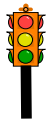
Recommendations from the Lothian Formulary Committee (FC) following Scottish Medicines Consortium (SMC) advice, NICE MTA advice, (FAF3) unlicensed and off-label medicines and (FAF2) medicines not considered by SMC

3 - Respiratory

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**
N-acetylcysteine 600mg capsules	Idiopathic pulmonary fibrosis (IPF), in combination with prednisolone +/- azathioprine 	Treatment to be initiated by specialists only. Patients responding to treatment at 3 months, as judged by a stable or increase in lung function, can be transferred to primary care prescribing under SCP arrangements (SCP to be developed). N-acetylcysteine 600mg capsules for the unlicensed indication, for use in combination with prednisolone and azathioprine in IPF has been categorised **AMBER** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	December 2006
aclidinium 322 micrograms inhalation powder (Eklira Genuair®) *Almirall S.A.* 12.11.12 *SMC Report No. 810/12*	Accepted for use: aclidinium (Eklira Genuair®) is accepted for use within NHS Scotland as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). In two phase III studies, aclidinium was statistically superior to placebo in improving lung function (forced expiratory volume in 1 second [FEV_1]) after 12 weeks and 24 weeks.	Included on the LJF as first choice drug for the indication in question. Included on the LJF, as second choice, for the indication in question.	January 2013 March 2016
aclidinium/formoterol fumarate dihydrate 340/12 micrograms inhalation powder (Duaklir Genuair®) *Almirall/AstraZeneca* 13.04.15 *SMC Report No. 1034/15*	Accepted for use: aclidinium (Duaklir Genuair®) is accepted for use within NHS Scotland as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease. In two 24-week comparator- and placebo-controlled phase III studies, treatment with aclidinium/formoterol 340/12 microgram resulted in statistically significant improvements in FEV_1 % predicted pre-dose (versus a LABA) and post-dose (versus a LAMA).	Included on the LJF, as second choice, for the indication in question.	March 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**
adrenaline tartrate 150 and 300 microgram solution for injection in a pre-filled pen (Jext®) *ALK-Abelló Ltd* 10.10.11 *SMC Report No. 687/11* PRODUCT UPDATE (abbreviated submission	Accepted for use: Adrenaline tartrate (Jext®) is accepted for use within NHS Scotland emergency treatment of severe acute allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs and other allergens as well as idiopathic or exercise induced anaphylaxis. For patients at risk of anaphylaxis and requiring adrenaline, this is a new presentation of adrenaline for emergency use. It has an extended shelf life (24 months) compared with some existing products.	Added to the formulary. Included on the Lothian Joint Formulary for indication in question.	April 2012
adrenaline for self administration (Emerade®) *iMed*	Emergency treatment of anaphylaxis	Included on the LJF as 1st choice.	July 2015
beclometasone dipropionate (Clenil Modulite®) *Trinity-Chiesi Pharmaceuticals Ltd* 07.08.06 *SMC Report No. 177/05* PRODUCT UPDATE (abbreviated submission)	Accepted for use: The Clenil Modulite® range of inhalers is accepted for use in NHS Scotland for the prophylactic management of mild, moderate or severe asthma in adults or children. They provide chlorofluorocarbon (CFC)-free inhalers with dose equivalence to CFC-containing inhalers. The cost is similar to another (CFC)-free inhaler, however doses are not equivalent to the other CFC-free inhaler product currently available.	Added to the formulary as first choice beclometasone CFC-free inhaler.	January 2008
beclometasone 100micrograms, formoterol 6micrograms metered dose inhaler (Fostair®) T*rinity-Chiesi Pharmaceuticals Ltd* 14.01.08 *SMC Report No. 373/07* PRODUCT UPDATE (abbreviated submission)	Accepted for use: beclometasone 100micrograms, formoterol 6micrograms metered dose inhaler (Fostair®) is accepted for use within NHS Scotland for the regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta$_2$-agonist) is appropriate: patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta$_2$-agonist; or patients already adequately controlled on both inhaled corticosteroids and long-acting beta$_2$-agonists. It should be used in patients for whom beclometasone and formoterol are appropriate choices of corticosteroid and long-acting beta-agonist, respectively, and for whom a metered dose inhaler is an appropriate delivery device. It has costs similar to other combination products containing a corticosteroid and long-acting beta$_2$-agonist to which it was clinically non-inferior. The 100micrograms dose of beclometasone in Fostair® is not bioequivalent to a 100micrograms dose of beclometasone in several other inhaler formulations. The Fostair® summary of product characteristics contains information on transferring from these inhalers to Fostair®.	Added to the Formulary.	April 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**
beclometasone dipropionate and formoterol fumarate dihydrate metered dose inhaler 100microgram / 6microgram (Fostair®) *Chiesi Ltd* 07.07.14 *SMC Report No. 976/14* PRODUCT UPDATE (abbreviated submission)	Accepted for use: beclometasone dipropionate and formoterol fumarate dihydrate metered dose inhaler 100microgram / 6microgram (Fostair®) is accepted for use within NHS Scotland for symptomatic treatment of patients with severe COPD (FEV_1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators. Fostair® should be used in patients for whom beclometasone and formoterol are appropriate choices of corticosteroid and long-acting $beta_2$-agonist respectively, and for whom a metered dose inhaler is an appropriate delivery device. The introduction of Fostair® is likely to be cost neutral. The 100mcg dose of beclometasone in Fostair® is not bioequivalent to a 100mcg dose of beclometasone in several other inhaler formulations.	Included on the LJF, as a first choice MDI for the indication in question.	October 2014
beclometasone with formoterol 100/6 micrograms/dose (Fostair® NEXThaler®) *Chiesi Ltd* January 2015 *NICE ESNM53*	Fostair® NEXThaler® is an inhaled corticosteroid (ICS) / long-acting beta-2 agonist (LABA) combination dry powder inhaler containing extrafine beclometasone/formoterol. Evidence from an 8-week randomised controlled trial suggests that in adults with stable asthma it is non-inferior to the pressurised metered dose inhaler (Fostair®), and superior to non-extrafine beclometasone dry powder inhaler in terms of change from baseline in mean pre-dose morning peak expiratory flow with no difference in adverse events. There are no published comparative studies at the higher licensed dose, or with other available ICS/LABA combination inhalers or studies with patient orientated primary outcomes. Regulatory status: Fostair® pressurised metered dose inhaler has been licensed in the UK since 2007. Fostair® NEXThaler® is a new dry powder formulation inhaler licensed for the regular treatment of asthma in adults aged 18 years and over where use of a combination product (ICS and LABA) is appropriate. It was launched in September 2014.	Routinely available in line with national guidance. Included on the LJF as second choice, for General Use, subject to clarification of the place in therapy by the Working Group. Included on the LJF as second choice, for General Use, for the indication in question, subject to clarification of the place in therapy by the Working Group.	March 2017
bilastine (Ilaxten®) *A Menarini PharmaU.K. S.R.L.* 08.08.11 *SMC Report No: 730/11* NONSUBMISSION	NOT RECOMMENDED: bilastine (Ilaxten®) is not recommended for use within NHS Scotland. Indication under review: symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria. 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	
budesonide 200micrograms (Novolizer®) inhaler *Meda Pharmaceuticals Ltd* 11.09.06 *SMC Report No. 306/06* PRODUCT UPDATE (abbreviated submission)	Accepted for use: budesonide (Novolizer®) inhaler is accepted for use within NHS Scotland for the treatment of persistent asthma in adults and children over 6 years of age. Budesonide (Novolizer®) inhaler offers an alternative to existing dry powder inhaled formulations of budesonide at a similar cost.	New formulation of a drug already included in the Formulary.	October 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**
budesonide inhaler 100micrograms, 200micrograms, 400micrograms (Easyhaler® Budesonide) *Ranbaxy (UK) Ltd* 13.03.06 *SMC Report No. 241/06* PRODUCT UPDATE (abbreviated submission)	Accepted for use: budesonide inhaler (Easyhaler® Budesonide) is accepted for use within NHS Scotland for the treatment of mild, moderate or severe persistent asthma in adults and children over 6 years of age. Easyhaler® Budesonide offers an alternative to existing dry powder inhaled formulations of budesonide at a reduced cost.	New formulation of a drug already included in the Formulary.	
budesonide CFC-free inhaler 100 micrograms and 200 micrograms per actuation (Pulmicort®) *AstraZeneca UK Ltd* 14.04.09 *SMC Report No. 536/09* PRODUCT UPDATE (abbreviated submission)	Accepted for use: budesonide CFC-free inhaler (Pulmicort®) is accepted for use in NHS Scotland for the treatment of asthma. Budesonide CFC-free inhaler (Pulmicort®) (hydrofluoroalkanes [HFA] pressurised metered dose inhaler [pMDI]) replaces the equivalent CFC-containing pMDI formulations at a similar cost per microgram.	New formulation of a drug already included in the Formulary.	April 2009
budesonide/formoterol 100/6, 200/6 turbohaler (Symbicort® SMART®) *Astra Zeneca UK Limited* 11.06.07 *SMC Report No. 362/07*	Accepted for use: budesonide/formoterol turbohaler (Symbicort® SMART®) is accepted for use within NHS Scotland, in adults, for the regular treatment of asthma where use of a combination (inhaled corticosteroid and long-acting beta2-agonist) is appropriate; Symbicort® is taken as regular maintenance treatment and as needed in response to symptoms. In patients using inhaled budesonide/formoterol as preventer therapy, use of the same inhaler for reliever therapy is associated with a longer time to first severe exacerbation than use of comparator reliever regimens. In addition, some patients may be able to reduce the dose of preventer therapy.	'Not preferred' as suitable alternatives exist.	December 2007
budesonide/formoterol inhaler (Symbicort Turbohaler®) *AstraZeneca UK Ltd* 10.05.04 *SMC Report No. 97/04*	Accepted for use: budesonide/formoterol inhaler (Symbicort Turbohaler®) is accepted for use within NHS Scotland for the symptomatic treatment of patients with severe COPD (FEV_1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators. It is the second of two long-acting β_2-agonist/corticosteroid combination inhaler preparations considered by SMC and licensed for the symptomatic treatment of patients with severe chronic obstructive pulmonary disease (COPD). The individual components have been available for many years and the combination product offers ease of administration and additional convenience. The combination appears to improve lung function to a greater extent than either of the individual constituents given alone. Comparative data with other combination products are limited at the present time.	Added to the Formulary. Symbicort® and Seretide® are first choice inhaled combination products (containing corticosteroids and long-acting β_2-agonist bronchodilator) in the LJF.	November 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**
budesonide/formoterol 200 micrograms/6 Inhalation powder and 400 micrograms/12 Inhalation powder (Symbicort Turbohaler®) budesonide/formoterol 200 micrograms/6 micrograms per actuation, pressurised inhalation, suspension (Symbicort®) *AstraZeneca UK Limited* 10.10.16 *SMC Report No. 1198/16* NON-SUBMISSION	NOT RECOMMENDED: budesonide/formoterol inhalation powder (Symbicort Turbohaler®) and pressurised inhalation, suspension (Symbicort®) are not recommended for use within NHS Scotland for the treatment of patients with chronic obstructive pulmonary disease (COPD) with forced expiratory volume in 1 second (FEV1) 50% to 70% predicted normal (post bronchodilator) and an exacerbation history despite regular bronchodilator therapy. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this patient group. As a result we cannot recommend its use within NHSScotland. SMC has previously issued accepted advice (97/04) for budesonide/formoterol inhaler (Symbicort Turbohaler) for the symptomatic treatment of patients with severe COPD (FEV1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators. This advice may be extended to (Symbicort®) pressurised inhalation, suspension.	NOT RECOMMENDED	
budesonide/formoterol 100micrograms/ 6micrograms and 200micrograms/ 6micrograms inhalation powder (Symbicort® SMART®) *AstraZeneca UK Ltd* 12.06.17 *SMC Report No. 1244/17* PRODUCT UPDATE (abbreviated submission)	The regular treatment of asthma where use of a combination (inhaled corticosteroid and a long-acting β2 adrenoceptor agonist is appropriate: patients not adequately controlled with inhaled corticosteroids and "as needed" short-acting β2 adrenoceptor agonists, or patients already adequately controlled on both inhaled corticosteroids and long-acting β2 adrenoceptor agonists.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.	May 2017
caffeine base 5mg/mL solution for injection *Viridian Pharma Ltd* 11.05.09 *SMC Report No. 550/09*	Restricted use: caffeine base 5mg/mL solution for injection is accepted for restricted use within NHS Scotland for the treatment of apnoea of prematurity. Short-term studies have demonstrated the efficacy of caffeine on apnoeic episodes and one longer-term study has shown reduction in disabilities relevant to these infants. It should be restricted to use on the advice of specialists in neonatal paediatrics. Prescribers should note that, although the SPC describes this product in terms of caffeine base (5mg/mL), the neonatal formulary and the British National Formulary for Children currently recommend prescribing the dose as caffeine citrate (equivalent to 10mg/mL).	Added to the Additional List, for Specialist Use only.	December 2009

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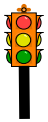
caffeine citrate, 20mg/mL, solution for infusion and oral solution (Peyona®) *Chiesi Limited* 09.09.13 *SMC Report No. 814/12* Patient Access Scheme	Accepted for use: caffeine citrate (Peyona®) is accepted for use within NHS Scotland for the treatment of primary apnoea of premature newborns. In premature infants with apnoea of prematurity, caffeine citrate significantly reduced apnoeic episodes compared with placebo. A long-term placebo-controlled study demonstrated a reduced risk of disabilities relevant to these infants. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of caffeine citrate (Peyona®). This SMC advice is contingent upon the continuing availability of the PAS or an equivalent or lower list price in NHS Scotland. This replaces advice previously issued by the Scottish Medicines Consortium for caffeine citrate (Peyona®) in September 2012 following a non-submission.	Included on the Additional List, for Specialist Use only, for the indication in question.	January 2014
ciclesonide 80, 160micrograms inhaler (Alvesco®) *Altana Pharma Limited* 11.07.05 *SMC Report No. 184/05*	Restricted use: ciclesonide (Alvesco®) is accepted for restricted use within NHS Scotland for the prophylactic treatment of persistent asthma in adults (18 years and older). Ciclesonide is restricted to asthma patients who require once a day administration and whose treatment is at step 2 or step 3 of the British Guideline on the Management of Asthma. Alternative inhaled steroids are available at lower costs.	To remain 'Not preferred' in Lothian as effective alternatives available.	April 2006
ciclesonide, 40-160micrograms metered dose inhaler (Alvesco®) *Altana Pharma* 12.06.06 *SMC Report No. 249/06*	Restricted use: ciclesonide (Alvesco®) is accepted for restricted use within NHS Scotland for treatment to control persistent asthma in adolescents (aged at least 12 years and <18 years). It is restricted to asthma patients who require once-daily administration of an inhaled corticosteroid and whose treatment is at step 2 or step 3 of the British Guideline on the Management of Asthma. Alternative inhaled steroids are available at lower cost.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	April 2008
ciclesonide 80micrograms, 160micrograms inhaler (Alvesco®) *Altana Pharma Ltd* 12.11.07 *SMC Report No. 412/07* PRODUCT UPDATE (abbreviated submission)	Accepted for use: ciclesonide inhaler (Alvesco®) is accepted for use within NHS Scotland at high doses (up to 640micrograms daily for up to 12 weeks) to control persistent asthma in adolescents and adults (12 years and older). The higher dose should be used in patients for whom ciclesonide is an appropriate choice of maintenance inhaled corticosteroid therapy. Alternative inhaled steroids are available at lower costs.	'Not preferred' as suitable alternatives exist.	October 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**
colistin (colistimethate sodium) 2million units for nebulisation (Colomycin®) *Forest*	Severe bronchiectasis after treatment failure with nebulised gentamicin 	Added to the Additional List, as second choice and prescribed in accordance with Shared Care Protocol. Colistin (Colomycin®) has been categorised **AMBER** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. General use with restrictions.	November 2008
doripenem, 500mg powder for solution for infusion (Doribax®) *Janssen-Cilag* 09.03.09 *SMC Report No. 539/09*	Restricted use: doripenem (Doribax®) is accepted for restricted use within NHS Scotland for the treatment of nosocomial pneumonia (including ventilator-associated pneumonia) in adults. Doripenem demonstrated similar clinical cure rates to other drugs used for the treatment of nosocomial pneumonia (including ventilator-associated pneumonia). It is an alternative option to existing carbapenems and should only be used on the advice of local microbiologists or specialists in infectious diseases. Doripenem is also licensed for the treatment of complicated urinary tract infections in adults. As the manufacturer has not made a submission for this indication, SMC cannot recommend the use of doripenem in the treatment of complicated urinary tract infections in adults.	'Not preferred' in Lothian. A submission has not been made to Formulary Committee regarding this product for this indication.	August 2010
erdosteine 300mg capsules (Erdotin®) *Edmond Pharma Sr.l/Galen Ltd.* 12.11.07 *SMC Report No. 415/07*	NOT RECOMMENDED: erdosteine (Erdotin®) is not recommended for use within NHS Scotland as an expectorant for the symptomatic treatment of acute exacerbations of chronic bronchitis in adults. Evidence for the clinical efficacy of erdosteine is limited and was obtained from studies that do not reflect current practice for the management of chronic obstructive pulmonary disease (COPD) in NHS Scotland. The manufacturer did not present a sufficiently robust clinical or economic case for erdosteine to gain acceptance by SMC.	NOT RECOMMENDED	
fluticasone furoate/vilanterol 92/22 micrograms inhalation powder (Relvar Ellipta®) *GlaxoSmithKline UK* 07.04.14 *SMC Report No. 953/14*	Restricted use: fluticasone furoate/vilanterol (Relvar Ellipta®) is accepted for restricted use within NHS Scotland for symptomatic treatment of adults with chronic obstructive pulmonary disease (COPD) with a forced expiratory volume in 1 second (FEV1) <70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy. SMC restriction: in patients with severe COPD (FEV1 <50% predicted normal). In a comparative, 12-week study there was no statistically significant difference between fluticasone furoate/vilanterol 92/22 micrograms and another inhaled corticosteroid/long acting beta agonist combination inhaler for change from baseline trough in 24-hour weighted-mean FEV1. Fluticasone furoate/vilanterol is also licensed for the treatment of asthma. SMC is due to issue advice for this indication in June 2014.	Included on the LJF as a first choice dry powder combination inhaler, 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**
fluticasone furoate / vilanterol 92/22, 184/22 micrograms inhalation powder (Relvar Ellipta®) *GlaxoSmithKline UK* 09.06.14 *SMC Report No. 966/14*	Accepted for use: fluticasone furoate / vilanterol (Relvar Ellipta®) is accepted for use within NHS Scotland as the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta$_2$-agonist and inhaled corticosteroid) is appropriate in patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta$_2$-agonists. There was no statistically significant difference between fluticasone furoate/vilanterol 92/22 micrograms daily and another inhaled corticosteroid/long acting beta$_2$-agonist combination (ICS/LABA) inhaler for 0 to 24 hour serial weighted mean forced expiratory volume in one second, at 24 weeks. Some alternative ICS/LABA combination inhalers are available at a lower daily cost.	For paediatric patients: Included on the Additional List, for Specialist Initiation, for the indication in question. This decision is subject to the outcome of the MHRA review regarding the colour of the packaging. The decision can be revisited when the formulary application for adult patients is submitted to FC. For adult patients: Included on the LJF, as first choice.	November 2014 March 2016
fluticasone proprionate and formoterol fumarate metered dose inhaler, 50microgram/5microgram, 125microgram/5 microgram 250microgram/10 microgram (flutiform®) *Napp Pharmaceuticals Ltd* 08.10.12 *SMC Report No. 736/11* PRODUCT UPDATE (abbreviated submission)	Accepted for use: fluticasone proprionate and formoterol fumarate metered dose inhaler (flutiform®) is accepted for use in NHS Scotland in the regular treatment of asthma where the use of a combination product [an inhaled corticosteroid (ICS) and a long-acting β_2 agonist (LABA)] is appropriate: • for patients not adequately controlled on ICS and 'as required' inhaled short-acting β_2 agonist or • for patients already adequately controlled on both an ICS and a LABA. Flutiform® should be used in patients for whom fluticasone and formoterol are appropriate choices of corticosteroid and long-acting beta-agonist, respectively, and for whom a metered dose inhaler is an appropriate delivery device. It has demonstrated clinical non-inferiority to another combination product containing a corticosteroid and long-acting beta$_2$-agonist and may offer cost savings.	Included on the Additional List for the indication in question, suitable for prescribing where fluticasone, formoterol and a MDI are suitable.	October 2012
fluticasone, salmeterol (Seretide Accuhaler®) *GlaxoSmithKline* 08.12.03 *SMC Report No. 82/03*	Accepted for use: fluticasone/salmeterol (Seretide Accuhaler®) is accepted for use within NHS Scotland for the treatment of patients with severe chronic obstructive pulmonary disease. It is the first of two long-acting β_2-agonist/corticosteroid combination inhaler preparations considered by SMC and licensed for the symptomatic treatment of patients with severe chronic obstructive pulmonary disease (COPD). The individual components have been available for many years and the combination product offers ease of administration and additional convenience. The combination appears to improve lung function to a greater extent than either of the individual constituents given alone. Comparative data with other combination products are limited at the present time.	Added to the Formulary. Combination inhaler for the treatment of severe COPD.	April 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**
formoterol 12micrograms metered dose inhaler (Atimos® Modulite®) *Trinity Chiesi Pharmaceuticals* 13.02.06 *SMC Report No. 239/06* PRODUCT UPDATE (abbreviated submission)	Accepted for use: formoterol 12micrograms metered inhaler (Atimos® Modulite®) is accepted for use in NHS Scotland for the long-term symptomatic treatment of persistent, moderate to severe asthma in patients requiring regular bronchodilator therapy in combination with long-term anti-inflammatory therapy (inhaled and/or oral glucocorticoids). It should be used in patients for whom formoterol is an appropriate choice of long-acting beta-agonist and for whom a metered dose inhaler is an appropriate delivery device.	New formulation of a drug already included in the Formulary.	December 2008
formoterol 12micrograms metered dose inhaler (Atimos® Modulite®) *Trinity-Chiesi Ltd* 08.10.07 SMC Report No. 349/07 PRODUCT UPDATE (abbreviated submission)	Accepted for use: formoterol 12micrograms metered dose inhaler (Atimos® Modulite®) is accepted for use in NHS Scotland for the relief of broncho-obstructive symptoms in patients with chronic obstructive pulmonary disease (COPD). It should be used in patients for whom formoterol is an appropriate choice of long-acting beta-agonist and for whom a metered dose inhaler is an appropriate delivery device.	New formulation of a drug already included in the Formulary.	December 2008
formoterol 12micrograms metered dose inhaler (Easyhaler®) *Ranbaxy (UK) Ltd* 11.06.07 *SMC Report No. 375/07* PRODUCT UPDATE (abbreviated submission)	Accepted for use: formoterol inhalation powder (Easyhaler® Formoterol) is accepted for use within NHS Scotland for the treatment of asthma in patients treated with inhaled corticosteroids and who also require a long-acting beta$_2$-agonist in accordance with current treatment guidelines; and for the relief of reversible airways obstruction in patients with chronic obstructive pulmonary disease (COPD) and requiring long-term bronchodilator therapy. It should be used in patients for whom formoterol is an appropriate choice of long-acting beta$_2$-agonist and a dry powder inhaler is an appropriate delivery device. It costs less than other inhalers delivering similar doses of formoterol.	New formulation of a drug already included in the Formulary.	October 2007
gentamicin 80mg vials (40mg/ml 2ml vials)	Severe bronchiectasis 	Added to the Additional List. Gentamicin has been categorised **AMBER** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. General use with restrictions.	November 2008
glycopyrronium 44 micrograms hard capsules of inhalation powder (Seebri Breezhaler®) *Novartis Pharmaceuticals Ltd.* 14.01.13 *SMC Report No. 829/12*	Accepted for use: glycopyrronium inhalation powder (Seebri Breezhaler®) is accepted for use within NHS Scotland as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). In two phase III studies, glycopyrronium was statistically superior to placebo in improving lung function (forced expiratory volume in 1 second [FEV$_1$]) after 12 weeks.	Included on the LJF as a joint second line treatment, for the indication in question.	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**
human alpha$_1$-proteinase inhibitor 1,000mg powder and solvent for solution for infusion (Respreeza®) *CSL Behring UK Limited* 08.08.16 *SMC Report No. 1157/16*	NOT RECOMMENDED: human alpha1-proteinase inhibitor (Respreeza®) is not recommended for use within NHS Scotland for maintenance treatment, to slow the progression of emphysema in adults with documented severe alpha$_1$-proteinase inhibitor (A1-PI) deficiency. Treatment with human A1-PI for two years reduced the rate of lung density loss compared with placebo; however, there is a lack of robust evidence concerning the clinical relevance of this outcome. No improvement in pulmonary exacerbations, lung function or quality of life was demonstrated. The submitting company did not present a sufficiently robust clinical or economic analysis and in addition their justification of the treatment's cost in relation to its benefits was not sufficient to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	NOT RECOMMENDED	
hypertonic sodium chloride 7% (Resp-Ease™) nebuliser solution	For mobilise lower respiratory tract secretions in mucous consolidation.	Included on the LJF as afirst choice, Specialist initiation, for the indication in question.	August 2016
icatibant acetate 30mg solution for injection in pre-filled syringes (Firazyr®) *Shire Human Genetic Therapies* 12.03.12 *SMC Report No. 476/08* RESUBMISSION Patient Access Scheme	Accepted for use: icatibant acetate (Firazyr®) is accepted for use within NHS Scotland for the symptomatic treatment of acute attacks of hereditary angioedema in adults (with C1-esterase-inhibitor deficiency). Icatibant treatment resulted in symptom relief in patients suffering acute abdominal, cutaneous and/or laryngeal attacks of hereditary angioedema. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of icatibant. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland.	Not included on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion. 'Not Preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	May 2012
indacaterol 150 and 300 micrograms inhalation powder hard capsules (Onbrez Breezhaler®) *Novartis Pharmaceuticals Ltd* 09.08.10 *SMC Report No. 619/10*	Accepted for use: indacaterol (Onbrez Breezhaler®) is accepted for use within NHS Scotland. Indication under review: maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD). Indacaterol has been found to be statistically superior to placebo and other long-acting bronchodilators in improving lung function (FEV1) after 12 weeks. Another long-acting beta2 agonist is available at lower cost.	Included on the LJF as a prescribing note.	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**
indacaterol maleate 143micrograms (equivalent to 110microgram indacaterol) with glycopyrronium bromide 63micrograms (equivalent to 50microgram glycopyrronium) inhalation powder hard capsules (Ultibro® Breezhaler® 85microgram/43microgram [delivered dose]) *Novartis Pharmaceuticals UK Limited* 08.12.14 *SMC Report No. 922/13* PRODUCT UPDATE (abbreviated submission)	Accepted for use: indacaterol maleate plus glycopyrronium bromide inhalation powder hard capsules (Ultibro® Breezhaler®) is accepted for use within NHS Scotland as maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). For patients in whom the combination of indacaterol maleate and glycopyrronium bromide is an appropriate choice of therapy, Ultibro® Breezhaler® provides the two ingredients in a single hard capsule at a lower cost than the individual components.	Included on the Additional List, for the indication in question. Suitable for patients in whom the combination is an appropriate choice of therapy.	December 2014
ivacaftor 150mg film-coated tablets (Kalydeco®) *Vertex Pharmaceuticals UK Ltd* 10.06.13 *SMC Report No. 827/12* RESUBMISSION	NOT RECOMMENDED: ivacaftor (Kalydeco®) is not recommended for use within NHS Scotland for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Ivacaftor has demonstrated superiority over placebo measured by absolute change in forced expiratory volume in one second (FEV1) % predicted in two phase III, double-blind randomised studies. The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition the company did not present a sufficiently robust economic assessment to gain acceptance by SMC.	NOT RECOMMENDED	
ivacaftor 50mg and 75mg granules in sachet (Kalydeco®) *Vertex Pharmaceuticals (Europe) Ltd.* 09.05.16 *SMC Report No. 1134/16*	NOT RECOMMENDED: ivacaftor (Kalydeco®) is not recommended for use within NHS Scotland. Indication under review: treatment of children with cystic fibrosis (CF) aged 2 years and older and weighing less than 25kg who have one of the following gating (class III) mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R. In an open-label single-arm study, acceptable safety was demonstrated in children aged 2 to 5 years. 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. This advice takes account of the views from a Patient and Clinician and Engagement (PACE) meeting.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
ivacaftor 150mg film-coated tablets (Kalydeco®) *Vertex Pharmaceuticals (Europe) Ltd.* 12.12.16 *SMC Report No. 1193/16*	NOT RECOMMENDED: ivacaftor (Kalydeco®) is not recommended for use within NHS Scotland for the treatment of patients with cystic fibrosis (CF) aged 18 years and older who have an R117H mutation in the CF transmembrane conductance regulator (CFTR) gene. Ivacaftor, compared to placebo, significantly increased percent predicted forced expiratory volume in one second ($ppFEV_1$) by 5.0% at 24 weeks in a subgroup of patients aged ≥18 years with CF and an R117H mutation of the CFTR gene. 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 sufficiently robust clinical and economic analyses to gain acceptance by SMC. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	NOT RECOMMENDED	
lumacaftor 200mg, ivacaftor 125mg film-coated tablet (Orkambi®) *Vertex Pharmaceuticals (Europe) Ltd.* 09.05.16 *SMC Report No. 1136/16*	NOT RECOMMENDED: lumacaftor, ivacaftor (Orkambi®) is not recommended for use within NHS Scotland. Indication under review: treatment of cystic fibrosis (CF) in patients aged 12 years and older who are homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene. Lumacaftor-ivacaftor, compared to placebo, significantly increased percent predicted forced expiratory volume in one second (ppFEV1) by less than 3% at six months and reduced the annual rate of pulmonary exacerbations in patients with CF homozygous for the F508del mutation of the CFTR gene. 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. This advice takes account of the views from a Patient and Clinician and Engagement (PACE) meeting.	NOT RECOMMENDED	
magnesium sulphate nebuliser solution	Acute severe asthma attack in patients aged 2 years or older who are unresponsive to an initial bronchodilator. 	Included on the LJF, as first choice, classified as **RED**, Specialist use only, under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian', for the indication in question.	March 2016
mannitol powder (Osmohale®) Pharmix	Diagnostic test for asthma, measuring bronchial hyperresponsiveness (BHR).	Added to the Additional List, Specialist Use Only	April 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**
mannitol 40mg inhalation powder hard capsule (Bronchitol®) *Pharmaxis Pharmaceuticals Ltd.* 09.12.13 *SMC Report No. 837/13* RESUBMISSION	Restricted use: mannitol (Bronchitol®) is accepted for restricted use within NHS Scotland for the treatment of cystic fibrosis (CF) in adults aged 18 years and above as an add-on therapy to best standard of care. SMC restriction: As an add-on to best standard of care in adult patients with CF who are not currently using dornase alfa due to lack of response, intolerance or ineligibility and have rapidly declining lung function and in whom other osmotic agents are considered unsuitable. In two phase III clinical studies in patients with CF, inhaled mannitol was superior to a control treatment (a sub-therapeutic dose of inhaled mannitol) measured by absolute change in forced expiratory volume in one second (FEV1) over 26 weeks.	Included on the LJF, for Specialist Initiation, for the indication in question. Suitable for shared care.	July 2014
mepolizumab 100mg powder for solution for injection (Nucala®) *GlaxoSmithKline UK Limited* 13.06.16 *SMC Report No. 1149/16* Patient Access Scheme	Restricted use: mepolizumab (Nucala®) is accepted for restricted use within NHS Scotland as an add-on treatment for severe refractory eosinophilic asthma in adult patients. SMC restriction: patients who have eosinophils of at least 150 cells per microlitre (0.15 x 109/L) at initiation of treatment and have had at least four asthma exacerbations in the preceding year or are receiving maintenance treatment with oral corticosteroids. Mepolizumab, compared to placebo, decreased the incidence of asthma exacerbations and permitted reductions in doses of maintenance oral corticosteroid in adult patients with severe eosinophilic asthma. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of mepolizumab. 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, for Specialist Use only, for the indication in question.	March 2017
mometasone furoate (Asmanex Twisthaler®) *Schering-Plough* 10.11.03 *SMC Report No. 79/03*	Restricted use: mometasone is the fourth inhaled steroid licensed for treatment of asthma. It is available as a dry powder inhaler. It has a similar efficacy and adverse event profile to other currently available inhaled steroids. It is suitable for use as a second line agent following treatment failure on first line inhaled steroids.	'Not preferred' in the Adult Formulary as effective alternatives are available. Not Preferred in the LJF for Children as effective alternatives are available.	November 2004 April 2005
montelukast 4mg and 5mg chewable tablets and 4mg granules (Singulair Paediatric®) *Merck, Sharp & Dohme Ltd* 09.07.07 *SMC Report No. 383/07*	Restricted use: montelukast chewable tablet and granules (Singulair Paediatric®) is accepted for restricted use within NHS Scotland as an alternative treatment option to low-dose inhaled corticosteroids for patients, [children 2 to 14 years of age] with mild persistent asthma who do not have a recent history of serious asthma attacks that required oral corticosteroid use, and who have demonstrated that they are not capable of using inhaled corticosteroids. It should be restricted to initiation by specialists in paediatric asthma care.	Already included as a prescribing note in the paediatric formulary.	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**
montelukast paediatric 4mg granules (Singulair®) *Merck Sharpe & Dohme Ltd* 09.08.04 *SMC Report No. 111/04* ABBREVIATED SUBMISSION	Accepted for use: montelukast paediatric 4mg granules (Singulair®) are accepted for use in NHS Scotland for the treatment of asthma as add-on therapy in those patients with mild to moderate persistent asthma who are inadequately controlled on inhaled corticosteroids and in whom 'as needed' short-acting beta-agonists provide inadequate clinical control of asthma. It is also accepted for the prophylaxis of asthma in which the predominant component is exercise-induced bronchoconstriction. This formulation is suitable for the treatment of children aged 6 months to 5 years, and the licence for montelukast has been extended to include children aged 6 months to 2 years, though the Summary of Product Characteristics adds that experience in those aged 6 to 12 months is limited. Its introduction is expected to have minimal resource implications in Scotland.	Added to the LJF for Children Formulary as a third line add-on therapy for children aged six months to two years, to be used in conjunction with bronchodilators and steroids. To be initiated by Specialists only.	April 2005
nintedanib 100mg and 150mg capsules (Ofev®) *Boehringer Ingelheim* 12.10.15 *SMC Report No. 1076/15* Patient Access Scheme	Restricted used: nintedanib (Ofev®) is accepted for restricted use within NHS Scotland. Indication under review: in adults for the treatment of idiopathic pulmonary fibrosis (IPF). SMC restriction: For use in patients with a predicted forced vital capacity (FVC) less than or equal to 80%. Nintedanib, compared to placebo, reduces the decline in pulmonary function assessed by forced vital capacity in patients with IPF. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of nintedanib. 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.	Included on the Additional list, Specialist use only, for the indication in question.	November 2015
olodaterol 2.5 microgram solution for inhalation (Striverdi® Respimat®) *Boehringer Ingelheim Ltd* 12.01.15 *SMC Report No. 974/14* RESUBMISSION	Accepted for use: olodaterol (Striverdi® Respimat®) is accepted for use within NHS Scotland as maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease. In two 48-week studies there was no significant difference between olodaterol 5 microgram and another long acting beta$_2$ agonist for the primary endpoints of trough forced expiratory volume in 1 second (FEV_1) and FEV_1 area under curve (0 to 3 hours) at week 24.	Not included on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion	March 2015
omalizumab 150mg powder and solvent for injection (Xolair®) *Novartis Pharmaceuticals UK Ltd.* 08.10.07 *SMC Report No. 259/06* RESUBMISSION	Restricted use: omalizumab (Xolair®) is accepted for restricted use within NHS Scotland as add-on therapy to improve asthma control in adult and adolescent patients (12 years of age and above) with severe persistent allergic asthma. It is restricted to initiation and monitoring by hospital physicians experienced in the diagnosis and treatment of severe persistent asthma. It is restricted to patients who are prescribed chronic systemic steroids and in whom all other treatments have failed. The response to omalizumab treatment should be assessed in all patients at 16 weeks and treatment should be discontinued in patients who have not shown a marked improvement in overall asthma control.	Added to the Additional List, for Specialist Use only.	October 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**
omalizumab 150 mg powder and solvent for solution for injection (Xolair®) *Novartis Pharmaceuticals UK Ltd.* 12.04.10 *SMC Report No. 611/10* PRODUCT UPDATE (abbreviated submission)	Restricted use: omalizumab (Xolair®) is accepted for restricted use within NHS Scotland. Licensed indication under review: add-on therapy to improve asthma control in children (6 to <12 years of age) with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist. Omalizumab treatment should only be considered for patients with convincing IgE (immunoglobulin E) mediated asthma. SMC restriction: Use is restricted to patients who are prescribed chronic systemic steroids and in whom all other treatments have failed. The response to omalizumab treatment should be assessed in all patients at 16 weeks and treatment should be discontinued in patients who have not shown a marked improvement in overall asthma control. The Scottish Medicines Consortium has previously accepted this product for restricted use in adults and adolescents (12 years of age and above). Omalizumab is listed in the British National Formulary for Children for the prophylaxis of allergic asthma.	Added to the Additional List, for Specialist Use only.	April 2010
omalizumab (Xolair®) 75mg, 150mg solution for injection as prefilled syringe Novartis Pharmaceuticals UK Ltd . 13.06.11 *SMC Report No 708/11* PRODUCT UPDATE (abbreviated submission	Accepted for use: omalizumab 75mg, 150mg (Xolair®) solution for injection is accepted for restricted use within NHS Scotland. Omalizumab is indicated in adults, adolescents (12 years of age and older) and children (6 to <12 years of age) with convincing IgE (immunoglobulin E) mediated asthma SMC restriction: Use is restricted to patients who are prescribed chronic systemic steroids and in whom all other treatments have failed. The response to omalizumab treatment should be assessed in all patients at 16 weeks and treatment should be discontinued in patients who have not shown a marked improvement in overall asthma control. SMC has previously accepted omalizumab (Xolair®) 150mg powder and solvent for injection for restricted use in adults, adolescents and children. This submission is for a new solution for injection formulation that will replace the existing formulation. The 150mg solution for injection formulation is bioequivalent to the 150mg powder and solvent for injection formulation and costs the same. The new 75mg strength is half the cost of the 150mg injection and should eliminate wastage that occurred previously with certain doses.	Added to the Additional List, for Specialist Use only, for Children	May 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**
omalizumab (Xolair®) 75mg, 150mg solution for injection as prefilled syringe *Novartis Pharmaceuticals UK Ltd.* 24.03.13 *NICE Technology Appriasal No 278* *Supersedes SMC Report No. 708/11* Patient Access Scheme	Omalizumab is recommended as an option for treating severe persistent confirmed allergic IgE-mediated asthma as an add-on to optimised standard therapy in people aged 6 years and older: •who need continuous or frequent treatment with oral corticosteroids (defined as 4 or more courses in the previous year), and •only if the manufacturer makes omalizumab available with the discount agreed in the patient access scheme. SMC previously issued advice recommending restricted use in patients who are prescribed chronic systemic steroids and in whom all other treatments have failed. The response to omalizumab treatment should be assessed in all patients at 16 weeks and treatment should be discontinued in patients who have not shown a marked improvement in overall asthma control. This NICE TA extends the indication for use of omalizumab. SMC has previously accepted omalizumab (Xolair®) 150mg powder and solvent for injection for restricted use in adults, adolescents and children. SMC report No 708/11 is for a new solution for injection formulation that will replace the existing formulation.	Included on the Additional List, for Specialist Use only for the indication in question, for Adults	August 2013
bee/wasp venom extract (Pharmalgen®) *ALK-Abello* February 2012 *NICE MTA 246*	Accepted for use: Pharmalgen is recommended as an option for the treatment of IgE-mediated bee and wasp venom allergy in people who have had: • a severe systemic reaction to bee or wasp venom, or • a moderate systemic reaction to bee or wasp venom and who have one or more of the following: a raised baseline serum tryptase, a high risk of future stings or anxiety about future stings. Treatment with Pharmalgen should be initiated and monitored in a specialist centre experienced in venom immunotherapy.	Included on the Additional List, specialist use only, for the indication in question.	July 2015
pirfenidone 267mg capsule (Esbriet®) *InterMune* 12.08.13 *SMC Report No:* *835/13* RESUBMISSION Patient Access Scheme	Restricted use: pirfenidone (Esbriet®) is accepted for restricted use within NHS Scotland in adults for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF). SMC restriction: For use in patient with a predicted forced vital capacity (FVC) less than or equal to 80%. Pirfenidone reduced the decline in lung function parameters associated with IPF compared to placebo in a pooled analysis of two similarly designed phase lll studies. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pirfenidone. 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.	December 2013
Pollinex Tree and Pollinex Grasses & Rye *Allergy Therapeutics*	Severe seasonal rhino-conjunctivitis with insufficient response to pharmacotherapy in children over 8 years.	Added to the Additional List, for Specialist Use only.	December 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**
prednisolone 1mg/mL oral solution and prednisolone 5mg tablets	For the acute wheeze in children.	Included on the LJF as a first choice, Specialist Use only, for the indication in question.	August 2016
roflumilast 500 microgram film coated tablets (Daxas®) *AstraZeneca UK Ltd* 11.09.17 *SMC Report No. 635/10* RESUBMISSION	NOT RECOMMENDED: roflumilast (Daxas®) is not recommended for use within NHS Scotland. Indication under review: for maintenance treatment of severe chronic obstructive pulmonary disease (COPD) (forced expiratory volume in one second [FEV1]) post-bronchodilator less than 50% predicted) associated with chronic bronchitis in adult patients with a history of frequent exacerbations as add on to bronchodilator treatment. The addition of roflumilast, compared with placebo, to combination inhaled corticosteroid (ICS) / long-acting beta agonist (LABA) treatment did not reduce the annual rate of moderate or severe COPD exacerbations in two double-blind, randomised studies of COPD patients with severe airflow limitation and history of at least two moderate or severe exacerbations in the previous year. The submitting company did not present a sufficiently robust clinical or economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
salbutamol (as sulphate) 100 micrograms per dose as powder for inhalation (Salbulin® MDPI Novolizer) *Meda Pharmaceuticals Ltd* 13.10.08 *SMC Report No. 504/08* PRODUCT UPDATE (abbreviated submission)	Accepted for use: salbutamol (as sulphate) 100 micrograms per dose as powder for inhalation (Salbulin MDPI Novolizer) is accepted for use within NHS Scotland in patients with reversible airways obstruction such as asthma for relief and prevention of asthma symptoms. It may be used in patients in whom treatment with this short-acting beta agonist is appropriate and for whom delivery by a breath-activated dry powder inhaler device offers advantages over other delivery systems. It should be used to relieve asthma symptoms when they occur and to prevent symptoms in circumstances known by the patient to precipitate symptoms, for example prior to exercise or allergen exposure. It should be used for patients in whom a short-acting beta-agonist is appropriate and for whom a dry powder inhaler is an appropriate delivery device. It has a similar cost to other dry powder inhaled formulations of salbutamol.	Added to the LJF Respiratory section.	October 2008
salmeterol 25micrograms inhaler (Serevent Evohaler®) *GlaxoSmithKline* 07.08.06 *SMC Report No. 292/06* PRODUCT UPDATE (abbreviated submission)	Accepted for use: salmeterol 25micrograms inhaler (Serevent Evohaler®) is accepted for use in NHS Scotland for the regular symptomatic treatment of reversible airways obstruction in patients with asthma, including those with nocturnal asthma or chronic obstructive pulmonary disease. It may also be used for the prevention of exercise-induced asthma. Where the use of this long-acting beta agonist by aerosol inhalation is appropriate, it offers a chlorofluorocarbon (CFC)-free option at no additional cost.	New formulation of a drug already included in the Formulary.	October 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**
salmeterol/fluticasone 50/500 micrograms inhaler (Seretide 500 Accuhaler®) *GlaxoSmithKline* 12.01.09 *SMC Report No. 450/08* RESUBMISSION	NOT RECOMMENDED: salmeterol/fluticasone 50/500 micrograms inhaler (Seretide 500 Accuhaler®) is not recommended for use within NHS Scotland for the symptomatic treatment of patients with chronic obstructive airways disease (COPD) with a forced expiratory volume in 1 second (FEV_1) 50% to <60% predicted normal (pre-bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy. While there was an improvement in lung function tests and a reduction in both moderate and severe exacerbations with salmeterol/fluticasone in comparison with placebo, there was no difference in mortality rate over 3 years. In addition, the manufacturer did not present a sufficiently robust economic case to gain acceptance by SMC.	NOT RECOMMENDED	
salmeterol xinafoate 25micrograms/ fluticasone propionate 50micrograms (Seretide 50 Evohaler®) *GlaxoSmithKline UK* 12.07.04 *SMC Report No. 108/04* PRODUCT UPDATE (abbreviated submission)	Accepted for use: Seretide 50 Evohaler® is accepted for use within NHS Scotland for the regular treatment of asthma where use of a combination of the long-acting beta agonist salmeterol and the inhaled corticosteroid fluticasone is appropriate for a child aged 4-12 years. The acquisition cost of the combination product is less than for the individual components given by aerosol inhalation and for the combination given by Accuhaler®.	Added to the LJF for Children as a combination product for children with moderate to severe asthma who are stable on the individual products.	April 2005
tiotropium 2.5micrograms respimat inhaler (Spiriva-Respimat®) *Boehringer Ingelheim Ltd* 10.12.07 *SMC Report No. 411/07* PRODUCT UPDATE (abbreviated submission)	Restricted use: tiotropium respimat inhaler (Spiriva Respimat®) is accepted for restricted use within NHS Scotland as maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease. It may be used for patients in whom tiotropium is an appropriate choice of maintenance bronchodilator treatment but it is restricted to patients who have poor manual dexterity and therefore have difficulty using the Handihaler device.	Added to the LJF as a 'new formulation of a drug already in the formulary'.	December 2007
tiotropium bromide (Spiriva®) *Boehringer Ingelheim* 06.12.02 *SMC Report No.19/02*	Accepted for use: Recommended for general use within NHS Scotland for maintenance treatment of chronic obstructive pulmonary disease (COPD). In clinical trials, tiotropium demonstrated superior efficacy to ipratropium and salmeterol in improving lung function (FEV_1). Generally, it has greater efficacy than ipratropium, and similar efficacy to salmeterol in improving dyspnoea, the use of rescue medication, the frequency of COPD exacerbations and hospitalisation due to exacerbations.	Approved for use - added to the LJF as a first choice drug for the treatment of moderate - severe COPD symptoms.	July 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**
tiotropium, 2.5 microgram, solution for inhalation (Spiriva® Respimat®) *Boehringer-Ingelheim Limited* 10.08.15 *SMC Report No. 1028/15*	Accepted for use: tiotropium (Spiriva® Respimat®) is accepted for use within NHS Scotland. Indication under review: As add-on maintenance bronchodilator treatment in adult patients with asthma who are currently treated with the maintenance combination of inhaled corticosteroids (≥800 micrograms budesonide/day or equivalent) and long-acting beta$_2$ agonists and who experienced one or more severe exacerbations in the previous year. Two phase III RCTs demonstrated that the addition of tiotropium significantly improved lung function and increased the time to the first severe exacerbation compared with placebo in patients with uncontrolled asthma despite treatment with high dose inhaled corticosteroid and a long acting beta$_2$ agonist.	Included on the LJF, for the indication in question.	November 2015
tiotropium/olodaterol 2.5 microgram/ 2.5 microgram inhalation solution (Spiolto® Respimat®) *Boehinger Ingelheim Ltd* 09.11.15 *SMC Report No. 1099/15* PRODUCT UPDATE (abbreviated submission)	Accepted: tiotropium/olodaterol (Spiolto® Respimat®) is accepted for use within NHS Scotland. Indication under review: maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). Spiolto® Respimat® should be used in patients for whom tiotropium and olodaterol are appropriate choices of antimuscarinic and long-acting beta$_2$-agonist respectively. Tiotropium/olodaterol (Spiolto® Respimat®) is available at a lower cost than the individual inhalers given separately.	Not included on the LJF because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine.	November 2015
umeclidinium / vilanterol, 55/22 micrograms, inhalation powder (Anoro®) *GlaxoSmithKline* 09.02.15 *SMC Report No. 978/14* RESUBMISSION	Accepted for use: umeclidinium/vilanterol (Anoro®) is accepted for use within NHS Scotland as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease. Two randomised controlled studies demonstrated that after 24 weeks of treatment, umeclidinium/vilanterol significantly improved lung function compared with an inhaled long-acting muscarinic antagonist in patients with moderate to very severe COPD. Indirect comparisons demonstrated comparable efficacy with other combinations of long acting muscarinic antagonist plus long acting beta agonist.	Included on the LJF, as first choice, for the indication in question.	March 2016
umeclidinium, 55 micrograms, powder for inhalation (Incruse®) *GlaxoSmithKline* 08.12.14 *SMC Report No. 1004/14*	Accepted for use: umeclidinium (Incruse®) is accepted for use within NHS Scotland as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). Two randomised controlled, phase III studies demonstrated that after 12 and 24 weeks of treatment umeclidinium improved lung function compared with placebo in patients with moderate to severe COPD. There was also improvement in symptomatic outcomes such as dyspnoea. Umeclidinium is an alternative to other long-acting muscarinic antagonists (LAMAs).	Included on the LJF, as first choice, for the indication in question.	March 2016