March 2015
aztreonam (Azactam®)	Treatment of severe infection caused by susceptible aerobic Gram-negative microorganisms; especially in those with a documented penicillin allergy.	Included on the additional list, Specialist use only, for the indication in question. Aztreonam has been classified as an alert antibiotic.	March 2016
boceprevir 200mg capsule (Victrelis®) Treatment experienced patients *Merck, Sharpe and Dohme Ltd* 10.10.11 *SMC Report No. 722/11*	Accepted for use: boceprevir (Victrelis®) is accepted for use within NHS Scotland. Treatment of chronic hepatitis C (HCV) genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients with compensated liver disease who have failed previous therapy. In the pivotal phase III randomised study, addition of boceprevir to current standard therapy in patients with HCV, who had failed previous therapy, increased the proportion of patients who achieved a sustained virologic response.	Added to the Additional List, for Specialist use only.	March 2012
boceprevir 200mg capsule (Victrelis®) Treatment naïve patients *Merck Sharpe and Dohme Ltd* 10.10.11 *SMC Report No. 723/11*	Accepted for use: boceprevir (Victrelis®) is accepted for use within NHS Scotland. Treatment of chronic hepatitis C (HCV) genotype 1 infection, in combination with peginterferon and ribavirin, in adult patients with compensated liver disease who are previously untreated. In the pivotal, phase III randomised study, addition of boceprevir to current standard therapy in patients with HCV who were previously untreated increased the proportion of patients with HCV who achieved a sustained virologic response.	Added to the Additional List, for Specialist use only.	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**
budesonide, 3mg, gastro-resistant capsules (Budenofalk®) *Dr Falk Pharma UK Ltd* 11.05.15 *SMC Report No. 1043/15*	Restricted use: budesonide (Budenofalk®) is accepted for restricted use within NHS Scotland. Indication under review: autoimmune hepatitis. SMC restriction: for use in non-cirrhotic patients who are intolerant of conventional oral corticosteroids (prednisolone) with severe corticosteroid-related side effects (actual or anticipated) such as psychosis, poorly controlled diabetes or osteoporosis In a phase IIb study, a significantly greater proportion of patients with non-cirrhotic autoimmune hepatitis achieved complete biochemical remission and a reduction in predefined corticosteroid-specific side effects when treated with budesonide plus an immunosuppressant compared with an alternative corticosteroid plus an immunosuppressant.	Not included on the LJF, because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine.	July 2015
camellia sinensis (green tea) leaf extract 10% ointment (Catephen®) *Kora Healthcare* 11.04.16 SMC Report No. 1133/16	Restricted: camellia sinensis (green tea) leaf extract (Catephen®) is accepted for restricted use within NHS Scotland. Indication under review: Cutaneous treatment of external genital and perianal warts (*condylomata acuminata*) in immunocompetent patients from the age of 18 years. SMC restriction: for use in patients not suitable for podophyllotoxin or who have not responded to treatment with podophyllotoxin. Complete clearance of baseline and new warts was achieved in a significantly higher proportion of patients treated for up to 16 weeks with camellia sinensis (green tea) 10% ointment than vehicle ointment, in two phase III randomised double-blind studies.	Included on the Additional List, Specialist Use only, for the indication in question.	May 2016
canakinumab 150mg powder for solution for injection (Ilaris®) *Novartis Pharmaceuticals UK Ltd* 07.08.17 *SMC Report No. 1268/17* NON SUBMISSION	NOT RECOMMENDED Treatment of the following autoinflammatory periodic fever syndromes in adults, adolescents and children aged 2 years and older: • tumour necrosis factor receptor associated periodic syndrome • hyperimmunoglobulin D syndrome / mevalonate kinase deficiency • Familial Mediterranean Fever	NOT RECOMMENDED	
caspofungin (Cancidas®) *Merck Sharpe & Dohme Ltd* 09.01.04 *SMC Report No. 74/03*	Restricted use: caspofungin (Cancidas®) provides an additional agent for the treatment of invasive candidiasis. Its use should be restricted to patients with fluconazole-resistant *Candida* infection who do not respond to, or cannot tolerate amphotericin B therapy or who are at an increased risk of serious side effects with amphotericin (e.g. transplant patients, especially those receiving bone marrow transplants).	Added to the Additional List, for Specialist Use only in patients with fluconazole-resistant *Candida* infection as recommended by the SMC.	March 2004

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**
caspofungin 50mg and 70mg powder for concentrate for solution for infusion (Cancidas®) *Merck Sharpe & Dohme* 07.02.05 *SMC Report No. 147/04*	Restricted use: caspofungin (Cancidas®) is accepted for restricted use within NHS Scotland for the empirical therapy for presumed fungal infections (such as Candida or Aspergillus) in febrile, neutropenic adult patients. It should be restricted to patients under the care of specialists experienced in the management of fungal disease. A comparative study found that caspofungin was as effective as a lipid formulation of amphotericin in terms of overall response. In addition it was better tolerated with fewer drug-related adverse events including less nephrotoxicity and infusion-related events. It is less expensive than another formulation of liposomal amphotericin, which has a licence for empirical use.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	April 2008
caspofungin acetate (Cancidas®) *Merck Sharpe & Dohme Ltd* 07.03.03 *SMC Report No. 30/03*	NOT RECOMMENDED: caspofungin acetate (Cancidas®) efficacy and safety data provided to support the possible benefits of caspofungin in the treatment of invasive aspergillosis were extremely limited, and in the form of one small, open-label, uncontrolled study. This evidence is not considered sufficiently robust to justify a recommendation for use at present. The applicant company has since confirmed that the results of a randomised clinical trial have been published in December 2002. The SMC will provide a further recommendation on this product once an additional submission has been made and assessed.	NOT RECOMMENDED	
caspofungin 50mg and 70mg powder for concentrate for solution for infusion (Cancidas®) *Merck Sharp & Dohme Ltd* 11.05.09 SMC Report No. 551/09 PRODUCT UPDATE (abbreviated submission)	Accepted for use: caspofungin acetate (Cancidas®) is accepted for use within NHS Scotland as empirical therapy for presumed fungal infections (such as Candida or Aspergillus) in febrile, neutropenic paediatric patients (12 months to 17 years). The Scottish Medicines Consortium has previously accepted this product for restricted use for this indication in adults. A comparative study in adults found that caspofungin was as effective as a lipid formulation of amphotericin in terms of overall response. In addition it was better tolerated with fewer drug-related adverse events including less nephrotoxicity and infusion-related events.	Added to the Additional List, Specialist Use only.	May 2009
caspofungin 50mg and 70mg powder for concentrate for solution for infusion (Cancidas®) *Merck Sharp & Dohme Ltd* 11.05.09 SMC Report No. 552/09 PRODUCT UPDATE (abbreviated submission)	Restricted use: caspofungin acetate (Cancidas®) is accepted for restricted use within NHS Scotland for the treatment of invasive candidiasis in paediatric patients (12 months to 17 years). The Scottish Medicines Consortium has previously accepted this product for restricted use for this indication in adults. Caspofungin provides an additional agent for the treatment of invasive candidiasis. Its use should be restricted to patients with fluconazole-resistant Candida infection who do not respond to, or cannot tolerate amphotericin B therapy or who are at an increased risk of serious side effects with amphotericin (eg. transplant patients, especially those receiving bone marrow transplants).	Added to the Additional List, Specialist Use only.	May 2009

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**
cefazolin sodium (Kefzol®) *Sandoz*	Treatment of meticillin-sensitive Staph aureus (MSSA) bacteraemia in renal patients. 	Added to the Additional List, for Specialist Use only. The Alert Antibiotic Policy will be updated accordingly. Cefazolin sodium for the treatment of MSSA bacteraemia in renal patients has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	January 2013
ceftaroline fosamil, 600mg, powder for concentrate for solution for infusion (Zinforo®) *AstraZeneca UK Ltd* 14.01.13 *SMC Report No. 830/12*	Restricted use: ceftaroline fosamil (Zinforo®) is accepted for restricted use within NHS Scotland for the treatment of complicated skin and soft tissue infections in adults. SMC restriction: use in patients with known or suspected meticillin resistant Staphylococcus aureus (MRSA) infection in the following settings: • For Gram-positive only infections where vancomycin iv is inappropriate/has not been tolerated or treatment modification is required; and daptomycin iv or linezolid iv is normally used. • For polymicrobial Gram-positive and common Gram-negative pathogens*, where vancomycin iv in combination with gentamicin iv is inappropriate/has not been tolerated or treatment modification is required; and daptomycin iv in combination with gentamicin iv, or linezolid iv in combination with gentamicin iv, or tigecycline iv is normally used. Ceftaroline should be used only on the advice of local microbiologists or specialists in infectious disease. In two randomised, controlled clinical studies, intravenous ceftaroline fosamil was non-inferior to intravenous vancomycin plus aztreonam in adult patients with complicated skin and skin structure infections. Ceftaroline is also licensed for the treatment of community acquired pneumonia. As the company submission related only to the treatment of skin and soft tissue infections, SMC cannot recommend the use of ceftaroline in community acquired pneumonia.	Included on the Additional List, Specialist Use only, for the indication in question. Ceftaroline has been classified as an alert antibiotic.	March 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**
ceftobiprole, 500mg, powder for concentrate for solution for infusion (Zevtera®) *Basilea Pharmaceutica International Ltd* 13.07.15 *SMC Report No. 943/14* RESUBMISSION	Restricted: ceftobiprole (Zevtera®) is accepted for restricted use within NHS Scotland. Indication under review: Ceftobiprole is indicated for the treatment of the following infections in adults: • Hospital-acquired pneumonia (HAP), excluding ventilator-associated pneumonia (VAP) • Community-acquired pneumonia (CAP) Consideration should be given to official guidance on the appropriate use of antibacterial agents. SMC restriction: for use in the treatment of HAP (excluding VAP) when activity is required against suspected methicillin-resistant *Staphylococcus aureus* (MRSA) and Gram-negative pathogens (including *Pseudomona aeruginosa*, *Escherichia coli* and *Klebsiella pneumoniae*) and when combination treatment that includes vancomycin or teicoplanin is inappropriate or has not been tolerated, or when treatment modification is required, i.e. as an alternative to linezolid-based regimens. In a randomised, double-blind phase III study of patients with HAP, the clinical cure rate for empirical treatment with ceftobiprole was non-inferior to the rate associated with intravenous linezolid plus an anti-pseudomonal cephalosporin.	Not included on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine.	September 2015
ceftolozane/tazobactam 1g/0.5g powder for concentrate for solution for infusion (Zerbaxa®) Merck, Sharp & Dohme Ltd 09.05.16 *SMC Report No. 1146/16*	NOT RECOMMENDED: ceftolozane/tazobactam (Zerbaxa®) is not recommended for use within NHS Scotland. Indication under review: for the treatment of the following infections in adults: - Complicated intra-abdominal infections - Acute pyelonephritis - Complicated urinary tract infections In a phase III, randomised, double-blind study, ceftolozane/tazobactam, in combination with metronidazole, demonstrated non-inferior efficacy to a carbapenem in patients with complicated intra-abdominal infections. In a phase III, randomised, double-blind study, ceftolozane/tazobactam demonstrated non-inferior efficacy to a quinolone antibiotic in patients with acute pyelonephritis or complicated urinary tract infections. 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 clinical and economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
cefuroxime 50mg powder for solution for injection (Aprokam®) *Thea Pharmaceuticals Ltd* 12.12.16 *SMC Report No. 932/13* PRODUCT UPDATE (abbreviated submission)	Accepted for use: cefuroxime (Aprokam®) is accepted for use within NHS Scotland as antibiotic prophylaxis of postoperative endophthalmitis after cataract surgery. Cefuroxime (Aprokam®) provides a licensed preparation and enables the off-label intracameral use of cefuroxime in cataract surgery to be avoided.	Included on the Additional List, Specialist Use only, for the indication in question.	December 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**
ciprofloxacin 3mg/mL + dexamethasone 1mg/mL ear drops (Cilodex®) *Novartis Pharmaceuticals UK Ltd* 10.07.17 *SMC Report No. 1256/17* PRODUCT UPDATE (abbreviated submission)	Treatment of the following infections in adults and children: Acute otitis media in patients with tympanostomy tubes (AOMT) Acute otitis externa SMC restriction: Treatment of acute otitis media in patients with tympanostomy tubes (AOMT).	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.	July 2017
clarithromycin 125mg, 187.5mg, 250mg granules for oral suspension (ClaroSip®) *Grunenthal Ltd* 13.02.06 *SMC Report No. 217/05* PRODUCT UPDATE (abbreviated submission)	NOT RECOMMENDED: clarithromycin as ClaroSip® granules for oral suspension is not recommended for use within NHS Scotland for the treatment of acute and chronic infections caused by clarithromycin susceptible organisms. It uses sip technology, where the granules are contained within a drinking straw. ClaroSip® incurs a cost premium of up to 20% compared to alternative oral liquid clarithromycin, with no proven advantage in terms of compliance.	NOT RECOMMENDED	
cobicistat (Tybost®) 150 mg film coated tablet *Gilead Sciences* 12.05.14 *SMC Report No. 933/13* NON SUBMISSION	NOT RECOMMENDED: cobicistat (Tybost®) is not recommended for use within NHS Scotland as a Pharmacokinetic enhancer of atazanavir 300 mg once daily or darunavir 800 mg once daily as part of antiretroviral combination therapy in human immunodeficiency virus-1 (HIV-1) infected adults. 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	
colistimethate sodium 1,662,500 IU dry powder for inhalation (Colobreathe®) *Forest Laboratories UK Limited* 27.03.13 *NICE Technology Appraisal No 276* Patient Access Scheme	NICE MTA 276 guidance recommends Colistimethate sodium DPI as an option for treating chronic pulmonary infection caused by P. aeruginosa in people with cystic fibrosis only if: •they would clinically benefit from continued colistimethate sodium but do not tolerate it in its nebulised form and thus tobramycin therapy would otherwise be considered and •the manufacturer provides colistimethate sodium DPI with the discount agreed as part of the patient access scheme to primary, secondary and tertiary care in the NHS.	**Adults** Included on the Additional List as a second-line threatment, for the indication in question (in adult patients), with Specialist Initiation. **Paediatrics** Included on the Additional list, Specialist use only, for the indication in question.	October 2013 November 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**
daclatasvir 30mg and 60mg film-coated tablets (Daklinza®) *Bristol-Myers Squibb* 10.11.14 *SMC Report No. 1002/14*	Restricted use: daclatasvir (Daklinza®) is accepted for restricted use within NHS Scotland in combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults. SMC restriction: use is restricted to patients with significant fibrosis (Metavir scores F3-F4) or compensated cirrhosis. In a phase II study 89% to 99% of patients with genotype 1 and 3 HCV treated with daclatasvir in various peginterferon-free regimens achieved a sustained virological response at 12 weeks (SVR12). In a phase III study of patients with genotype 4 HCV, the superiority of daclatasvir with peginterferon-alfa plus ribavirin (PR) versus placebo + PR was demonstrated for the primary endpoint of SVR12.	Included on the Additional List, for Specialist Use only, for the indication in question.	December 2014
dalbavancin 500mg powder for concentrate for solution for infusion (Xydalba®) *Allergan/Actavis* 16.01.17 *SMC Report No. 1105/15*	Restricted use: dalbavancin (Xydalba®) is accepted for restricted use within NHS Scotland for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults. SMC restriction: • for second-line use or when meticillin-resistant Staphylococcus aureus (MRSA) infection is suspected, or on the advice of local microbiologists or specialists in infectious disease, and • the patient is initially hospitalised due to ABSSSI, requires intravenous antibiotics, but is eligible for early discharge as soon as their medical condition does not require further inpatient treatment. In two phase III double-blind studies of patients with ABSSSI, dalbavancin was non-inferior to the comparator for clinical response at end of treatment in the clinically evaluable population.	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 have not responded to an invitation to apply for formulary inclusion for this medicine	March 2017
daptomycin 350mg powder for concentrate for solution for infusion (Cubicin®) *Chiron Corporation Limited* 10.04.06 *SMC Report No. 248/06*	Restricted use: daptomycin (Cubicin®) is accepted for restricted use within NHS Scotland for the treatment of complicated skin and soft tissue infections in adults. Daptomycin should be restricted to use in patients with known or suspected *methicillin-resistant Staphylococcus aureus* (MRSA) infection and on the advice of local microbiologists or specialists in infectious disease. Daptomycin has a higher acquisition cost than some alternative treatments; it does not, however, require therapeutic drug monitoring.	Added to the Additional List, for Specialist Use only. Use must be sanctioned by a consultant microbiologist or consultant in infectious diseases physician and the consultant in charge of the patient.	December 2007
daptomycin 500 mg powder for intravenous infusion (Cubicin®) *Novartis Pharmaceuticals UK Ltd* 15.01.07 *SMC Report No. 338/06* PRODUCT UPDATE (abbreviated submission)	Restricted use: daptomycin 500mg powder for intravenous infusion (Cubicin®) is accepted for restricted use within NHS Scotland for the treatment of complicated skin and soft-tissue infections in adults. Daptomycin should be restricted to use in patients with known or suspected *methicillin-resistant Staphylococcus aureus* (MRSA) infection and on the advice of local microbiologists or specialists in infectious disease. The new strength allows patients weighing over 87.5kg to be treated with a single 500mg vial at a reduced cost compared to two vials of the 350mg strength. Daptomycin has a higher acquisition cost than some alternative treatments; it does not, however, require therapeutic drug monitoring.	Added to the Additional List, for Specialist Use only. Use must be sanctioned by a consultant microbiologist or consultant in infectious diseases physician and the consultant in charge of the patient.	December 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**
daptomycin 350mg and 500 mg vials of powder for solution for infusion (Cubicin®) *Novartis Pharmaceuticals UK Limited* 10.03.08 *SMC Report No. 449/08*	Restricted use: daptomycin, (Cubicin®) is accepted for restricted use within NHS Scotland for the treatment of Staphylococcus aureus bacteraemia (SAB) when associated with right-sided infective endocarditis (RIE) or with complicated skin and soft-tissue infections in adults. Daptomycin should be restricted to use in patients with known or suspected methicillin-resistant S. aureus (MRSA) infection and on the advice of local microbiologists or specialists in infectious disease. Daptomycin has been shown to be as effective as standard therapy in patients with S. aureus bacteraemia with or without endocarditis, though data on the subgroup of patients with RIE due to MRSA are very limited. Daptomycin has a higher acquisition cost than some alternative treatment; it does not, however, require therapeutic drug monitoring.	Added to the Additional List, for Specialist Use only.	July 2009
daptomycin (Cubicin®) powder for concentrate for solution for injection or infusion *Novartis Pharmaceuticals UK Ltd* 07.03.16 *SMC Report No. 1141/16* NON SUBMISSION	NOT RECOMMENDED: daptomycin (Cubicin®) is not recommended for use within NHS Scotland. Indication under review: Treatment of paediatric (1 to 17 years of age) patients with complicated skin and soft-tissue infections. 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	
darunavir 300mg tablets (Prezista®) *Tibotec (a division of Janssen-Cilag Ltd)* 11.06.07 *SMC Report No. 378/07*	Accepted for use: darunavir (Prezista®) is accepted for use within NHS Scotland, co-administered with ritonavir and in combination with other antiretroviral medicinal products, for the treatment of human immunodeficiency virus (HIV-1) infection in highly pre-treated adult patients who have failed on more than one regimen containing a protease inhibitor (PI). At 24 and 48 weeks, darunavir, in combination with low dose ritonavir, showed a significant improvement in the reduction of viral load compared with other protease inhibitor plus ritonavir regimens.	Added to the Additional List.	December 2007
darunavir, 400mg tablets (Prezista®) *Tibotec, a division of Janssen-Cilag Ltd* 07.09.09 *SMC Report No. 566/09*	Accepted for use: darunavir (Prezista®) co-administered with low dose ritonavir and in combination with other antiretroviral medicinal products is accepted within NHS Scotland for the treatment of human immunodeficiency virus (HIV-1) infection in antiretroviral therapy (ART) naïve adults. After 48 weeks the combination of darunavir and ritonavir was non-inferior to a standard boosted protease inhibitor regimen in ART naïve adults. The combined regimen was associated with lower incidences of diarrhoea and lipid adverse effects.	Added to the Additional List, for Specialist Use only.	August 2010
darunavir 75mg, 150mg, 300mg, 600mg film-coated tablets (Prezista®) *Tibotec, a subsidiary of Janssen-Cilag* 08.02.10 *SMC Report No. 604/10* PRODUCT UPDATE (abbreviated submission)	Accepted for use: darunavir (Prezista®) is accepted for use within NHS Scotland, co administered with low dose ritonavir in combination with other antiretroviral medicinal products, for the treatment of human immunodeficiency virus (HIV-1) infection in highly pre-treated children and adolescents, from the age of 6 years and at least 20kg body weight, who have failed on more than one regimen containing a protease inhibitor (PI). Darunavir is listed in the British National Formulary for Children for the treatment of HIV resistant to other protease inhibitors. The Scottish Medicines Consortium has previously accepted this product for use in this indication in adults.	Added to the Additional List.	March 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**
darunavir 400mg tablets (Prezista®) *Janssen* 08.08.11 *SMC Report No. 707/11*	Accepted for use: darunavir (Prezista®) 400mg is accepted for use within NHS Scotland. Indication under review: darunavir 800mg once daily co-administered with low dose ritonavir (100mg once daily) for the treatment of HIV-1 infection in antiretroviral therapy experienced adults with no darunavir resistance associated mutations and who have plasma HIV-1 RNA <100,000 copies/mL and CD4+ cell count ≥100 cells/mm3. Darunavir 800mg/ritonavir 100mg once daily was demonstrated to be non inferior to darunavir 600mg/ritonavir 100mg twice daily, when administered with an optimised background regimen that consisted of at least two nucleoside reverse transcriptase inhibitors in treatment experienced HIV infected patients.	Not included on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion. 'Not Preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	May 2012
darunavir oral suspension 100mg/mL (Prezista®) *Janssen-Cilag Ltd* 08.04.13 *SMC Report No. 861/13* PRODUCT UPDATE (abbreviated submission)	Restricted use: darunavir oral suspension (Prezista®) is accepted for restricted use within NHS Scotland co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients as well as antiretroviral therapy (ART)-experienced paediatric patients from the age of 3 years and at least 15 kg body weight. SMC restriction: to be prescribed for patients <18 years under the supervision of specialists in paediatric HIV. Darunavir is listed in the British National Formulary for Children for the treatment of HIV resistant to other protease inhibitors. The Scottish Medicines Consortium has previously accepted darunavir for use in this indication in adults and in highly pre-treated children and adolescents, from the age of 6 years and at least 20kg body weight, who have failed on more than one regimen containing a protease inhibitor.	Included on the LJF for the indication in question.	April 2013
darunavir 400mg, 800mg film-coated tablets and oral suspension 100mg/mL (Prezista®) *Janssen-Cilag Ltd* 10.03.14 *SMC Report No. 948/14* PRODUCT UPDATE (abbreviated submission)	Restricted use: darunavir (Prezista®) is accepted for restricted use within NHS Scotland co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in paediatric patients 12 to 17 years of age and at least 40kg body weight who are: antiretroviral therapy (ART) naïve; or, ART-experienced with no darunavir resistance associated mutations and who have plasma HIV-1 RNA <100,000 copies/mL and CD4+ cell count ≥100 cells/mm3. SMC restriction: in patients <18 years, to be prescribed under the supervision of specialists in paediatric HIV. The Scottish Medicines Consortium has previously accepted darunavir for use in this indication in adults and in highly pre-treated children and adolescents, from the age of 6 years and at least 20kg body weight, who have failed on more than one regimen containing a protease inhibitor. Darunavir is listed in the British National Formulary for Children in combination with other antiretroviral drugs, for HIV infection resistant to other protease inhibitors in children previously treated with antiretrovirals.	Included on the Additional List, for Specialist Use only, for the indication in question.	February 2014

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**
darunavir 75mg, 150mg, 400mg, 600mg, 800mg film-coated tablets and oral suspension 100mg/mL (Prezista®) *Janssen-Cilag Ltd* 13.07.15 *SMC Report No. 1069/15* PRODUCT UPDATE (abbreviated submission)	Restricted use: darunavir (Prezista®) is accepted for restricted use within NHS Scotland. Indication under review: once daily darunavir co-administered with low dose ritonavir in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in paediatric patients aged 3 to 12 years and ≥15kg who are 1) treatment-naive or 2) treatment-experienced with no darunavir resistance-associated mutations, plasma-HIV-1 RNA <100,000 copies/mL, and CD4+ count >100x10^6 cells/L. SMC restriction: to be prescribed under the supervision of specialists in paediatric HIV. Darunavir is listed in the British National Formulary for Children in combination with other antiretroviral drugs for HIV infection in children previously treated with antiretrovirals or not previously treated with antiretroviral therapy. The Scottish Medicines Consortium has previously accepted darunavir in this indication in paediatric patients aged 12 to 17 years and at least 40kg body weight, and in combination with other antiretroviral medicinal products in antiretroviral (ART)-experienced paediatric patients from the age of 3 years and at least 15kg body weight.	Included on the Additional List, Specialist Use only, for the indication in question.	July 2015
darunavir 800mg, cobicistat 150mg film-coated tablet (Rezolsta®) *Janssen-Cilag Ltd.* 10.08.15 *SMC Report No. 1081/15*	Accepted for use: darunavir/cobicistat (Rezolsta®) is accepted for use within NHS Scotland. Indication under review: In combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years or older. Genotypic testing should guide its use. Pharmacokinetic studies have demonstrated that darunavir/cobicistat is bioequivalent (in terms of darunavir exposure) to ritonavir-boosted darunavir. No comparative efficacy studies have been reported.	Included on the additional list, specialist use, for the indication in question.	October 2015
dequalinium chloride 10mg vaginal tablets (Fluomizin®) *Kora Healthcare* 07.11.16 *SMC Report No. 1194/16*	Restricted use: dequalinium chloride (Fluomizin®) is accepted for restricted use within NHS Scotland for the treatment of bacterial vaginosis. SMC restriction: In patients for whom the initial treatment is not effective or well tolerated. Non-inferiority of dequalinium vaginal tablets to an antibiotic vaginal cream was demonstrated in a study that included treatment-naive and treatment-experienced patients.	Not included on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion.	December 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**
dolutegravir 50mg film-coated tablets (Tivicay®) *ViiV Healthcare/GlaxoSmithKline* 12.05.14 *SMC Report No. 961/14* Patient Access Scheme	Accepted for use: dolutegravir (Tivicay®) is accepted for use within NHS Scotland in combination with other antiretroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age. In phase III clinical studies, dolutegravir has demonstrated non-inferiority or superiority to three comparator antiretroviral medicines in treatment-naïve adults with HIV, and superiority to an alternative integrase inhibitor in treatment-experienced adults. (All study patients also received two nucleoside reverse-transcriptase inhibitors). This SMC advice takes account of the benefits of a patient access scheme (PAS) that improves the cost-effectiveness of dolutegravir. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.	**For adults:** Included on the Additional List, for Specialist Use only, for the indication in question. **For adolescents above 12 years of age:** Included on the Additional list, Specialist use only, for the indication in question.	May 2014 November 2015
dolutegravir 10mg, 25mg, 50mg film-coated tablets (Tivicay®) *ViiV Healthcare UK* 10.07.17 *SMC Report No. 1253/17* Patient Access Scheme	In combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected children aged >6 to 12 years of age.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.	July 2017
dolutegravir 50mg, abacavir 600mg plus lamivudine 300mg film-coated tablets (Triumeq®) *ViiV Healthcare UK Ltd* 08.12.14 *SMC Report No. 1009/14* PRODUCT UPDATE (abbreviated submission) Patient Access Scheme	Accepted for use: dolutegravir, abacavir plus lamivudine tablets (Triumeq®) are accepted for use within NHS Scotland for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age weighing at least 40 kg. In patients for whom this combination is appropriate, it offers a single tablet at a lower cost per dose compared with the individual components. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of (Triumeq®). 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, for the indication in question.	November 2015
doripenem 500mg powder for solution for infusion (Doribax®) *Janssen Cilag* 09.02.09 *SMC Report No. 529/09*	Restricted use: doripenem (Doribax®) is accepted for restricted within NHS Scotland for the treatment of complicated intra-abdominal infections in adults. In patients with complicated intra-abdominal infection, doripenem is associated with clinical cure rates non-inferior to those of another carbapenem. Doripenem should be restricted to use as a second or third-line treatment of complicated intra-abdominal infections resistant to current conventional treatments. It should be used only on the advice of local microbiologists or specialists in infectious diseases.	'Not preferred' in Lothian. A submission has not been made to Formulary Committee regarding this product for this indication.	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**
drotrecogin alfa [activated] (Xigris®) *Eli Lilly* 04.10.02 SMC Report No. 13/02	Restricted use: drotrecogin alfa [activated] is a significant advance in the treatment of patients with severe sepsis with multiple-organ failure. It supplements the existing treatment strategies of infection eradication and support for failing organs/systems. When added to the best standard care of patients with severe sepsis it significantly reduces mortality in the most severely ill patients, i.e. those with more than one new failing organ/system and/or those with an APACHE II score >25. A register of recipients of this preparation should be established and maintained to provide additional information about its effectiveness and safety in the clinical setting.	Approved for use - added to the Additional List.	May 2003
efavirenz 600mg, emtricitabine 200mg, tenofovir disoproxil 245mg as fumarate (Atripla®) *Bristol Myers Squibb/Gilead Sciences/Merck Sharp & Dohme Ltd* 07.04.08 *SMC Report No. 442/08* PRODUCT UPDATE (abbreviated submission)	Accepted for use: efavirenz is accepted for use in NHS Scotland for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults with virologic suppression to HIV-1 RNA levels of < 50 copies/ml on their current combination antiretroviral therapy for more than three months. Patients must not have experienced virological failure on any prior antiretroviral therapy and must be known not to have harboured virus strains with mutations conferring significant resistance to any of the three components contained in this fixed dose combination prior to initiation of their first antiretroviral treatment regimen. It may be used to simplify the regimen of patients for whom this combination is indicated (see above) and in whom all three agents are appropriate components at the doses provided by this fixed dose combination.	New formulation of drugs already in the Formulary.	April 2008
efavirenz 50mg, 100mg and 200mg hard capsules and 600mg film-coated tablets (Sustiva®) *Bristol Myers Squibb* 07.12.15 *SMC Report No. 1125/15* PRODUCT UPDATE (abbreviated submission)	Accepted: efavirenz (Sustiva®) is accepted for use within NHS Scotland. Indication under review: antiviral combination treatment of human immunodeficiency virus-1 (HIV-1) infected children aged 3 months to 3 years and weighing at least 3.5kg. For patients at least 3 months old and weighing at least 3.5kg who cannot swallow capsules, the capsule contents can be administered with a small amount of food using the capsule sprinkle method of administration. Efavirenz is listed in the British National Formulary for Children for the treatment of HIV infection.	Included on the additional list for the indication in question.	December 2015

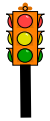
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
elbasvir 50 mg, grazoprevir 100mg film-coated tablet (Zepatier®) *Merck Sharp and Dohme Ltd* 16.01.17 *SMC Report No. 1203/17* Patient Access Scheme	Accepted for use: elbasvir-grazoprevir (Zepatier®) is accepted for use within NHS Scotland for the treatment of chronic hepatitis C (CHC) in adults. (The efficacy of elbasvir-grazoprevir has not been demonstrated in genotypes 2, 3, 5 and 6. Elbasvir-grazoprevir is not recommended in patients infected with these genotypes). In patients with genotype 1a, 1b or 4, elbasvir-grazoprevir significantly increased sustained virologic suppression compared with a regimen containing a non-structural protein 5A (NS5A) inhibitor, an interferon and ribavirin. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of elbasvir-grazoprevir. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only. Included on the Additional List, Specialist Use only, for the indication in question.	January 2017
eltrombopag, 25mg, 50mg, 75mg film-coated tablets (Revolade®) *GlaxoSmithKline* 09.12.13 *SMC Report No. 919/13* Patient Access Scheme	Accepted for use: eltrombopag (Revolade®) is accepted for use within NHS Scotland in adult patients with chronic hepatitis C virus infection, for the treatment of thrombocytopenia, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy. Two double-blind, randomised, controlled studies in patients with chronic hepatitis C virus infection and thrombocytopenia demonstrated significantly higher sustained viral response rates in patients who continued treatment with eltrombopag during interferon-based antiviral therapy than in those patients whose eltrombopag treatment was discontinued on initiation of antiviral therapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of eltrombopag. This SMC 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, for Specialist Use only, for the indication in question. A treatment protocol has been requested from the clinical team.	February 2014
elvitegravir 150mg, cobicistat 150mg, emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg film coated tablet (Stribild®) *Gilead Sciences Ltd* 12.08.13 *SMC Report No. 887/13* Patient Access Scheme	Accepted for use: elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil (as fumarate) film coated tablet (Stribild®) is accepted for use within NHS Scotland. Indication under review: treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years and over who are antiretroviral treatment-naïve or are infected with HIV-1 without known mutations associated with resistance to the three antiretroviral agents in Stribild®. Stribild® was at least as effective as two other recommended antiretroviral regimens in treatment-naïve HIV-1 infected patients. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of Stribild®. This SMC 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, for the indication in question.	October 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**
elvitegravir 150mg, cobicistat 150mg, emtricitabine 200mg, tenofovir alafenamide 10mg film-coated tablet (Genvoya®) *Gilead Sciences Ltd* 09.05.16 *SMC Report No. 1142/16* Patient Access Scheme	Accepted for use: elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide film-coated tablet (Genvoya®) is accepted for use within NHS Scotland. Indication under review: the treatment of adults and adolescents (aged 12 years and older with body weight at least 35kg) infected with human immunodeficiency virus-1 (HIV-1) without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir. In two phase III, randomised, double-blind studies (in treatment-naïve adults with HIV-1), and one phase III, randomised, open-label study (in treatment-experienced adults with HIV-1), Genvoya® was non-inferior to alternative antiretroviral regimens at achieving/maintaining a high rate of viral suppression (plasma HIV-1 RNA <50 copies/mL) at week 48. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of Genvoya®. 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, for Specialist Use only, for the indication in question.	July 2016
emtricitabine 200mg hard capsules (Emtriva®) *Gilead Sciences International* 13.02.06 *SMC Report No. 105/04* RESUBMISSION	Accepted for use: emtricitabine (Emtriva®) is accepted for use within NHS Scotland for the treatment of HIV-1 infected adults in combination with other antiretroviral agents. It should be prescribed only by HIV specialists. This indication is based on studies in treatment-naïve patients and treatment-experienced patients with stable virological control in whom, as part of antiretroviral therapy (ART) regimens, it has shown virological responses comparable with other ART. There is no experience of use in patients who are failing their current regimen or who have failed multiple regimens.	Approved for use - added to the Additional List.	April 2006
emtricitabine / tenofovir disoproxil 200mg/245mg tablet (Truvada®) *Gilead Sciences Ltd* 13.02.06 *SMC Report No. 237/06* PRODUCT UPDATE (abbreviated submission)	Accepted for use: emtricitabine/tenofovir disoproxil 200mg/245mg tablet (Truvada®) is accepted for use in NHS Scotland for the treatment of Human Immunodeficiency Virus (HIV-1) infected adults in combination with other antiretroviral medicinal products. Both constituents are nucleoside reverse transcriptase inhibitors. The demonstration of the benefit of the combination emtricitabine and tenofovir disoproxil fumarate in antiretroviral therapy is based solely on studies performed in treatment-naïve patients.	Added to the Formulary as second choice, for Specialist Use only. For use only in treatment- naïve patients known to be abacavir intolerant.	May 2006
emtricitabine/tenofovir disoproxil 200mg/245mg film-coated tablets (Truvada®) *Gilead Sciences Ltd* 10.04.17 *SMC Report No. 1225/17*	In combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in adults at high risk.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.	July 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**
emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg, rilpivirine (as hydrochloride) 25mg, film-coated tablet (Eviplera®) *Gilead Sciences Limited* 13.02.12 *SMC Report No. 759/12* PRODUCT UPDATE (abbreviated submission)	Accepted for use: emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg, rilpivirine (as hydrochloride) 25mg, film-coated tablet (Eviplera®) is accepted for use in NHS Scotland for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naive adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/ml. As with other antiretroviral therapies, genotypic resistance testing should inform the use of Eviplera®. This combination tablet has been shown to be bioequivalent to the individual components given separately. It is available at pro rata cost to the individual components and may be used to simplify the regimen of patients for whom this combination of HIV therapies is appropriate at the doses provided in this fixed dose combination.	Added to the Additional List for Specialist Use only. Included on the Lothian Joint Formulary for the indication in question.	April 2012
emtricitabine / tenofovir disoproxil 200mg/245mg film-coated tablets (Truvada®) *Gilead Sciences Ltd.* 10.07.17 *SMC Report No. 1263/17* NON SUBMISSION	NOT RECOMMENDED: Treatment of HIV-1 infected adolescents aged 12 to <18 years with nucleoside reverse transcriptase inhibitor resistance or toxicities precluding the use of first line agents.	Not routinely available as not recommended for us in NHSScotland.	July 2017
emtricitabine/tenofovir alafenamide 200mg/25mg, 200mg/10mg film-coated tablets (Descovy®) *Gilead Sciences Ltd* 08.08.16 *SMC Report No. 1169/16* PRODUCT UPDATE (abbreviated submission)	Accepted for use: emtricitabine/tenofovir alafenamide (Descovy®) is accepted for use within NHS Scotland in combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35kg) infected with human immunodeficiency virus type 1. For adult patients in whom emtricitabine/tenofovir is an appropriate combination, Descovy® (emtricitabine/tenofovir alafenamide) offers an alternative to Truvada® (emtricitabine/ tenofovir disoproxil) at no additional cost, and may also be used in patients from 12 years of age.	Included on the Additional List, Specialist Use only, for the indication in question.	August 2016
enfuvirtide (Fuzeon®) *Roche* 11.08.03 *SMC Report No. 56/03*	Restricted use: enfuvirtide (Fuzeon®) is restricted to use by clinicians experienced in the management of HIV infected patients. It is licensed for use in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected patients who have received treatment with and failed on regimens containing at least one medicinal product from each of the following antiretroviral classes, protease inhibitors, non-nucleoside reverse transcriptase inhibitors and nucleoside reverse transcriptase inhibitors, or who have intolerance to previous antiretroviral regimens.	Approved for use - added to the Additional List.	September 2003

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**
entecavir, 0.5 and 1mg tablets (Baraclude®) *Bristol-Myers Squibb Pharmaceuticals Ltd* 09.10.06 *SMC Report No. 320/06*	Accepted for use: entecavir (Baraclude®) is accepted for use within NHS Scotland for the treatment of chronic hepatitis B virus infection in adults with compensated liver disease and evidence of active viral replication, persistently elevated serum alanine aminotransferase levels and histological evidence of active inflammation and or fibrosis. Clinical studies have shown that entecavir is more effective than lamivudine in nucleoside-naïve HBeAg positive and negative patients and in lamivudine refractory patients.	Added to the Additional List. Treatment to be initiated in secondary care for 1 month, thereafter prescribing to be continued in primary care under a shared care protocol.	December 2007
entecavir, 0.5mg and 1mg film-coated tablets and 0.05 mg/mL oral solution (Baraclude®) *Bristol-Myers Squibb Pharmaceuticals Ltd* 16.01.12 *SMC Report No. 747/11*	NOT RECOMMENDED: entecavir (Baraclude®) is not recommended for use within NHS Scotland for the treatment of chronic hepatitis B virus (HBV) infection in adults with decompensated liver disease. Entecavir demonstrated a superior virological response in adults with chronic HBV and decompensated liver disease compared with another nucleoside/nucleotide analogue. However there is no comparative evidence versus the relevant comparator. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
entecavir,0.5 and 1mg film-coated tablets and 0.05mg/mL oral solution (Baraclude®) *Bristol-Myers Squibb Pharmaceuticals Ltd* 11.05.15 *SMC Report No. 1049/15* PRODUCT UPDATE (abbreviated submission)	Restricted use: entecavir (Baraclude®) is accepted for restricted use within NHS Scotland as treatment of chronic hepatitis B virus infection in nucleoside naive paediatric patients from 2 to <18 years of age with compensated liver disease who have evidence of active viral replication and persistently elevated serum alanine aminotransferase levels, or histological evidence of moderate to severe inflammation and/or fibrosis. SMC restriction: to be prescribed under the supervision of specialists in paediatric infectious diseases. While the benefits of viral suppression in adults are acknowledged the benefits of anti-viral treatment in children are less well established. In clinical studies, the antiviral efficacy of entecavir in children is reported to be lower than in adults. However there is a potential need for treatment in a very small number of paediatric patients and this is the first licensed medicine for hepatitis B in this age group.	Included on the Additional List, Specialist Use only, for the indication in question.	July 2015
ertapenem (Ivanz®) *Merck Sharpe & Dohme* 13.12.04 *SMC Report No. 134/04*	Restricted use: ertapenem is accepted for restricted use within NHS Scotland for the treatment of intra-abdominal infections in adults. Ertapenem should only be used second or third line treatment of community acquired intra-abdominal infections resistant to the current conventional treatments and under the advice of local microbiologists or specialists in infectious diseases.	'Not preferred' as suitable alternatives exist.	January 2005

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**
ertapenem sodium infusion (Invanz®) Paediatric *Merck Sharpe & Dohme* 07.08.06 *SMC Report No. 291/06* PRODUCT UPDATE (abbreviated submission)	Restricted use: ertapenem is accepted for restricted use within NHS Scotland for the treatment of intra-abdominal infections in children and adolescents. Ertapenem should only be used second line for the treatment of the community acquired intra-abdominal infections resistant to the current conventional treatments and under the advice of local microbiologists or specialists in infectious diseases.	'Not preferred' as suitable alternatives exist.	October 2007
ertapenem, 1g vial of powder for solution for intravenous infusion (Invanz®) *Merck Sharp & Dohme Ltd* 15.01.07 *SMC Report No. 335/06*	Restricted use: ertapenem for intravenous infusion (Invanz®) is accepted for restricted use within NHS Scotland for the treatment of diabetic foot infections of the skin and soft tissue when caused by bacteria known or very likely to be susceptible to ertapenem and where broad spectrum parenteral therapy is appropriate. It is restricted to use by specialists managing diabetic foot infection or on the advice of a microbiologist. Ertapenem showed non-inferiority to a penicillin/beta-lactamase inhibitor combination in the pivotal trial. Although ertapenem has a greater acquisition cost than some treatment options, its once-daily dosing regimen may allow changes in service delivery that have individual patient or organisational benefits. Efficacy of ertapenem in the treatment of diabetic foot infection with concurrent osteomyelitis has not been established.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	June 2008
ertapenem, 1g vial of powder for concentrate for solution for intravenous infusion (Invanz®) *Merck, Sharp & Dohme Limited* 08.10.07 *SMC Report No. 404/07*	Restricted use: ertapenem (Invanz®) is accepted for restricted use within NHS Scotland for the prophylaxis of surgical site infection following elective colorectal surgery in adults. It is effective in reducing the incidence of surgical site infection, although there are currently no comparisons with regimens used in Scotland. It is restricted to use in line with local antimicrobial policies and Microbiologist advice.	'Not preferred' as suitable alternatives exist.	December 2008
ertapenem (Invanz®) *Merck Sharpe and Dohme Limited*	For multi-resistant infections treatment in Outpatient Parenteral Antimicrobial Treatment (OPAT) clinic. 	Added to the Additional List, for Specialist Use only. The Alert Antibiotic Policy will be updated. Ertapenem has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	February 2014
etravirine 100mg tablet (Intelence®) *Tibotec* 10.08.09 *SMC Report No. 530/09* RESUBMISSION	Accepted for use: etravirine (Intelence®), in combination with a boosted protease inhibitor and other antiretroviral medicinal products, is accepted for use within NHS Scotland for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced adult patients. In HIV-1 infected adults, with resistance to currently available non-nucleoside reverse transcriptase inhibitors (NNRTIs) and at least three primary protease inhibitor (PI) mutations, who were receiving an optimised background regimen that included boosted darunavir plus nucleoside reverse transcriptase inhibitors (NRTIs) and optional enfuvirtide, etravirine achieved significant improvements in virological, immunological and clinical outcomes when compared with placebo.	Added to the Additional List, for Specialist Use only	September 2009

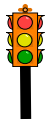
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
etravirine 25mg, 100mg, 200mg tablets (Intelence®) *Janssen-Cilag* 09.09.13 *SMC Report No. 901/13* PRODUCT UPDATE (abbreviated submission)	Restricted use: etravirine (Intelence®) is accepted for restricted use within NHS Scotland in combination with a boosted protease inhibitor and other antiretroviral medicinal products, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced paediatric patients from 6 years to less than 18 years of age. SMC restriction: to be prescribed under the supervision of specialists in paediatric HIV. SMC has previously accepted etravirine for use in combination with a boosted protease inhibitor and other antiretroviral medicinal products for the treatment of HIV-1 infection in antiretroviral treatment experienced adult patients. Etravirine is listed in the British National Formulary for Children 2012-2013 for the treatment of HIV infection.	Included on the Additional List, Specialist Use only for the indication in question.	August 2013
fosamprenavir 700mg tablets and oral suspension 50mg/ml (Telzir®) *GlaxoSmithKline UK* 11.07.05 *SMC Report No. 188/05*	Accepted for use: fosamprenavir (Telzir®) in combination with low dose ritonavir is accepted for use within NHS Scotland for the treatment of Human Immunodeficiency Virus Type 1 (HIV-1) infected adults in combination with other antiretroviral medicinal products. It should be prescribed by HIV specialists only.	Added to the Additional List, for Specialist Use only.	October 2005
fosamprenavir 50mg/ml oral suspension and 700mg film-coated tablet (Telzir®) *GlaxoSmithKline UK Ltd* 07.09.09 *SMC Report No. 431/07* PRODUCT UPDATE (abbreviated submission)	Accepted for use: fosamprenavir (Telzir®) in combination with low dose ritonavir is accepted for use within NHS Scotland for the treatment of Human Immunodeficiency Virus Type 1 (HIV-1) infected adolescents and children of six years and above in combination with other antiretroviral medicinal products. Fosamprenavir is listed in the British National Formulary for Children for the treatment of HIV infection. The Scottish Medicines Consortium has previously accepted this product for use in this indication in adults.	Added to the Additional List, for Specialist Use only.	September 2009
fosfomycin (Fosfocina®) (injection) *Laboratories ERN, S.A., Barcelona*	Treatment of multiresistant Pseudomonas aeruginosa infection in adult cystic fibrosis patients. 	Added to the Additional List for Specialist Use only. Added to the Alert Antibiotic policy. fosfomycin (fosfocina®) has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian' Specialist Use only.	June 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**
fosfomycin (Fomicyt®) (IV infusion) *Nordic Pharma* 09.03.15 *SMC Report No. 1033/15* PRODUCT UPDATE (abbreviated submission)	Restricted use: fosfomycin (Fomicyt®) is accepted for restricted use within NHS Scotland as treatment of the following infections in adults and children including neonates: Acute osteomyelitis, Complicated urinary tract infections, Nosocomial lower respiratory tract infections, Bacterial meningitis, Bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above. Fosfomycin should be used only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of the infections listed above, or when these alternative antibacterial agents have failed to demonstrate efficacy. Consideration should be given to national guidance on the appropriate use of antibacterial agents. Initiation by microbiologists or infectious disease specialists. Unlicensed preparations of intravenous fosfomycin are commonly used in the NHS in Scotland to treat multi-drug resistant gram negative organisms. This provides a licensed preparation. Estimated patient numbers are expected to be small.	Added to the additional list with initiation restricted to microbiologist or infectious disease specialists. Included in Alert Antibiotic List.	March 2015
fosfomycin trometamol granules for oral solution (equivalent to 3g fosfomycin) (Monuril®) *Profile Pharma Ltd* 12.09.16 *SMC Report No. 1163/16* PRODUCT UPDATE (abbreviated submission)	Accepted for use: fosfomycin trometamol (Monuril®) is accepted for use within NHS Scotland. Indication under review: • Treatment of acute lower uncomplicated urinary tract infections, caused by pathogens sensitive to fosfomycin in adult and adolescent females. • Prophylaxis in diagnostic and surgical transurethral procedures. Consideration should be given to national guidance on the appropriate use of antibacterial agents. Unlicensed preparations of oral fosfomycin have been used in the NHS in Scotland. The availability of fosfomycin trometamol (Monuril®) provides a licensed preparation. Estimated patient numbers are expected to be small.	Included on the Additional List, for Specialist Use only, for the indication in question.	October 2016
interferon alfa 2b (Viraferon® and Intron A®) 18 million IU, solution for injection, multidose pen in combination with ribavirin (Rebetol®) capsules 200mg *Schering Plough* 12.06.06 *SMC Report No. 258/06*	Accepted for use: interferon alfa 2b (Viraferon® and Intron A®) in combination with ribavirin (Rebetol®) is accepted for use within NHS Scotland for the treatment of children and adolescents 3 years of age and older, who have chronic hepatitis C, not previously treated, without liver decompensation and who are positive for serum HCV-RNA. The combination is effective in eliminating hepatitis C virus in children and adolescents. The decision to treat should be made on a case by case basis, taking into account any evidence of disease progression such as hepatic inflammation and fibrosis, as well as prognostic factors for response, HCV genotype and viral load. The expected benefit of treatment should be weighted against the safety findings observed for paediatric subjects in the clinical trials.	Added to the Additional List.	March 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**
isavuconazole, 200mg powder for concentrate for solution for infusion and 100mg hard capsules (Cresemba®) *Basilea Pharmaceutica International Ltd* 11.04.16 *SMC Report No. 1129/16* Patient Access Scheme	Accepted: isavuconazole (Cresemba®) is accepted for use within NHS Scotland. Indication under review: in adults for the treatment of: invasive aspergillosis mucormycosis in patients for whom amphotericin B is inappropriate A phase III, randomised, double-blind, non-inferiority study demonstrated that, in the treatment of invasive aspergillosis, isavuconazole was non-inferior to a triazole antifungal for all-cause mortality through day 42, and had a similar overall response at the end of treatment. A phase III, open-label, single-arm study demonstrated that, in the treatment of mucormycosis, isavuconazole had a treatment effect on all-cause mortality and overall response. The treatment effect was considered to be comparable to that observed in external control studies of a polyene antifungal. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of isavuconazole. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. 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, Specialist Use only. Included on the Additional List, Specialist Use only, for the indication in question.	March 2017
lamivudine/zidovudine fixed-dose combination (Combivir®) *GlaxoSmithKline UK Ltd* 07.09.09 *SMC Report No. 569/09* PRODUCT UPDATE (abbreviated submission)	Accepted for use: lamivudine/zidovudine fixed dose combination (Combivir®) in antiretroviral combination therapy is accepted for use within NHS Scotland for the treatment of Human Immunodeficiency Virus Type 1 (HIV-1) in paediatric patients weighing 14kg to 30kg. This combination is listed in the British National Formulary for Children for the treatment of HIV infection. It was previously licensed for use in adults and adolescents weighing at least 30kg. The availability of both the combination product and its active ingredients pre-date the establishment of the Scottish Medicines Consortium.	Added to the Additional List, for Specialist Use only.	September 2009
lansoprazole orodispersible tablet 15mg, 30mg (Zoton® FasTab®) *Wyeth* 09.01.06 *SMC Report No. 229/05* PRODUCT UPDATE (abbreviated submission)	Accepted for use: lansoprazole orodispersible tablet (Zoton® FasTab®) is accepted for use in NHS Scotland, in combination with appropriate antibiotics, for the eradication of *Helicobacter pylori* from the upper gastrointestinal tract in patients with ulcer-like dyspepsia in whom *Helicobacter pylori* infection has been demonstrated. The standard formulation of lansoprazole also has this indication.	Extension to licence of a drug already included in the Formulary.	

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**
ledipasvir/sofosbuvir, 90mg/400mg, film-coated tablet (Harvoni®) *Gilead Sciences Ltd.* 09.03.15 *SMC Report No. 1030/15*	Restricted use: ledipasvir/sofosbuvir, 90mg/400mg, film-coated tablet (Harvoni®) is accepted for restricted use within NHS Scotland as treatment of chronic hepatitis C (CHC) in adults. Genotype 1 and 4 CHC only. In three, uncontrolled phase III studies conducted in treatment-naïve and treatment-experienced non-cirrhotic and cirrhotic patients with genotype 1 CHC, ledipasvir/sofosbuvir ± ribavirin achieved sustained virological response (at 12 weeks post treatment) rates of 93% to 99%, which were significantly superior to historical control rates. No clinical or economic data were presented for genotype 3 patients with cirrhosis and/or prior treatment failure.	Included on the Additional List, for Specialist Use only, for the indication in question.	April 2015
ledipasvir/sofosbuvir 90mg/400mg film-coated tablet (Harvoni®) *Gilead Sciences Ltd.* 07.09.15 *SMC Report No. 1084/15*	Restricted: ledipasvir/sofosbuvir (Harvoni®) is accepted for restricted use within NHS Scotland. Indication under review: Treatment of genotype 3 chronic hepatitis C (CHC) in adults. SMC restriction: patients who are ineligible for or unable to tolerate interferon. Efficacy data are limited to a phase II open-label study. The addition of ledipasvir to sofosbuvir plus ribavirin is expected to increase antiviral activity, although the magnitude of this effect is not well characterised. SMC has previously accepted ledipasvir/sofosbuvir for restricted use in genotype 1 and 4 CHC; this now extends advice to include use in genotype 3 CHC.	Included on the additional list, specialist use, for the indication in question.	October 2015
levofloxacin (Tavanic®) *Hoechst Marion Roussel*	Pneumococcal infection in patients with severe allergy to penicillins and cephalosporins - new use request	'Not preferred' as effective alternatives available.	May 2005
levofloxacin (Tavanic®) *Sanofi – Aventis*	Treatment of lower respiratory tract infection in cystic fibrosis 	Added to Additional list – Categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label) use of Medicines in NHS Lothian', for cystic fibrosis patients - Specialist use only	May 2012
levofloxacin	For community acquired pneumonia where Legionella pneumophilia is confirmed or strongly suspected as the causative organism.	Added to the Additional List, for Specialist Use only. Added to the Alert Antibiotic Policy.	December 2014

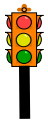
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
levofloxacin 240mg nebuliser solution (Quinsair®) *Raptor Pharmaceuticals Europe B.V* 08.08.16 *SMC Report No. 1162/16* Patient Access Scheme	Restricted use: levofloxacin (Quinsair®) is accepted for restricted use within NHS Scotland for the management of chronic pulmonary infections due to Pseudomonas aeruginosa in adult patients with cystic fibrosis. SMC restriction: for use as a third line treatment option after colistimethate sodium (first line) and tobramycin (second line). In a phase III open-label randomised study, levofloxacin was non-inferior to another inhaled antimicrobial for change in lung function, measured by relative change in forced expiratory volume in one second (FEV1) percent predicted. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of levofloxacin. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.	Included on the Additional List, Specialist initiation, for the indication in question.	November 2016
lopinavir 200mg, ritonavir 50mg tablet (Kaletra®) *Abbott Laboratories Ltd* 13.11.06 *SMC Report No. 326/06* PRODUCT UPDATE (abbreviated submission)	Accepted for use: lopinavir 200 mg, ritonavir 50 mg tablet (Kaletra®) is accepted for use in NHS Scotland for the treatment of HIV-1 infected adults and children above the age of 2 years, in combination with other antiretroviral agents. For patients for whom this drug combination is appropriate, it is associated with a reduced pill burden compared to an existing solid oral dose formulation containing these drugs at no increased cost.	Additional List to be amended - lopinavir with ritonavir capsules to be replaced with the new formulation of Kaletra®.	September 2007
maraviroc, 150 mg and 300 mg tablets (Celsentri®) *Pfizer Ltd* 13.10.08 *SMC Report No. 458/08* RESUBMISSION	NOT RECOMMENDED: maraviroc (Celsentri®) is not recommended for use within NHS Scotland in combination with other antiretroviral medicinal products, for treatment-experienced adult patients infected with only CCR5-tropic HIV-1 detectable. When added to optimised background therapy, maraviroc was associated with a significant reduction in viral load compared with addition of placebo in heavily pre-treated patients. However, the manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
micafungin 50 and 100mg powder for solution for infusion (Mycamine®) *Astellas Pharma Ltd* 08.09.08 *SMC Report No. 497/08*	Restricted use: micafungin (Mycamine®) is accepted for restricted use within NHS Scotland. It is restricted to use in the treatment of invasive candidiasis in adults, elderly, and children (including neonates). Micafungin has been shown to be non-inferior to caspofungin and liposomal amphotericin B in the treatment of patients with invasive candidiasis, the majority of whom had candidaemia and were non-neutropenic. It was effective in the treatment of both C. albicans and non-albicans Candida species.	'Not preferred' as suitable alternatives exist.	May 2009

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**
micafungin 50 and 100mg powder for solution for infusion (Mycamine®) *Astellas Pharma Ltd* 08.09.08 *SMC Report No. 497/08*	NOT RECOMMENDED: micafungin (Mycamine®) is not recommended for use within NHS Scotland for the treatment of oesophageal candidiasis in adult, elderly and adolescent ≥16 years of age) patients for whom intravenous therapy is appropriate. The manufacturer did not supply any economic analysis and therefore the cost effectiveness could not be assessed.	NOT RECOMMENDED	
micafungin 50 and 100mg powder for solution for infusion (Mycamine®) *Astellas Pharma Ltd* 08.09.08 *SMC Report No. 497/08*	NOT RECOMMENDED: micafungin (Mycamine®) is not recommended for use within NHS Scotland for prophylaxis of Candida infection in adults, elderly, and children (including neonates) undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia (absolute neutrophil count < 500 cells/µl) for 10 or more days. The manufacturer did not supply any economic analysis and therefore the cost effectiveness could not be assessed.	NOT RECOMMENDED	
miconazole, 50mg muco-adhesive buccal tablets (Loramyc®) *SpePharm UK Ltd* 07.02.11 *SMC Report No. 517/08* RESUBMISSION	NOT RECOMMENDED: miconazole muco-adhesive buccal tablets (Loramyc®) is not recommended for use within NHS Scotland. Indication under review: The treatment of oropharyngeal candidiasis (OPC) in immunocompromised patients. Miconazole muco-adhesive buccal tablets were shown to be non-inferior in the treatment of OPC to another locally-acting miconazole preparation in patients with cancer of the head and neck who had received radiotherapy, and to another locally-acting anti-fungal in HIV-positive patients. There are no data comparing miconazole buccal tablets to treatments currently used in practice in Scotland in this patient group. Overall the manufacturer did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
miconazole oral 2% gel (Daktarin®) *Cilag Ltd and McNeil Products Ltd* Local formulary process	For the treatment of oral thrush in breastfed infants ≤4 months of age as well as those > 4months of age. 	Routinely available in line with local or regional guidance. Included on the LJF as a prescribing note, 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 a prescribing note, General Use. Classified as GREEN under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	March 2017
moxifloxacin (Avelox®) *Bayer* 13.10.03 *SMC Report No. 69/03*	Restricted use: moxifloxacin (Avelox®), a new fluoroquinolone antibiotic, should be reserved as a second-line treatment for community-acquired pneumonia in accordance with British Thoracic Society (BTS) and Scottish Intercollegiate Guidelines Network (SIGN) guidance.	'Not preferred' in the Adult Formulary as effective alternatives are available. Not Preferred in the LJF for Children as effective alternatives are available.	November 2003 April 2005

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**
moxifloxacin (Avelox®) *Bayer* 13.10.03 *SMC Report No. 70/03*	Restricted use: moxifloxacin (Avelox®), a new fluoroquinolone antibiotic, for the treatment of acute exacerbations of chronic bronchitis, should be restricted to patients who fail to respond to conventional therapy or in whom this is contra-indicated. Its use should be in accordance with British Thoracic Society (BTS) and Scottish Intercollegiate Guidelines Network (SIGN) guidance.	'Not preferred' in the Adult Formulary as effective alternatives are available. Not Preferred in the LJF for Children as effective alternatives are available.	November 2003 April 2005
moxifloxacin intravenous, 400mg/250mL, solution for infusion (Avelox®) *Bayer Schering* 13.12.10 *SMC Report No. 650/10*	Restricted use: moxifloxacin intravenous (Avelox®) is accepted for restricted use within NHS Scotland. Indication under review: the treatment of community acquired pneumonia (CAP). It should be used only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of these infections. Consideration should be given to official guidance on the appropriate use of antibacterial agents. SMC restriction: use only on the advice of microbiologists or specialists in infectious diseases. In several studies, sequential intravenous/oral moxifloxacin has been shown to be non-inferior to a range of comparative therapies. Intravenous moxifloxacin is also licensed for the treatment of complicated skin and skin structure infections. The manufacturer's submission related only to use in CAP, therefore SMC cannot recommend its use in the treatment of skin infections.	'Not Preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	March 2012
moxifloxacin (Avelox®) *Bayer*	CF/bronchiectasis patients when therapy failed or co-amoxiclav and clarithromycin resistance - new use request	'Not Preferred' in the Children's Formulary as effective alternatives are available.	April 2005
moxifloxacin (Avelox®) *Bayer Schering*	As part of tuberculosis treatment regimen if the patient infection is resistant to one or more first line antibacterial agents and is sensitive to moxifloxacin. 	Added to the Additional List, for Specialist Use only. moxifloxacin (Avelox®) has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	December 2012
nevirapine 50mg, 100mg, 400mg prolonged release tablets (Viramune prolonged release tablets®) *Boehringer Ingelheim Ltd* 13.02.12 *SMC Report No. 760/12* PRODUCT UPDATE (abbreviated submission)	Accepted for use: nevirapine prolonged release tablets (Viramune®) are accepted for use in NHS Scotland in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infected adults, adolescents, and children three years and above and able to swallow tablets. Once daily dosing with the nevirapine prolonged release formulation demonstrated non-inferior efficacy to the immediate release nevirapine formulation at 48 weeks in both treatment-naïve and treatment-experienced patients. When combined with other HIV therapies the once daily formulation may provide a more convenient dosing schedule for patients.	Added to the Additional List, for Specialist Use only.	March 2012

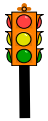
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
ombitasvir 12.5mg / paritaprevir 75mg / ritonavir 50mg (Viekirax®) film-coated tablet and dasabuvir 250mg (Exviera®) film-coated tablet *AbbVie* 08.06.15 *SMC Report No. 1051/15*	Accepted for use: ombitasvir/paritaprevir/ritonavir (Viekirax®) is accepted for use within NHS Scotland. dasabuvir (Exviera®) is accepted for use within NHS Scotland. Indications under review: Ombitasvir/paritaprevir/ritonavir (Viekirax®) for use in combination with dasabuvir (Exviera®) with or without ribavirin for the treatment of genotype 1 chronic hepatitis C (CHC) in adults Ombitasvir/paritaprevir/ritonavir (Viekirax®) for use in combination with ribavirin for the treatment of genotype 4 CHC in adults In six phase III studies, conducted in patients with genotype 1 CHC, rates of sustained virological response at 12 weeks post-treatment were achieved in ≥96% of patients who received licensed treatment regimens of ombitasvir/paritaprevir/ritonavir + dasabuvir, irrespective of sub-genotype, previous treatment and presence of cirrhosis.	Included on the Additional List, specialist use only, for the indication in question.	July 2015
oseltamivir 30mg, 45mg, 75mg capsules and 6mg/mL powder for oral suspension (Tamiflu®) *Roche Products Limited* 07.03.16 *SMC Report No. 1127/16* PRODUCT UPDATE (abbreviated submission)	Accepted: oseltamivir (Tamiflu®) is accepted for use within NHS Scotland. Indication under review: Treatment of influenza in children aged <1 year including full term neonates who present with symptoms typical of influenza, when influenza virus is circulating in the community. Efficacy has been demonstrated when treatment is initiated within two days of first onset of symptoms. Oseltamivir is listed in the British National Formulary for Children (November 2015) for use in children aged <1 year including neonates. Oseltamavir has previously been accepted for use for this indication in patients aged ≥1 year in NHS Scotland as NHS Healthcare Improvement Scotland advised that NICE Multiple Technology Appraisal No. 168 was valid for Scotland.	Included on the additional list.	March 2016
palivizumab (Synagis®) *Abbott*	Prevention of serious disease caused by respiratory syncytial virus	Added to the Additional List for pre-term babies or infants with particular medical conditions. Note: - Already on the Additional List for paediatric cardiac patients (2004)	November 2010
pegylated interferon alfa-2a (Pegasys®) *Roche* 06.09.02 SMC Report No. 10/02	Restricted use: pegylated interferon alfa-2a is an appropriate treatment for the treatment of adult patients which chronic hepatitis C under the overall supervision of specialists experienced in the management of this disorder. This treatment involves a weekly injection from a pre-filled syringe that reduces inconvenience to patients whilst increasing the response rate over interferon alfa-2a alone or in combination with ribavirin.	Approved for use - added to the Additional List.	March 2003

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**
pegylated interferon alfa 2a, 180micrograms for subcutaneous injection (Pegasys®) *Roche* 11.07.05 *SMC Report No. 186/05*	Accepted for use: pegylated interferon alfa 2a (Pegasys®) is accepted for use within NHS Scotland for the treatment of HBeAg-positive or HBeAg-negative chronic hepatitis B in adult patients with compensated liver disease and evidence of viral replication, increased ALT and histologically verified liver inflammation and/or fibrosis. Compared with conventional interferon alfa 2a, it offers comparable efficacy and the convenience of once-weekly rather than three-times weekly subcutaneous administration. It has been shown to be cost effective when compared to a number of comparator medicines in a range of patient groups.	Added to the Additional List, for Specialist Use only.	July 2007
peginterferon alfa-2a, 135 microgram/mL and 180 microgram/mL pre-filled injections of solution for subcutaneous injection (Pegasys®) *Roche Products Limited* 10.08.09 *SMC Report No. 561/09*	Accepted for use: peginterferon alfa-2a (Pegasys®) is accepted for use within NHS Scotland in combination with ribavirin for the treatment of chronic hepatitis C in adult patients who have failed previous treatment with interferon alfa (pegylated or non-pegylated) alone or in combination with ribavirin. Non-responders to previous hepatitis C treatment, predominantly with virus genotype 1, achieved sustained viral responses of 8% and 15% following 48 weeks and 72 weeks of combination treatment respectively. The manufacturer did not provide comparative clinical or cost-effectiveness data versus peginterferon alfa-2b.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	May 2011
pegylated interferon alpha-2a, 135 and 180microgram/mL pre-filled syringe, 135 and 180microgram/mL pre-filled pen (Pegasys®) *Roche Products Limited* 10.06.13 *SMC Report No. 871/13* PRODUCT UPDATE (abbreviated submission)	Restricted use: pegylated interferon alpha-2a (Pegasys®) is accepted for restricted use within NHS Scotland in combination with ribavirin, is indicated for the treatment of chronic hepatitis C (CHC) in treatment-naïve children and adolescents five years of age and older, who are positive for serum hepatitis-C-virus ribonucleic acid (HCV-RNA). When deciding to initiate treatment in childhood, it is important to consider growth inhibition induced by combination therapy. The reversibility of growth inhibition is uncertain. The decision to treat should be made on a case-by-case basis. SMC restriction: prescribing by specialist in paediatric infectious disease or paediatric gastroenterology. Results from phase lll studies in paediatric patients suggest that efficacy and safety in this patient group is broadly similar to that in adults, with the exception of the reported effects on growth in children. The Scottish Medicines Consortium has previously accepted this product for restricted use in adults. Pegylated interferon alpha-2a is listed in the British National Formulary for Children 2012-2013 for the treatment of chronic hepatitis C.	Not preferred' in Lothian, as suitable alternatives exist. ViraferonPeg® is the preferred pegylated interferon in children in NHS Lothian	August 2013
pegylated interferon alfa-2b (ViraferonPeg®) *Schering-Plough* 10.05.02 SMC Report No. 02/02	Restricted use: pegylated interferon alfa-2b (ViraferonPeg®) is an appropriate treatment for the management of adult patients with chronic hepatitis C under the overall supervision of specialists experienced in the management of this disorder. This treatment involves a once weekly injection that reduces inconvenience to patients whilst increasing the response rate to both pegylated interferon alfa-2b alone or in combination with ribavirin.	'Not preferred' as Pegasys® preferred.	March 2003

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**
pegylated interferon α 2b (ViraferonPeg®), 50, 80, 100, 120 or 150 micrograms powder for solution for injection in pre-filled pen, in combination with ribavirin (Rebetol®), 200mg capsules *Schering-Plough UK and Ireland* 11.08.08 *SMC Report No. 488/08*	Accepted for use: pegylated interferon α 2b (ViraferonPeg®) in combination with ribavirin (Rebetol®) is accepted within NHS Scotland for the treatment of adult patients with chronic hepatitis C who have failed previous treatment with interferon alfa (pegylated or non-pegylated) and ribavirin combination therapy or interferon alfa (pegylated or non-pegylated) monotherapy. A sustained virologic response rate of 23% was achieved in a single arm study where relapsed or non-responding patients were treated with peginterferon α 2b and ribavirin. Re-treatment was more cost-effective with patients who had previously responded but relapsed compared to patients who did not respond to initial therapy.	'Not preferred' in Lothian, as suitable alternatives exist. Pegasys® is preferred pegylated interferon for adult patients.	August 2009
pegylated interferon alfa-2b 50, 80, 100, 120 or 150 micrograms powder for solution for injection in pre-filled pen (ViraferonPeg®) *MSD Ltd* 03.07.12 *SMC Report No. 794/12* PRODUCT UPDATE (abbreviated submission)	Accepted for use: pegylated interferon alfa-2b (ViraferonPeg®) is accepted for use within NHS Scotland in a combination regimen with ribavirin for the treatment of children 3 years of age and older and adolescents, who have chronic hepatitis C, not previously treated, without liver decompensation, and who are positive for HCV-RNA. This treatment involves a once weekly injection that reduces inconvenience to patients whilst increasing the response rate to pegylated interferon alfa-2b in combination with ribavirin.	Included on the Additional List, Specialist Use only, for the indication in question	August 2013
piperacillin plus tazobactam	For the treatment of neonates with suspected or confirmed late onset blood stream infection defined as infection arising greater than 72 hours after birth in infants currently on the neonatal unit at the RIE. 	Added to the LJF as a first-line treatment, for Specialist Use only. Piperacillin plus tazobactam has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	February 2014
piperacillin / tazobactam	For the treatment of Pseudomonas or Enterobacteriaceae infections with borderline resistance (high MICs) and/or complicated source of infection in critical care within the RIE, WGH and SJH. Extended time infusion. 	Added to the Additional List, for Specialist Use only. Piperacillin / tazobactam has been categorised **RED** under the ADTC 'Policy and procedures for the use of unlicensed medicines.'	July 2014
posaconazole 40mg/ml oral suspension (Noxafil®) *Schering Plough* 12.06.06 *SMC Report No. 256/06*	Accepted for use: posaconazole (Noxafil®) is accepted for use for use within NHS Scotland for the treatment of adults with specific invasive fungal infections refractory to or intolerant of specified antifungal agents. The evidence to support the licensed use of posaconazole is limited to one open-label, non-comparative study mainly in patients refractory to treatment with amphotericin.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	April 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**
posaconazole 40mg/ml oral suspension (Noxafil®) *Schering Plough* 11.06.07 *SMC Report No. 379/07*	Restricted use: posaconazole (Noxafil®) is accepted for restricted use within NHS Scotland for prophylaxis of invasive fungal infections in immunocompromised patients. It is restricted to patients in whom there is a specific risk of *Aspergillus* infection or where fluconazole or itraconazole are not tolerated.	Included on the Additional List, Specialist Use only, for the indication in question.	October 2013
posaconazole 300mg concentrate for solution for infusion (Noxafil®) *Merck Sharp & Dohme Limited* 13.07.15 *SMC Report No. 1067/15* PRODUCT UPDATE (abbreviated submission)	Accepted: posaconazole concentrate for solution for infusion (Noxafil®) is accepted for use within NHS Scotland. Indication under review: for use in the treatment of the following fungal infections in adults: • Invasive aspergillosis in patients with disease that is refractory to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products; • Fusariosis in patients with disease that is refractory* to amphotericin B or in patients who are intolerant of amphotericin B; • Chromoblastomycosis and mycetoma in patients with disease that is refractory to itraconazole or in patients who are intolerant of itraconazole; • Coccidioidomycosis in patients with disease that is refractory to amphotericin B, itraconazole or fluconazole or in patients who are intolerant of these medicinal products. For prophylaxis of invasive fungal infections (IFI) in the following patients: • Patients receiving remission-induction chemotherapy for acute myelogenous leukaemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged neutropenia and who are at high risk of developing IFI; • Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease (GVHD) and who are at high risk of developing IFI. Posaconazole 300mg solution for infusion will generally result in higher plasma concentrations than posaconazole oral suspension and is expected to result in similar plasma concentrations as the tablet formulation. Posaconazole solution for infusion is more expensive than oral preparations. It is intended for patients who are not able to receive an oral formulation, and should be used for the minimum time required. Patients should be switched to an oral formulation of posaconazole as soon as clinically practical.	Included on the Additional List for prophylaxis of invasive fungal infections for patients who are unable to receive an oral formulation. **Not included** for the treatment of fungal infections.	July 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**
raltegravir, 400mg film-coated tablet (Isentress®) *Merck, Sharp and Dohme Limited* 12.05.08 *SMC Report No. 461/08*	Restricted use: raltegravir, 400mg film-coated tablet (Isentress®) is accepted for restricted use within NHS Scotland in combination with other antiretroviral medicinal products agents for the treatment of Human Immunodeficiency Virus (HIV-1) infection in treatment experienced adult patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy. It is restricted to patients with triple class resistant HIV-1 infection. Addition of raltegravir to optimised background therapy in treatment experienced patients with documented resistance to at least one drug in each of the three HIV antiviral classes, significantly increased the number of patients achieving clinically significant reductions in viral load.	Added to the Additional List, for Specialist Use only.	July 2008
raltegravir, 400mg film-coated tablet (Isentress®) *Merck, Sharp and Dohme Limited* 10.05.10 *SMC Report No: 613/10*	Restricted use: raltegravir (Isentress®) is accepted for restricted use within NHS Scotland. Licensed indication under review: in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients. SMC restriction: to patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug-drug interactions. Raltegravir has been shown to be non-inferior to efavirenz in combination with tenofovir and emtricitabine in treatment naïve patients. In two small open-label studies, raltegravir demonstrated maintenance of viral suppression over 24 weeks when substituted for enfuvirtide in a combination regimen in highly pre-treated patients with a history of triple class failure or intolerance. The health economic case was demonstrated only for a sub-population of patients within the licensed indication. SMC has previously issued advice for raltegravir in the treatment of HIV infection and this extends the advice to cover a wider patient population.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	May 2011
raltegravir 25mg, 100mg chewable and 400mg film-coated tablets (Isentress®) *MSD Ltd* 09.09.13 *SMC Report No. 902/13* PRODUCT UPDATE (Abbreviated submission)	Restricted use: raltegravir (Isentress®) is accepted for restricted use within NHS Scotland in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adolescents and children aged 2 to 17 years. SMC restriction: to patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug-drug interactions; raltegravir should to be prescribed under the supervision of specialists in paediatric HIV. The chewable and film-coated tablets are not bioequivalent and therefore are not interchangeable. SMC has previously accepted raltegravir 400mg film-coated tablets for restricted use in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infection in adult patients. Raltegravir is listed in the British National Formulary for Children for the treatment of HIV infection.	Included on the Additional List, Specialist Use only for the indication in question.	August 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**
raltegravir (Isentress®)	For post exposure prophylaxis for HIV in combination with tenofovir / emtricitabine (Truvada®). 	Added to the Additional List, for Specialist Use only. Raltegravir (Isentress®) has been categorised **RED** under the ADTC 'Policy and procedures for the use of unlicensed medicines.'	July 2014
raltegravir granules for oral suspension 100mg (Isentress®) *Merck Sharp & Dohme Limited* 09.11.15 *SMC Report No. 1102/15* PRODUCT UPDATE (abbreviated submission)	Restricted: raltegravir granules for oral suspension (Isentress®) are accepted for restricted use within NHS Scotland. Indication under review: in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adults, adolescents, children, toddlers and infants from the age of 4 weeks. SMC restriction: patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug-drug interactions; raltegravir granules should be prescribed under the supervision of specialists in paediatric HIV. The granules for oral suspension are licensed for use in patients weighing 3kg to 20kg and provide an alternative formulation for infants where chewable tablets are not suitable. Because the formulations are not bioequivalent, neither the granules for oral suspension nor thechewable tablets should be substituted for the 400 mg film-coated tablet. SMC has previously accepted raltegravir 25mg and 100mg chewable tablets and raltegravir 400mg film-coated tablets for restricted use in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infection in adolescents and children aged 2 to 17 years and in adult patients. Raltegravir is listed in the British National Formulary for Children for the treatment of HIV infection.	Included on the Additional list, Specialist use only, for the indication in question.	November 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**
raltegravir chewable tablets 25mg, 100mg (Isentress®) *Merck Sharp & Dohme Limited* 09.11.15 *SMC Report No. 1113/15* PRODUCT UPDATE (abbreviated submission)	Restricted: raltegravir chewable tablets (Isentress®) are accepted for restricted use within NHS Scotland. Indication under review: in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in children from the age of 4 weeks to <2 years. SMC restriction: patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug-drug interactions; raltegravir chewable tablets should be prescribed under the supervision of specialists in paediatric HIV. The chewable tablets are not bioequivalent to the film-coated tablets and therefore are not interchangeable. SMC has previously accepted raltegravir 25mg and 100mg chewable tablets and raltegravir 400mg film-coated tablets for restricted use in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infection in adolescents and children aged 2 to 17 years and in adult patients. Raltegravir is listed in the British National Formulary for Children for the treatment of HIV infection.	Included on the Additional list, Specialist use only, for the indication in question.	November 2015
retapamulin (Altargo®) *GlaxoSmithKline UK* 07.04.08 *SMC Report No. 472/08* NON SUBMISSION	NOT RECOMMENDED: retapamulin (Altargo®) is not recommended for use within NHSScotland for the short term treatment of the following superficial skin infections: impetigo and infected small lacerations, abrasions, or sutured wounds. 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	
rifampicin, isoniazid, pyrazinamide, ethambutol hydrochloride (Voractiv®) Film-coated Tablets *Genus Pharmaceuticals* 13.05.13 *SMC Report No. 876/13* NON SUBMISSION	NOT RECOMMENDED: rifampicin, isoniazid, pyrazinamide, ethambutol hydrochloride (Voractiv®) is not recommended for use within NHS Scotland for initial treatment of tuberculosis according to World Health Organisation (WHO) guidelines. 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	
rilpivirine 25mg film-coated tablet (Edurant®) *Janssen-Cilag* 13.02.12 *SMC Report No. 758/12*	Accepted for use: rilpivirine (Edurant®) is accepted for use within NHS Scotland in combination with other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load ≤100,000 HIV-1 RNA copies/mL. The non-inferiority of rilpivirine over another non-nucleoside reverse transcriptase inhibitor (when given in combination with two nucleoside reverse transcriptase inhibitors) for virological response was demonstrated in two phase III, comparative, multi-centre studies in antiretroviral treatment-naïve patients.	Added to the Additional List for Specialist Use only. Included on the Lothian Joint Formulary for the indication in question.	April 2012

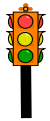
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
rilpivirine 25mg film-coated tablet (Edurant®) *Janssen-Cilag Ltd* 08.08.16 *SMC Report No. 1168/16* PRODUCT UPDATE (abbreviated submission)	Accepted for use: rilpivirine (Edurant®) is accepted for use within NHS Scotland in combination with other antiretroviral medicinal products, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve patients aged 12 to 18 years of age and older with a viral load (VL) ≤ 100,000 HIV-1 RNA copies/mL. The Scottish Medicines Consortium has previously accepted rilpivirine in this indication in adult patients.	Included on the Additional List, Specialist Use only, for the indication in question.	August 2016
rilpivirine 25mg, emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg tablet (Eviplera®) *Gilead Sciences Ltd.* 07.04.14 *SMC Report No. 951/14*	Accepted for use: rilpivirine, emtricitabine, tenofovir disoproxil fumarate tablet (Eviplera®) is accepted for use within NHS Scotland for the treatment of adults infected with human immunodeficiency virus type 1 (HIV-1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine, and with viral load ≤100,000 HIV-1 RNA copies/mL. As with other antiretroviral medicinal products, genotypic resistance testing and/or historical resistance data should guide the use of Eviplera®. Rilpivirine, emtricitabine, tenofovir (Eviplera®) maintained virological suppression in patients switched from other antiretroviral regimens. There is no evidence of efficacy in patients switching from other antiretroviral regimens due to virological failure. SMC issued advice in February 2012 regarding the use of Eviplera® in antiretroviral treatment-naive adult patients. The current advice extends use to antiretroviral treatment-experienced patients.	Included on the Additional List, for Specialist Use only, for the indication in question.	May 2014
rilpivirine/emtricitabine/tenofovir alafenamide 200mg/25mg/25mg film-coated tablets (Odefsey®) *Gilead Sciences Ltd* 10.10.16 *SMC Report No. 1189/16* PRODUCT UPDATE (abbreviated submission)	Accepted for use: rilpivirine/emtricitabine/tenofovir alafenamide (Odefsey®) is accepted for use within NHS Scotland treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg), infected with human immunodeficiency virus type 1 (HIV-1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine, and with viral load HIV-1 RNA ≤100,000 copies/mL. For adult patients in whom emtricitabine/rilpivirine/tenofovir is an appropriate combination, Odefsey® (emtricitabine/rilpivirine/tenofovir alafenamide) offers an alternative to Eviplera® (emtricitabine/rilpivirine/tenofovir disoproxil) at no additional cost. Odefsey may also be used in patients from the age of 12 years.	Included on the Additional List, for Specialist Use only, for the indication in question.	October 2016
simeprevir 150mg hard capsules (Olysio®) *Janssen* 13.10.14 *SMC Report No. 988/14*	Accepted for use: simeprevir (Olysio®) is accepted for use within NHS Scotland in combination with other medicinal products for the treatment of chronic hepatitis C in adult patients. In four double-blind phase III studies, when given as part of triple regimen in combination with peginterferon-alfa and ribavirin, simeprevir was superior to placebo in treatment naive and prior relapsed patients and non-inferior to another direct acting antiviral drug in treatment experienced patients with genotype 1 hepatitis C virus.	Included on the Additional List, for Specialist Use only, for the indication in question.	October 2014

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**
sofosbuvir 400mg tablet (Sovaldi®) *Gilead Sciences Ltd.* 09.06.14 *SMC Report No. 964/14*	Restricted use: sofosbuvir (Sovaldi®) is accepted for restricted use within NHS Scotland in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults. SMC restriction: Sofosbuvir is accepted for use in patients with genotypes 1 to 6. Use in treatment-naive patients with genotype 2 is restricted to those who are ineligible for, or are unable to tolerate, peginterferon alfa. Use of the 24-week interferon-free regimen of sofosbuvir in combination with ribavirin in patients with genotype 3 is restricted to those who are ineligible for, or are unable to tolerate, peginterferon alfa. Sofosbuvir in combination with ribavirin, or peginterferon plus ribavirin, produced sustained virological suppression in patients with all genotypes of hepatitis C. It is the first medicine licensed for use in interferon-free regimens and may be associated with improved tolerability compared to standard interferon-based regimens. No clinical or economic data were presented for treatment-experienced patients with genotype 1.	Included on the Additional List, for Specialist Use only, for the indication in question. Prescribing of sofosbuvir is to be in line with the SMC recommendation and the UK Consensus Guidelines.	July 2014
sofosbuvir 400mg, velpatasvir 100mg film-coated tablets (Epclusa®) *Gilead Sciences Ltd.* 07.11.16 *SMC Report No. 1195/16*	Restricted use: sofosbuvir-velpatasvir (Epclusa®) is accepted for restricted use within NHS Scotland for the treatment of chronic hepatitis C virus (HCV) infection in adults. SMC restriction: in patients with genotype 3 (GT3) chronic HCV infection. Sofosbuvir-velpatasvir for 12 weeks, compared with sofosbuvir plus ribavirin for 24 weeks, significantly improved sustained virologic suppression in adults with genotype 3 chronic HCV infection.	Included on the Additional List, for Specialist Use only, for the indication in question.	December 2016
tedizolid phosphate 200mg film-coated tablets and 200mg powder for concentrate for solution for infusion (Sivextro®) *Cubist (UK) Limited/Merck Sharp & Dohme Limited* 10.08.15 *SMC Report No. 1080/15*	Restricted use: tedizolid phosphate (Sivextro®) is accepted for restricted use within NHS Scotland. Indication under review: The treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults. SMC restriction: • Use in patients with ABSSSI caused by Gram-positive *Staphylococcus aureus* (specifically methicillin-resistant *Staphylococcus aureus* [MRSA] isolates) • Use of tedizolid phosphate is restricted to use as an alternative oxazolidinone antibacterial on the specific advice of local microbiologists or specialists in infectious disease. In two randomised, double-blind clinical studies, tedizolid phosphate was non-inferior to another oxazolidinone antibacterial in adult patients with ABSSSI. The presenting company did not submit any evidence for SMC to consider around the use of tedizolid phosphate in “mixed infections”, where the infection involves both Gram-positive and Gram-negative organisms.	Not included on the LJF, because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine.	October 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**
telaprevir, 375mg, film-coated tablets (Incivo®) *Janssen* 12.12.11 *SMC Report No 742/11*	Accepted for use: telaprevir (Incivo®) is accepted for use within NHS Scotland in combination with peginterferon alfa and ribavirin, is indicated for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease (including cirrhosis) who have previously been treated with interferon alfa (pegylated or non-pegylated) alone or in combination with ribavirin, including relapsers, partial responders and null responders. In the pivotal phase III randomised study, the addition of telaprevir to current standard therapy in patients with genotype 1 chronic hepatitis C virus, who had failed previous therapy, significantly increased the proportion of patients who achieved a sustained virologic response.	Added to the Additional List, for Specialist use only.	March 2012
telaprevir 375mg film-coated tablets (Incivo®) *Janssen* 12.12.11 *SMC Report No 743/11*	Accepted for use: telaprevir (Incivo®) is accepted for use within NHS Scotland in combination with peginterferon alfa and ribavirin, for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease (including cirrhosis) who are treatment-naïve. In the pivotal phase III randomised study, addition of telaprevir to current standard therapy in treatment-naïve patients with genotype 1 chronic hepatitis C virus, significantly increased the proportion of patients who achieved a sustained virologic response, even in patients treated for a shorter overall duration using response-guided therapy.	Added to the Additional List, for Specialist use only.	March 2012
telavancin hydrochloride (Vibativ®) 250 mg and 750 mg powder for concentrate for solution for infusion *Clinigen Healthcare Ltd* 10.11.14 *SMC Report No: 1015/14* NON SUBMISSION	NOT RECOMMENDED: telavancin hydrochloride (Vibativ®) is not recommended for use within NHS Scotland for the treatment of adults with nosocomial pneumonia (NP) including ventilator associated pneumonia, known or suspected to be caused by methicillin-resistant Staphylococcus aureus (MRSA). 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	
telbivudine, 600mg film-coated tablets (Sebivo®) *Novartis Pharmaceuticals UK Limited* 11.02.08 *SMC Report No. 438/08*	Accepted for use: telbivudine (Sebivo®) is accepted for use within NHS Scotland for the treatment of chronic hepatitis B in adult patients with compensated liver disease and evidence of viral replication, persistently elevated serum alanine aminotransferase levels and histological evidence of active inflammation and/or fibrosis. For a number of therapeutic endpoints telbivudine proved to be equivalent or superior to a comparator nucleoside reverse transcriptase inhibitor.	'Not Preferred' as suitable alternatives exist.	December 2008
temocillin powder for injection or infusion (Negaban®) *Eumedica*	*Burkholderia cepacia* lung infection in cystic fibrosis	Added to the Additional List, for Specialist Use only in cystic fibrosis patients. Added to the Alert Antibiotic Policy.	May 2010 March 2013

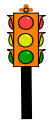
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
temocillin 1g powder for solution for injection (Negaban®) *Eumedica*	As an alternative to carbapenems in the treatment of septicaemia, urinary tract infection or lower respiratory tract infection where Enterobacteriaceae or Burkholderia cepacia suspected or confirmed; and Pseudomonas, anaerobes, or Gram-positive organism unlikely or covered by other agents.	Added to the Additional List, for Specialist Use only. Added to the Alert Antibiotic Policy.	March 2013
tenofovir alafenamide (Vemlidy®) 25mg film-coated tablets *Gilead Sciences Ltd* 10.04.17 *SMC Report No: 1238/17* NON SUBMISSION	Treatment of chronic hepatitis B in adults and adolescents (aged 12 years and older with body weight at least 35 kg).	NOT RECOMMENDED	April 2017
tenofovir disoproxil fumarate (Viread®) *Gilead Sciences Ltd* 14.06.02 *SMC Report No. 03/02*	Accepted for use: tenofovir disoproxil fumarate is recommended in combination with other antiretroviral agents in HIV infected patients over 18 years of age experiencing virological failure. Tenofovir produces a clinically relevant viral response in heavily pre-treated patients experiencing early virological failure. Tenofovir should be initiated under the general supervision of specialists experienced in the management of HIV/AIDS patients.	Added to the Additional List as a further treatment option in HIV-infected patients - Specialist Use only.	March 2004
tenofovir disoproxil (as fumarate), 245 mg film-coated tablet (Viread®) *Gilead Sciences* 07.07.08 *SMC Report No. 479/08*	Accepted for use: tenofovir (Viread®) is accepted for use within NHS Scotland for the treatment of chronic hepatitis B in adults with compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis. Tenofovir has been shown to be significantly more effective than another nucleoside reverse transcriptase inhibitor in achieving a complete composite response (virological plus histological response) in a greater proportion of patients with chronic hepatitis B infection with HBeAg positive and HBeAg negative disease.	Added to Formulary as First choice, replacing entecavir and lamivudine for treatment of chronic hepatitis B.	October 2008
tenofovir disoproxil (as fumarate), 245mg, film-coated tablet (Viread®) *Gilead Sciences Ltd* 12.09.11 *SMC Report No. 720/11*	Accepted for use: tenofovir disoproxil (as fumarate) (Viread®) is accepted for use within NHS Scotland treatment of chronic hepatitis B in adults with decompensated liver disease. Interim results of an ongoing phase II study assessing the safety of tenofovir disoproxil in the treatment of chronic hepatitis B in patients with decompensated liver disease demonstrated that tenofovir was as well tolerated as another nucleoside/nucleotide analogue. Comparative efficacy was not tested in this study, but has been extrapolated from a mixed treatment comparison in treatment-naïve patients with compensated liver disease and hepatitis B e-antigen positive infection.	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**
tenofovir disoproxil (as fumarate) 123mg, 163mg, 204mg film-coated tablets (Viread®) *Gilead Sciences Ltd* 09.09.13 *SMC Report No: 900/13* PRODUCT UPDATE (abbreviated submission)	Restricted use: tenofovir disoproxil (Viread®) is accepted for restricted use within NHS Scotland in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected paediatric and adolescent patients aged 6 to < 12 years, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents SMC restriction: to be prescribed under the supervision of specialists in paediatric infectious diseases. SMC has previously accepted tenofovir disoproxil for use in combination with other antiretroviral agents in HIV infected patients over 18 years of age experiencing virological failure. Tenofovir disoproxil is listed in the British National Formulary for Children 2012-2013 for the treatment of HIV infection.	Included on the Additional List, Specialist Use only for the indication in question.	August 2013
tenofovir disoproxil (as fumarate) 245mg film-coated tablets (Viread®) *Gilead Sciences Ltd* 09.09.13 *SMC Report No: 904/13* PRODUCT UPDATE (abbreviated submission)	Restricted use: tenofovir disoproxil (Viread®) is accepted for restricted use within NHS Scotland for: HIV-1 infection - in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected paediatric and adolescent patients aged 12 to < 18 years, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents. Hepatitis B infection - for the treatment of chronic hepatitis B in adolescents aged 12 to < 18 years of age with compensated liver disease and evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis. SMC restriction: to be prescribed under the supervision of specialists in paediatric infectious diseases. SMC has previously accepted tenofovir disoproxil for use in combination with other antiretroviral agents in HIV infected patients over 18 years of age experiencing virological failure. SMC has previously accepted tenofovir disoproxil for use in the treatment of chronic hepatitis B in adults with compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis and in patients with decompensated liver disease. Tenofovir disoproxil is listed in the British National Formulary for Children 2012-2013 for the treatment of hepatitis B infection and HIV infection.	Included on the Additional List, Specialist Use only for the indication in question.	August 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**
tenofovir disoproxil (as fumarate) 33mg/g oral granules (Viread®) *Gilead Sciences Ltd* 09.09.13 *SMC Report No: 905/13* PRODUCT UPDATE (abbreviated submission)	Restricted use: tenofovir disoproxil (Viread®) is accepted for restricted use within NHS Scotland for: HIV-1 infection - in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected paediatric patients, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents, from 2 to < 6 years of age, and above 6 years of age for whom a solid dosage form is not appropriate; and, in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults for whom a solid dosage form is not appropriate. Hepatitis B infection - for the treatment of chronic hepatitis B in adults for whom a solid dosage form is not appropriate with compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis; decompensated liver disease; and, for the treatment of chronic hepatitis B in adolescents 12 to <18 years of age for whom a solid dosage form is not appropriate with compensated liver disease and evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis. SMC restriction: in patients <18 years, to be prescribed under the supervision of specialists in paediatric infectious diseases. SMC has previously accepted tenofovir disoproxil for use in combination with other antiretroviral agents in HIV infected patients over 18 years of age experiencing virological failure. SMC has previously accepted tenofovir disoproxil for use in the treatment of chronic hepatitis B in adults with compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis and in patients with decompensated liver disease. Tenofovir disoproxil is listed in the British National Formulary for Children 2012-2013 for the treatment of hepatitis B infection and HIV infection.	***Paediatric patients*** - Included on the Additional List, Specialist Use only for the indication in question. ***Adult patients*** - Included on the Additional List for the indication in question when a solid dosage form is not appropriate. For Specialist Use only in the HIV indication. Shared Care Protocol will be revied for the hepatitis B infection.	August 2013
tenofovir / emtricitabine (Truvada®)	For post exposure prophylaxis for HIV in combination with raltegravir (Isentress®). 	Added to the Additional List, for Specialist Use only. Tenofovir / emtricitabine (Truvada®) has been categorised **RED** under the ADTC 'Policy and procedures for the use of unlicensed medicines.'	July 2014
ticarcillin / clavulanic acid (Timentin®) *GSK*	For Stenotrophomonas maltophilia lung infection in cystic fibrosis.	Added to the Additional List, for Specialist Use only.	July 2014

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**
tigecycline 50mg vial of powder tigecycline for intravenous infusion (Tygacil®) *Wyeth* 10.07.06 *SMC Report No. 276/06*	Restricted use: tigecycline (Tygacil®) is accepted for restricted use within NHS Scotland for the treatment of complicated skin and soft-tissue infections. Tigecycline is associated with clinical cure rates in patients with complicated skin and skin structure infections non-inferior to those with a combination of a glycopeptide and a monocyclic beta-lactam antibiotic. It is restricted to use as a 2nd or 3rd line agent under the advice of local microbiologists or specialists in infectious diseases.	Added to the Additional List, for Specialist Use only.	September 2007
tigecycline 50mg vial of powder tigecycline for intravenous infusion (Tygacil®) *Wyeth* 10.07.06 *SMC Report No. 277/06*	Restricted use: tigecycline (Tygacil®) is accepted for restricted use within NHS Scotland for the treatment of complicated intra-abdominal infection. Tigecycline is associated with clinical cure rates in patients with complicated intra-abdominal infections non-inferior to those with a broad-spectrum beta-lactam antibiotic. It is restricted to 2nd line use under the advice of local microbiologists or specialists in infectious disease.	Added to the Additional List, for Specialist Use only.	September 2007
tigecycline (Tygacil®) 50 mg powder for solution for infusion *Pfizer Limited* 07.09.15 *SMC Report No. 1101/15*	NOT RECOMMENDED: tigecycline (Tygacil®) 50 mg powder for solution for infusion is not recommended for use within NHS Scotland. Indication under review: Treatment in children from the age of eight years for the following infections: • complicated skin and soft tissue infections, excluding diabetic foot infections • complicated intra-abdominal infections 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	
tipranavir, 250mg capsule (Aptivus®) *Boehringer Ingelheim Limited* 11.09.06 *SMC Report No. 226/05* RESUBMISSION	Restricted use: tipranavir (Aptivus®) in combination with low dose ritonavir is accepted for restricted use within NHS Scotland for the treatment of HIV-1 infection in highly pre-treated adult patients with virus resistant to multiple protease inhibitors. At 48 weeks, tipranavir, in combination with low dose ritonavir, showed a significant improvement in the reduction of viral load compared with other protease inhibitor plus ritonavir regimens. Although the overall rate and type of adverse events were similar, tipranavir had a higher incidence of hepatotoxicity, hyperlipidaemia, bleeding events and rash. Tipranavir is more expensive than other protease inhibitors and it is restricted to patients with a tipranavir mutation score of less than 4.	Added to the Additional List, for Specialist Use only. For restricted use in HIV-1 infection in patients with multiple resistance to other protease inhibitors and a tipranavir mutation score of less than 4.	December 2006

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**
tipranavir (Aptivus®) 100mg/ml oral solution *Boehringer Ingelheim International* 08.02.10 *SMC Report No. 602/10* PRODUCT UPDATE (abbreviated submission)	Restricted use: tipranavir (Aptivus®) in combination with low dose ritonavir is accepted for restricted use within NHS Scotland for combination antiretroviral treatment of HIV-1 infection in highly pre-treated children from 2 to 12 years of age with virus resistant to multiple protease inhibitors. The marketing authorisation for tipranavir states that it should only be used as part of an active combination antiretroviral regimen in patients with no other therapeutic options. In adult patients the Scottish Medicines Consortium has restricted tipranavir to patients with a tipranavir mutation score of less than 4 and this restriction should also apply to this licence extension covering children from 2 to 12 years of age. Tipranavir is listed in the British National Formulary for Children for the treatment of HIV infection.	Added to the Additional List	March 2010
tipranavir (Aptivus®) 250mg soft capsule *Boehringer Ingelheim International* 08.02.10 *SMC Report No. 616/10* PRODUCT UPDATE (abbreviated submission)	Restricted use: tipranavir 250mg soft capsules (Aptivus®) in combination with low dose ritonavir are accepted for restricted use within NHS Scotland for combination antiretroviral treatment of HIV-1 infection in highly pre-treated adolescents 12 years of age or older with virus resistant to multiple protease inhibitors. The marketing authorisation for tipranavir states that it should only be used as part of an active combination antiretroviral regimen in patients with no other therapeutic options. In adult patients the Scottish Medicines Consortium has restricted tipranavir to patients with a tipranavir mutation score of less than 4 and this restriction should also apply to this licence extension covering adolescents 12 years of age and older. Tipranavir is listed in the British National Formulary for Children for the treatment of HIV infection.	Added to the Additional List.	March 2010
tobramycin 300mg/4mL nebuliser solution (Bramitob®) *Trinity Chiesi Pharmaceuticals Ltd* 09.03.09 *SMC Report No. 314/06* NEW PRODUCT (abbreviated submission)	Accepted for use: tobramycin 300mg/4ml nebuliser solution (Bramitob®) is accepted for use in NHS Scotland for the management of chronic pulmonary infection due to Pseudomonas aeruginosa in patients with cystic fibrosis aged 6 years and older. Consideration should be given to official guidance on the appropriate use of antibacterial agents. This preparation offers an alternative to an existing nebuliser solution at a lower cost per dose.	Added to the Additional List, as an alternate brand of nebulised tobramycin. Included on the LJF, as first choice, Specialist initiation. Included on the Additional List, Specialist initiation, for the indication in question.	August 2011 March 2016 July 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**
tobramycin 28mg inhalation powder, hard capsules (TOBI Podhaler®) *Novartis Pharmaceuticals UK Limited* 11.06.12 *SMC Report No. 783/12* Patient Access Scheme	Accepted for use: tobramycin inhalation powder, hard capsules (TOBI Podhaler®) is accepted for use within NHS Scotland as suppressive therapy of chronic pulmonary infection due to Pseudomonas aeruginosa in adults and children aged 6 years and older with cystic fibrosis. Consideration should be given to official guidance on the appropriate use of antibacterial agents. Tobramycin inhalation powder (TOBI Podhaler®) has demonstrated non-inferiority to tobramycin inhalation solution (via a nebuliser) measured by relative change in FEV_1 % predicted over three treatment cycles in a phase III, open-label, randomised study. This preparation offers an alternative to nebulised tobramycin. The company did not make a case for cost-effectiveness relative to other nebulised antimicrobials. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tobramycin inhalation powder (TOBI Podhaler®). This SMC advice is contingent upon the continuing availability of the patient access scheme in Scotland.	Included on the Additional List for the indication in question as an alternative option for patients instead of nebuliser.	August 2012
tobramycin (Tymbrineb®) 300mg/5mL nebuliser solution	Treatment of chronic pulmonary *Pseudomonas aerugionosa* infection in children and adults (6 years and older).	Included on the Additional List, Specialist initiation, for the indication in question.	July 2016
valganciclovir (Valcyte®) *Roche* 06.12.02 *SMC Report No. 21/02*	Restricted use: valganciclovir offers a convenient oral alternative to ganciclovir. It is currently only licensed for the management of CMV retinitis in AIDS patients. Its use should be under the overall supervision of an expert ophthalmologist and a physician experienced in the management of HIV / AIDS patients.	Added to the Additional List as a replacement for IV ganciclovir (for Specialist Use only).	January 2004
valganciclovir (Valcyte®) *Roche* 08.09.03 *SMC Report No. 62/03* PRODUCT UPDATE (abbreviated submission)	Restricted use: valganciclovir has been approved for prevention of cytomegalovirus (CMV) disease in CMV-negative patients who have received a solid organ transplanted from a CMV-positive donor. It can be given once daily compared with three times daily for existing treatment, thereby improving compliance and convenience. Use of valganciclovir should only be initiated by physicians in transplantation or infectious disease units.	Added to the Additional List as a replacement for ganciclovir. Shared care protocol to be developed.	January 2004
valganciclovir (Valcyte®) *Roche*	As pre-emptive therapy for CMV infection in recipients of allogeneic haematopoietic stem cell transplants where surveillance detects CMV reactivation before development of CMV disease 	Added to the LJF, for Specialist Use only. **RED** (Specialist Use only)	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**
valganciclovir powder for 50mg/ml oral solution (Valcyte®) *Roche* 07.12.09 *SMC Report No 586/09* PRODUCT UPDATE (abbreviated submission)	Restricted use: valganciclovir powder for 50mg/ml oral solution (Valcyte®) is accepted for restricted use in NHS Scotland for the induction and maintenance treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS). Its use should be under the overall supervision of an expert ophthalmologist and a physician experienced in the management of HIV / AIDS patients. In patients for whom valganciclovir is an appropriate choice of therapy this is the only licensed formulation for those undergoing haemodialysis (creatinine clearance <10ml/minute). Otherwise its use should be restricted to patients unable to use the less costly solid oral dosage form.	New formulation of a drug already included in the Formulary.	December 2009
valganciclovir powder for 50mg/ml oral solution (Valcyte®) *Roche* 07.12.09 *SMC Report No 587/09* PRODUCT UPDATE (abbreviated submission)	Restricted use: valganciclovir powder for 50mg/ml oral solution (Valcyt®) is accepted for restricted use in NHS Scotland for the prevention of CMV disease in CMV-negative patients who have received a solid organ transplant from a CMV-positive donor. Valganciclovir should only be initiated by physicians experienced in the care of post-transplant patients. In patients for whom valganciclovir is an appropriate choice of therapy this is the only licensed formulation for those undergoing haemodialysis (creatinine clearance <10ml/minute). Otherwise its use should be restricted to patients unable to use the less costly solid oral dosage form.	New formulation of a drug already in the Formulary.	December 2009
valganciclovir, 450mg tablets, 50mg/ml powder for oral solution (Valcyte®) *Roche Products Ltd* 17.01.11 *SMC Report No 662/10*	Restricted use: Valganciclovir (Valcyte®) is accepted for restricted use within NHS Scotland. Indication under review: prevention of cytomegalovirus (CMV) disease in CMV negative patients who have received a solid organ transplant from a CMV positive donor. The marketing authorisation has been amended to allow the duration of CMV prophylaxis in kidney transplant patients to be increased from 100 days to 200 days post-transplantation SMC restriction: valganciclovir should be initiated by physicians experienced in the care of post-transplant patients. In a randomised controlled study there was a significant reduction in the incidence of CMV disease at 12 months following 200-day versus 100-day prophylaxis.	Added to the Additional Lists.	March 2012
voriconazole (VFEND®) *Pfizer Limited* 10.01.03 SMC Report No. 25/02	Restricted use: voriconazole should be used only in suspected or confirmed cases of invasive aspergillosis; for infections caused by *Fusarium spp* and *Scedosporium spp*; or serious invasive candidiasis refractory to fluconazole. It should be administered primarily to immunocompromised patients with progressive, possibly life-threatening infections.	Added to the Additional List. Specialist use only.	August 2004

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**
voriconazole (VFEND®) powder for oral suspension (40mg/ml) *Pfizer Limited* 13.12.04 *SMC Report No. 142/04* PRODUCT UPDATE (abbreviated submission)	Restricted use: voriconazole (VFEND®) as a powder for oral suspension (40mg/ml) is accepted for restricted use in NHS Scotland. As previously stated by SMC (January 2003), voriconazole should be used only in suspected or confirmed cases of invasive aspergillosis; for infections caused by *Fusarium spp* and *Scedosporium spp*; or serious invasive candidiasis refractory to fluconazole. It should be administered primarily to immunocompromised patients with progressive, possibly life-threatening infections. The oral bio-availability of voriconazole is almost complete, allowing patients to be switched between intravenous and oral therapy, and the oral liquid formulation of voriconazole provides an alternative for patients who cannot take tablets. The cost per day is similar to that with tablets, and markedly less than with infusion.	Added to the Additional List. Specialist use only.	February 2005
voriconazole 50mg, 200mg tablets, 40mg/ml oral suspension, 200mg vials for infusion (Vfend®) *Pfizer Limited* 05.08.05 *SMC Report No. 194/05*	Restricted use: voriconazole (Vfend®) is accepted for restricted use within NHS Scotland for the treatment of candidaemia in non-neutropenic patients. Voriconazole provides an additional agent for the treatment of candidaemia in non-neutropenic patients. Its use is restricted to patients with fluconazole-resistant Candida infection who do not respond to, or cannot tolerate amphotericin B therapy or who are at an increased risk of serious side-effects with amphotericin.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	April 2008
voriconazole (Vfend®) 50 mg and 200 mg film-coated tablets / 200 mg powder for solution for infusion / 200 mg powder and solvent for solution for infusion / 40 mg/ml powder for oral suspension *Pfizer Ltd* 10.11.14 *SMC Report No. 1014/14* NON SUBMISSION	NOT RECOMMENDED: voriconazole (Vfend®) is not recommended for use within NHS Scotland for prophylaxis of invasive fungal infections in high risk allogeneic hematopoietic stem cell transplant (HSCT) recipients. 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	