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

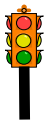
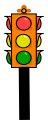
4 – Central Nervous System

In alphabetical order

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
agomelatine, 25mg film-coated tablets (Valdoxan®) *Servier Laboratories UK Ltd* 13.09.10 *SMC Report No 564/09* RESUBMISSION	NOT RECOMMENDED: agomelatine (Valdoxan®) is not recommended for use within NHS Scotland for the treatment of major depressive episodes in adults. When used in a flexible dosing schedule, agomelatine significantly reduced the symptoms of depression and increased the number of patients who responded to treatment compared with placebo. There are limited comparative data against existing antidepressants and the results of such comparisons are variable. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
alfentanil (Rapifen®) injection and sublingual / buccal spray *Janssen-Cilag*	Moderate to severe opioid responsive pain for use under specialist supervision, and incident pain 	Added to the Additional List, for initiation by Specialists. Alfentanil (Rapifen®) has been categorised **AMBER** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	March 2007
aripiprazole (Abilify®) *Bristol-Myers Squibb / Otsuka* 09.08.04 *SMC Report No. 95/04*	Accepted for use: aripiprazole (Abilify®) is accepted for use within NHS Scotland for the treatment of schizophrenia. It is one of several atypical antipsychotic medicines that improve symptoms of an acute relapse and reduce the risk of relapse comparable to a typical antipsychotic. The evidence of comparable efficacy to other atypical antipsychotics is limited. It is associated with a lower incidence of extra-pyramidal side effects than typical antipsychotics, and comparable to other atypicals. It is associated with less elevation of serum prolactin, less lipid abnormalities and less clinically significant weight gain over the short-term compared with other atypical antipsychotics. It does not adversely effect blood glucose nor have a clinically significant advantage compared to other antipsychotics with respect to this.	Added to the Additional List, for Specialist Use only. Use of aripiprazole and all atypical antipsychotics to be reviewed September 2005 with view to producing shared care protocol if appropriate.	August 2004
aripiprazole (Abilify®) 5mg tablets *Bristol-Myers Squibb* 11.07.05 *SMC Report No. 187/05* PRODUCT UPDATE (abbreviated submission)	Restricted use: aripiprazole tablets 5mg (Abilify®) are accepted for restricted use in NHS Scotland for the treatment of schizophrenia. Where aripiprazole is an appropriate antipsychotic, this new dosage is restricted to patients who may benefit from a dose reduction to 5mg daily, taking account of SMC advice issued in August 2004. This 5mg tablet is the same price as the 10mg and 15mg tablets.	Added to the Additional List, for Specialist Use only. New strength of tablet already classified as Additional List.	

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**
aripiprazole 5mg, 10mg, 15mg, 30mg tablets; 10mg, 15mg orodispersible tablets; 1mg/mL oral solution (Abilify®) *Bristol-Myers Squibb Pharmaceuticals Ltd,* *Otsuka Pharmaceuticals (UK) Ltd* 08.06.09 *SMC Report No. 498/08* RESUBMISSION	NOT RECOMMENDED: aripiprazole oral formulations (Abilify®) are not recommended within NHS Scotland for the treatment of moderate to severe manic episodes in bipolar I disorder and for the prevention of a new manic episode in patients who experienced predominantly manic episodes and whose manic episodes responded to aripiprazole treatment. Aripiprazole demonstrated superior efficacy to placebo in reducing manic symptoms at week three and a treatment effect comparable to other agents used in the treatment of bipolar I disorder was maintained at week 12. Aripiprazole also demonstrated superior efficacy to placebo in prevention of relapse. Aripiprazole has not been directly compared to other atypical antipsychotics in this indication, although there is only one other atypical antipsychotic licensed for prevention of new manic episodes. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
aripiprazole solution for intramuscular injection 7.5mg/mL in a 9.75mg vial (Abilify®) *Bristol-Myers Squibb Pharmaceuticals Ltd* 08.12.08 *SMC Report No. 522/08* PRODUCT UPDATE (abbreviated submission)	Accepted for use: aripiprazole intramuscular injection (Abilify®) is accepted for use in NHS Scotland for the rapid control of agitation and disturbed behaviours in patients with schizophrenia when oral therapy is not appropriate. Where aripiprazole is an appropriate antipsychotic, this new formulation provides rapid control of symptoms at an equivalent cost to solid oral dosage forms. SMC has not recommended aripiprazole for use within NHS Scotland for the treatment of manic episodes in bipolar 1 disorder. Therefore this formulation is not recommended for the rapid control of agitation and disturbed behaviours in patients with manic episodes in bipolar 1 disorder.	'Not preferred' in Lothian as suitable alternatives exist.	November 2009
aripiprazole 5, 10, 15, 30mg oral tablets, 10, 15mg orodisperible tablets and 1mg/1mL oral solution(Abilify®) *Bristol-Myers Squibb* 09.08.10 *SMC Report No. 630/10* PRODUCT UPDATE (abbreviated submission)	Restricted use: aripiprazole tablets, orodisperible tablets and oral solution (Abilify®) are accepted for restricted use within NHS Scotland. Indication under review: The treatment of schizophrenia in adolescents 15 years and older. SMC restriction: Restricted to initiation and management under the supervision of a child/adolescent psychiatrist. Aripiprazole has demonstrated short and long-term efficacy in adolescents in the 15 to 17 year old subgroup which is similar to that observed in the adult patient population. The Scottish Medicines Consortium has previously accepted this product for use in schizophrenia in adults. Aripiprazole is one of several atypical antipsychotic medicines that improve symptoms of an acute relapse and reduce the risk of relapse comparable to a typical antipsychotic. The evidence of comparable efficacy to other atypical antipsychotics is limited. It is associated with a lower incidence of extra-pyramidal side effects than typical antipsychotics, and comparable to other atypicals. It is associated with less elevation of serum prolactin, less lipid abnormalities and less clinically significant weight gain over the short-term compared with other atypical antipsychotics. It does not adversely effect blood glucose nor have a clinically significant advantage compared to other antipsychotics with respect to this.	Added to the Additional List, for Specialist Use only for use in children 15 years and older.	August 2010

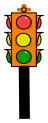
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
aripiprazole 5mg, 10mg, 15mg, 30mg tablets, 10mg, 15mg orodispersible tablets, 1mg/mL oral solution (Abilify®) *Otsuka Pharmaceutical (UK) Ltd* 09.09.13 *SMC Report No. 891/13*	Restricted use: aripiprazole oral (Abilify®) is accepted for restricted use within NHS Scotland for the treatment up to 12 weeks of moderate to severe manic episodes in Bipolar I Disorder in adolescents aged 13 years and older. SMC restriction: restricted to initiation and management under the supervision of a child/adolescent psychiatrist. Aripiprazole demonstrated superior efficacy to placebo in reducing manic symptoms at 4 weeks. Aripiprazole has not been directly compared to other atypical antipsychotics, none of which are licensed for this indication although they are used off-label in clinical practice.	Included on the Additional List, for Specialist Use only, for the indication in question.	May 2014
aripiprazole 400mg powder and solvent for prolonged release suspension for injection (Abilify Maintena®) *Otsuka Pharmaceuticals and Lundbeck Ltd* 12.05.14 *SMC Report No. 962/14*	Accepted for use: aripiprazole prolonged release suspension for injection (Abilify Maintena®) is accepted for use within NHS Scotland for maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole. In a comparative study, aripiprazole prolonged release suspension for injection was as effective as oral aripiprazole in reducing the risk of impending relapse over 26 weeks in stabilised schizophrenic patients. Weaknesses in the indirect comparison limit the reliability of relative efficacy and safety with prolonged release injection forms of other atypical antipsychotics.	Included on the Additional List, for Specialist Initiation, for the indication in question.	October 2014
asenapine 5mg, 10mg sublingual tablet (Sycrest®) *Lundbeck Ltd* 12.03.12 *SMC Report No. 762/12*	NOT RECOMMENDED: asenapine (Sycrest®) is not recommended for use within NHS Scotland for the treatment of moderate to severe manic episodes associated with bipolar I disorder, in adults. Asenapine when used as monotherapy demonstrated superior efficacy to placebo in reducing manic symptoms as measured using the Young Mania Rating Score at three weeks with maintenance of effect at 12 weeks. In addition, asenapine in combination with lithium or valproate demonstrated superior efficacy to lithium or valproate monotherapy. There are no direct comparative data when asenapine is used as add-on treatment. Indirect comparisons with other second generation antipsychotic agents used as monotherapy and as adjunctive therapy suggested equivalent efficacy. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
atomoxetine capsules 10mg to 60mg (Strattera®) *Eli Lilly & Company Ltd* 11.07.05 *SMC Report No. 153/05* RESUBMISSION	Restricted use: atomoxetine (Strattera®) is accepted for restricted use within NHS Scotland for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children of 6 years and older or in adolescents. It is restricted to use in patients who do not respond to stimulants or in whom stimulants are contraindicated or not tolerated. It is restricted to use by physicians with appropriate knowledge and expertise in treating ADHD. This advice concerns use in children and adolescents only and does not cover use in adults. Atomoxetine (Strattera) it is not a Controlled Drug under the Misuse of Drugs regulations 2001.	Added to the LJF for Children as a Prescribing Note, for patients who do not respond to stimulants, e.g. dexamfetamine, methylphenidate, or in whom stimulants are contra-indicated or not tolerated. The first choice drug for ADHD in the Formulary is methylphenidate and second choice is dexamfetamine.	August 2005

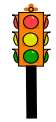
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
atomoxetine 10mg, 18mg, 25mg, 40mg, 60mg, 80mg and 100mg capsules (Strattera®) *Eli Lilly and Company* 11.11.13 *SMC Report No. 909/13*	Accepted for use: atomoxetine (Strattera®) is accepted for use within NHS Scotland for the treatment of attention-deficit/hyperactivity disorder (ADHD) in adults as part of a comprehensive treatment programme. The presence of symptoms that were pre-existing in childhood should be confirmed. Short term studies in adults have shown that atomoxetine improves symptoms of ADHD compared to placebo. The economic case for atomoxetine has been demonstrated for a treatment duration of one year.	Included on the LJF as a second choice drug, for Specialist Initiation, for the indication in question.	December 2013
atomoxetine oral solution 4mg/mL (Strattera®) *Eli Lilly and Company Limited* 07.12.15 *SMC Report No.1107/15* PRODUCT UPDATE (abbreviated submission)	Restricted: atomoxetine oral solution (Strattera®) is accepted for restricted use within NHS Scotland. Indication under review: treatment of attention-deficit/hyperactivity disorder (ADHD) in children of 6 years and older, in adolescents and in adults as part of a comprehensive treatment programme. Treatment must be initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist, or psychiatrist. Diagnosis should be made according to current DSM criteria or the guidelines in ICD. SMC restriction: to use in patients who are unable to swallow capsules. Atomoxetine oral solution demonstrated bioequivalence to atomoxetine capsules. The availability of the oral solution will provide a formulation acceptable to patients who cannot swallow capsules. Any overall budget impact is likely to be small.	Included on the LJF for the indication in question. Prescribe for patients who cannot swallow capsules only.	December 2015
baclofen (Lioresal®) *Novartis*	Use in maintenance treatment of alcohol abstinence in alcohol dependant patients. 	It was agreed that baclofen should be added to the Additional List. Baclofen use in maintenance treatment of alcohol abstinence in alcohol dependant 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.	July 2008
baclofen (Lioresal®) *Novartis*	Adjunct to high-dose chlordiazepoxide, in gamma-butyrolactone (GBL) withdrawal and to prevent relapse in formerly GBL-dependent patients. 	Added to the Additional List, for Specialist Use only. Baclofen adjunct to high-dose chlordiazepoxide in GBL withdrawal and to prevent relapse in formerly GBL 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.	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**
botulinum toxin A, 50 Allergan units, 100 Allergan units, 200 Allergan units, powder for solution for injection (Botox®) *Allergan Ltd.* 13.02.17 *SMC Report No. 692/11* 2nd RESUBMISSION	Restricted use: botulinum toxin A (Botox®) is accepted for restricted use within NHS Scotland for prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine). SMC restriction: use in adults with chronic migraine whose condition has failed to respond to≥3 prior oral prophylactic treatments, where medication overuse has been appropriately managed. In pooled analysis of the two pivotal phase III studies, botulinum toxin type A (Botox®) significantly reduced the frequency of headache days compared with placebo.	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.	April 2017
botulinum toxin type A, 50 and 100 LD_{50} units powder for solution for injection (Xeomin®) *Merz Pharma UK Ltd* 10.10.11 *SMC Report No. 731/11* PRODUCT UPDATE (abbreviated submission)	Accepted for use: botulinum toxin type A (Xeomin®) is accepted for use within NHS Scotland. Post-stroke spasticity of the upper limb presenting with flexed wrist and clenched fist in adults. In patients for whom botulinum toxin, type A is an appropriate choice of therapy, this offers an alternative formulation to the comparator product containing conventional botulinum toxin, type A complex.	Included on the Additional List, Specialist Use only, for the indication in question.	May 2016
botulinum toxin type A 50, 100 and 200 units (Botox®) *Allergan Ltd* 07.07.14 SMC Report No. 986/14 NON SUBMISSION	NOT RECOMMENDED: botulinum toxin type A (Botox®) is not recommended for use within NHS Scotland for focal lower limb spasticity, including the treatment of ankle disability due to lower limb spasticity associated with stroke in 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	
brivaracetam 10mg, 25mg, 75mg, 100mg film-coated tablets; 10mg/mL oral solution; 10mg/mL solution for injection/infusion (Briviact®) *UCB Pharma Ltd.* 11.07.16 *SMC Report No. 1160/16*	Restricted use: brivaracetam (Briviact®) is accepted for restricted use within NHS Scotland as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy. SMC restriction: for use in patients with refractory epilepsy and treatment should be initiated by physicians who have appropriate experience in the treatment of epilepsy. In a pooled analysis of three fixed-dose, placebo-controlled, phase III studies there were statistically significant reductions in the frequency of partial-onset seizures with brivaracetam versus placebo.	Included on the Additional List, Specialist initiation, for the indication in question.	November 2016

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
bupivacaine HCL 1.0mg/mL and 1.25mg/mL plus fentanyl (as citrate) 2 microgram/mL solution for infusion (Bufyl®) *Goldshield Pharmaceuticals Ltd* 12.03.12 *SMC Report No. 761/12* PRODUCT UPDATE (abbreviated submission)	Accepted for use: bupivacaine HCL 1.0mg/mL and 1.25mg/mL plus fentanyl (as citrate) 2 microgram/mL solution for infusion (Bufyl®) is accepted for use in NHS Scotland as epidural analgesia to relieve pain during labour and to control post operative pain. For patients in whom the combination of bupivacaine and fentanyl is an appropriate choice of therapy, Bufyl® provides two fixed-dose, pre-mixed preparations.	Not included on the LJF because the NHS Lothian decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question.	November 2013
buprenorphine (Transtec®) patch *Napp Pharmaceuticals* 13.09.04 *SMC Report No. 116/04*	NOT RECOMMENDED: buprenorphine (Transtec®) patch is not recommended for use within NHS Scotland for the treatment of moderate to severe cancer pain and severe pain that does not respond to non-opioid analgesics. No comparative data have been provided with alternative transdermal or oral opioid preparations. The case for buprenorphine patches as a cost-minimising option when compared to the other transdermal opioid preparation marketed in the UK was not demonstrated. The licence holder has indicated their decision to resubmit.	NOT RECOMMENDED	
buprenorphine transdermal patches 5, 10 and 20micrograms/hour new 7-day formulation (BuTrans®) *Napp Pharmaceuticals Ltd* 12.01.09 *SMC Report No. 234/06* RESUBMISSION	NOT RECOMMENDED: buprenorphine transdermal patches (Butrans®) are not recommended for use within NHS Scotland for the treatment of severe opioid responsive pain conditions, which are not adequately responding to non-opioid analgesics. In the patient population considered in this submission, severe osteoarthritis pain in elderly patients whose pain is not adequately controlled by non-opioid analgesics, or for whom other analgesics are not suitable, buprenorphine transdermal 7-day patch was superior to placebo and similar in efficacy to comparator agents. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by the SMC.	NOT RECOMMENDED	
buprenorphine 5, 10, 15 and 20 microgram/hour transdermal patch (Butec®) *Qdem Pharmaceuticals Limited* 16.01.17 *SMC Report No. 1213/17*	Restricted use: buprenorphine transdermal patches (Butec®) are accepted for restricted use within NHS Scotland in adults, for the treatment of chronic non-malignant pain of moderate intensity when an opioid is necessary for obtaining adequate analgesia. SMC restriction: for use in elderly patients (over 65 years). Non-inferiority was demonstrated between buprenorphine weekly patches and twice daily oral tramadol in patients with moderate to severe osteoarthritic pain. Non-inferiority was also demonstrated between buprenorphine weekly patches plus oral paracetamol and co-codamol in patients with severe osteoarthritic pain.	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

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**
buprenorphine 2mg, 8mg oral lyophilisate (Espranor®) *Martindale Pharma* 12.06.17 *SMC Report No. 1245/17* Patient Access Scheme PRODUCT UPDATE (abbreviated submission)	Substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. Treatment with buprenorphine oral lyophilisate is intended for use in adults and adolescents aged 15 years or over who have agreed to be treated for addiction. SMC restriction: to patients in whom methadone is not suitable.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.	May 2017
buprenorphine/naloxone 2mg/0.5mg, 8/2mg sublingual tablet (Suboxone®) *Schering Plough* 12.03.07 *SMC Report No. 355/07*	Restricted use: buprenorphine/naloxone (Suboxone®) is accepted for restricted use within NHS Scotland for substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. In the pivotal trial buprenorphine/naloxone was superior to placebo and had similar efficacy and safety to buprenorphine. There are currently no published trials comparing buprenorphine/naloxone with methadone. Buprenorphine/naloxone is restricted to those patients in whom methadone is not suitable and for whom the use of buprenorphine is considered appropriate.	Added to the Additional List. FC would support the further development of a SCP.	November 2011
buprenorphine and naloxone (Suboxone®) *Schering-Plough*	Substitution treatment for opioid drug dependence as an alternative maintenance treatment when methadone is not suitable (off-label dose of 32mg daily.) 	It was agreed that buprenorphine and naloxone should be added to the Additional List. Suboxone® use for treatment for opioid drug dependence as an alternative maintenance treatment when methadone is not suitable(off-label dose of 32mg daily) has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	July 2008
capsaicin, 179mg, cutaneous patch (Qutenza®) *Astellas Pharma UK Limited* 07.02.11 *SMC Report No. 673/11*	Restricted use: capsaicin (Qutenza®) is accepted for restricted use within NHS Scotland. Indication under review: For the treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain. SMC restriction: use of this product is restricted to the treatment of adults with post-herpetic neuralgia (PHN) who have not achieved adequate pain relief from, or who have not tolerated, conventional first and second-line treatments. Treatment should be under the supervision of a specialist in pain management. Evidence was presented for patients with PHN only. Capsaicin patch significantly reduced pain scores compared to a low-concentration control patch in three clinical studies. The manufacturer did not submit data on the use of capsaicin patch in other neuropathies therefore SMC cannot recommend its use in these patient groups	Added to the Additional List, for Specialist Use only, dependent upon appropriate training in the administration of the patches.	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**
capsaicin, 179mg, cutaneous patch (Qutenza®) *Astellas Pharma Ltd* 13.10.14 *SMC Report No.673/11* RESUBMISSION	Restricted use: capsaicin (Qutenza®) is accepted for restricted use within NHS Scotland for the treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain. SMC restriction: to use in patients who have not achieved adequate pain relief from, or have not tolerated, conventional first and second line treatments. A phase IV, open-label, randomised, controlled study showed that capsaicin patch was non-inferior to an oral analgesic in adult patients with peripheral neuropathic pain.	Included on the Additional List, for Specialist Use only, for the indication in question. For use in the third line setting only.	January 2015
capsaicin (Qutenza®) 179mg cutaneous patch *Astellas Pharma Ltd* 07.03.16 *SMC Report No. 1140/16* NON SUBMISSION	NOT RECOMMENDED: capsaicin (Qutenza®) is not recommended for use within NHS Scotland. Indication under review: Treatment of peripheral neuropathic pain in diabetic adults either alone or in combination with other medicinal products for pain. 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	
chlordiazepoxide (Librium®) *Meda Pharmaceuticals*	Adjunct to baclofen in gamma-butyrolactone (GBL) withdrawal 	Added to the Additional List, for Specialist Use only. Chlordiazepoxide adjunct to baclofen in GBL withdrawal 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 2010
clostridium botulinum type A neurotoxin complex (Botox®) *Allergan* 07.03.11 *SMC Report No. 80/03* 2ND RESUBMISSION	Accepted for use: clostridium botulinum toxin type A (Botox®) is accepted for use within NHS Scotland. Indication under review: focal spasticity, including the treatment of wrist and hand disability due to upper limb spasticity associated with stroke in adults. In a placebo-controlled study, botulinum toxin type A was significantly superior to placebo in terms of the disability assessment scale and efficacy was maintained across repeated injections in an open-label extension study with a duration of one year.	Included on the Additional List, Specialist Use only, for the indication in question.	May 2016
clostridium botulinum neurotoxin type A, 100 unit powder for solution for injection (Xeomin®) *Merz Pharma UK Ltd* 09.06.08 *SMC Report No. 464/08*	Accepted for use: clostridium botulinum neurotoxin type A (Xeomin®) is accepted for use within NHS Scotland for the symptomatic management of blepharospasm and cervical dystonia of a predominantly rotational form (spasmodic torticollis) in adults. For both indications, a similar improvement in symptoms has been shown compared to another clostridium botulinum neurotoxin type A.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	November 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**
clostridium botulinum type A toxin-haemagglutinin complex 300 units and 500 units (Dysport®) *Ipsen Limited* 14.01.13 *SMC Report No. 353/07* RESUBMISSION	Restricted use: clostridium botulinum type A toxin-haemagglutinin complex (Dysport®) is accepted for restricted use within NHS Scotland for the treatment of focal spasticity, including the treatment of arm symptoms associated with focal spasticity in conjunction with physiotherapy. SMC restriction: for focal spasticity of the upper limbs associated with stroke. Clostridium botulinum type A toxin-haemagglutinin complex (Dysport®) produces a localised reduction in muscle tone in patients with post-stroke upper limb spasticity and can improve patient disability at 16 weeks. It continues to be effective after repeated administrations with no new adverse events apparent.	Not included on the LJF, pending protocol. Not included on the LJF because clinicians do not support the formulary inclusion.	April 2013 May 2016
co-careldopa (levodopa 20mg/mL and carbidopa monohydrate 5mg/mL) intestinal gel (Duodopa®) *Abbvie Ltd.* 13.06.16 *SMC Report No. 316/06* 2nd RESUBMISSION Patient Access Scheme	Restricted use: co-careldopa (Duodopa®) intestinal gel is accepted for restricted use within NHS Scotland for the treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyper-/dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results. SMC restriction: for use in patients not eligible for deep brain stimulation. In a phase III, 12-week study, co-careldopa intestinal gel significantly reduced 'off' time compared with oral levodopa plus a dopa decarboxylase inhibitor. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of co-careldopa intestinal gel. 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.	Not included on the LJF, because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine.	July 2016
diamorphine hydrochloride 720 microgram/actuation and 1600 microgram/actuation nasal spray (Ayendi®) *Wockhardt UK Ltd* 08.08.16 *SMC Report No. 1172/16* PRODUCT UPDATE (abbreviated submission)	Accepted for use: diamorphine hydrochloride (Ayendi®) is accepted for use within NHS Scotland for the treatment of acute severe nociceptive pain in children and adolescents in a hospital setting. Diamorphine hydrochloride nasal spray (Ayendi®) should be administered in the emergency setting by practitioners experienced in the administration of opioids in children and with appropriate monitoring. Unlicensed intranasal diamorphine has been used in the NHS in Scotland for the treatment of severe pain in children in the emergency setting. The availability of diamorphine hydrochloride nasal spray (Ayendi®) provides a licensed preparation.	Included on the Additional List, Specialist Use only, for the indication in question.	August 2016
dexamphetamine	Treatment of Attention Deficit Hyperactivity Disorder in Adults (>18yr) 	Added to the Formulary as a Prescribing note, and prescribed in accordance with the SCP. General use with restrictions. Dexamphetamine (Dexetrine®) has been categorised **AMBER** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	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**
diclofenac 1% gel patches (Voltarol Gel Patch®) *Novartis* 07.11.05 *SMC Report No. 199/05*	NOT RECOMMENDED: Diclofenac 1% gel patch (Voltarol Gel Patch®) is not recommended for use within NHS Scotland for the local symptomatic treatment of pain in epicondylitis and ankle sprain. Diclofenac gel patch provides analgesia similar to that obtained with a topical gel formulation of this drug. However, on a gram per gram basis, patches cost over 40% more than the gel formulation.	NOT RECOMMENDED	
diclofenac, 75mg/2ml of solution for intravenous injection (Dyloject®) *Javelin Pharmaceuticals UK Limited* 10.03.08 *SMC Report No. 446/08*	Restricted use: diclofenac (Dyloject ®) is accepted for restricted use within NHS Scotland for the treatment or prevention of post-operative pain by intravenous injection, in supervised health-care settings. When given as an intravenous bolus, it showed non-inferiority to a comparator non-steroidal anti-inflammatory drug infusion at providing pain relief over an initial 4 hour period and caused less thrombophlebitis. The manufacturer's submission related only to intravenous use of diclofenac (Dyloject ®) in the post-operative setting. SMC cannot recommend its use by the intramuscular route.	'Not preferred' in Lothian as suitable alternatives exist.	November 2008
diclofenac 4% spray gel (Mobigel Spray ®) *Goldshield Group Plc* 13.12.10 *SMC Report No. 667/10* NON SUBMISSION	NOT RECOMMENDED: diclofenac 4% spray gel (Mobigel Spray ®) is not recommended for use within NHS Scotland. Indication under review: for the local symptomatic relief of mild to moderate pain and inflammation following acute blunt trauma of small and medium-sized joints and periarticular structures. 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	
donepezil 5mg and 10mg orodispersible tablets (Aricept® Evess) *Eisai Ltd* 26.02.07 *SMC Report No. 307/06* PRODUCT UPDATE (abbreviated submission)	Accepted for use: donepezil orodispersible tablet (Aricept Evess®) is accepted for use within NHS Scotland for the symptomatic treatment of mild to moderately severe Alzheimer's dementia in patients for whom donepezil is appropriate and who have difficulty in swallowing solid oral dose formulations. It costs the same as standard formulations of donepezil.	New formulation of a drug already included in the Formulary.	October 2007
droperidol (Xomolix®) *Prostrakan*	Anticipated problematic post operative nausea and vomiting (PONV)	Added to the Additional List, for Specialist Use only.	August 2010
duloxetine 30mg, 60mg capsules (Cymbalta®) *Eli Lilly & Co Ltd/Boehringer Ingelheim* 12.09.05 *SMC Report No. 195/05*	Restricted use: duloxetine (Cymbalta®) is accepted for restricted use within NHS Scotland for the treatment of major depressive episodes in accordance with existing guidelines (i.e. in patients who have not responded to or are unable to tolerate initial treatment options). On the basis of the limited comparative data available, duloxetine appears to offer similar efficacy to other antidepressants in this treatment position at a similar cost.	Added to the Additional List.	March 2007

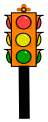
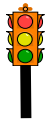
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
duloxetine 30mg and 60mg capsules (Cymbalta®) *Eli Lilly and Company Limited/Boehringer Ingelheim* 11.09.06 *SMC Report No. 285/06*	Restricted use: duloxetine (Cymbalta®) is accepted for restricted use for the treatment of diabetic peripheral neuropathic pain in adults. Duloxetine relieved peripheral neuropathic pain compared with placebo in patients with diabetes. It is restricted to initiation by prescribers experienced in the management of diabetic peripheral neuropathic pain as 2nd or 3rd line therapy.	Added to the LJF as a Prescribing Note.	November 2008
duloxetine (Cymbalta®) 30mg & 60 mg hard gastro-resistant capsules *Eli Lilly and Company Limited* 13.10.08 *SMC Report No. 514/08* NONSUBMISSION	NOT RECOMMENDED: duloxetine (Cymbalta®) is not recommended for use within NHS Scotland for the treatment of generalised anxiety disorder. 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 NHS Scotland.	NOT RECOMMENDED	
escitalopram (Cipralex®) *Lundbeck Ltd* 07.03.03 *SMC Report No. 17/02* RESUBMISSION	Accepted for use: Treatment of major depressive episodes escitalopram has been shown to be as effective as citalopram in short-term use and the health economic model submitted suggests that it is also cost-effective. However, the resource usage assumptions and clinical evidence underpinning the model are not robust and no clear benefits are demonstrated over the parent product - citalopram or other effective and cheaper agents.	Following a resubmission to the Formulary Committee, escitalopram remains 'Not preferred' in Lothian for the treatment of depression.	March 2006
escitalopram 5mg, 10mg and 20mg tablets (Cipralex®) *Lundbeck Limited* 08.05.06 *SMC Report No. 253/06*	Accepted for use: escitalopram (Cipralex®) is accepted for use within NHS Scotland for the treatment of generalised anxiety disorder in situations where pharmacological therapy is appropriate. Escitalopram shows similar efficacy to the other selective serotonin re-uptake inhibitor licensed for the treatment of generalised anxiety disorder.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	April 2008
escitalopram, 5mg, 10mg, and 20mg tablets and 10mg/mL oral drops (Cipralex®) *Lundbeck Ltd* 08.10.07 *SMC Report No. 406/07*	NOT RECOMMENDED: escitalopram (Cipralex®) is not recommended for use within NHS Scotland for treatment of obsessive compulsive disorder. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
escitalopram 5, 10 and 20 mg Film-coated tablets and 10 mg/ml oral drops, solution (Cipralex®) *Lundbeck Limited* 12.05.08 *SMC Report No. 475/08* NON SUBMISSION	NOT RECOMMENDED: escitalopram (Cipralex) is not recommended for use within NHSScotland for the treatment of social anxiety disorder. 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	
eslicarbazepine acetate 800mg tablets (Zebinix®) *Eisai Ltd.* 08.11.10 *SMC Report No. 592/09* RESUBMISSION Patient Access Scheme	Restricted use: eslicarbazepine acetate (Zebinix®) is accepted for restricted use within NHS Scotland. Indication under review: as adjunctive therapy in adults with partial-onset seizures with or without secondary generalisation. SMC restriction: patients with highly refractory epilepsy who have been heavily pre-treated and remain uncontrolled with existing anti-epileptic drugs. Eslicarbazepine acetate reduces seizure frequency compared to placebo over a 12-week maintenance period. Direct comparative data versus other anti-epileptic drugs are unavailable, particularly comparisons with other cheaper agents with a very similar mode of action. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of eslicarbazepine acetate. This SMC advice is contingent upon the continuing availability of the PAS in Scotland.	Added to the Additional List, Specialist Initiation.	April 2011
etoricoxib (Arcoxia®) 30mg, 60 mg, 90 mg & 120 mg film-coated Tablets *Merck Sharp & Dohme Limited* 14.01.13 SMC Report No. 847/12 NON SUBMISSION	NOT RECOMMENDED: etoricoxib (Arcoxia®) is not recommended for use within NHS Scotland for short-term treatment of moderate pain associated with dental surgery. 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	
extended release epidural morphine, 10mg/ml (10mg, 15mg and 20mg) (Depodur®) *Flynn Pharma Ltd* 08.03.10 *SMC Report No. 528/09* RESUBMISSION	NOT RECOMMENDED: extended release epidural morphine (Depodur®) is not recommended for use within NHS Scotland for the relief of post-operative pain following major orthopaedic, abdominal or pelvic surgery. Extended-release epidural morphine has shown some advantages in terms of efficacy versus a single dose of epidural opioid. However, as there are limited comparative data versus epidural analgesia techniques currently used in NHS Scotland it was difficult to assess clinical efficacy in relation to current Scottish practice. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
fentanyl transdermal patches (Durogesic®) *Janssen-Cilag Ltd* 10.01.03 SMC Report No. 24/02	Restricted use: fentanyl transdermal patches (Durogesic®) is recommended for restricted use within NHS Scotland. Transdermal fentanyl should be considered as a second-line alternative for patients with intractable pain due to non-malignant conditions. It should be reserved for patients whose pain has initially been controlled by oral means, the pain being relatively stable. Its use should focus on such patients who have difficulty swallowing or have problems with opiate induced constipation. N.B: Transdermal patches are significantly more expensive than oral therapy.	Approved for use - added to the Additional List. Strict protocol to be adopted restricting use for patients whose pain has been stabilised by oral opiates who have difficulty swallowing or have problems with opiate induced constipation.	May 2003
fentanyl (Durogesic® D Trans®) transdermal patches *Janssen-Cilag* 11.07.05 *SMC Report No. 189/05* PRODUCT UPDATE (abbreviated submission)	Restricted use: Transdermal fentanyl (Durogesic D Trans®) patch is accepted for restricted use within NHS Scotland for patients with chronic intractable pain due to non-malignant conditions. It should be considered as a second-line alternative, reserved for patients whose pain has initially been controlled by oral means, the pain being stable. Its use should focus on patients who have difficulty swallowing or have problems with opiate-induced constipation. This reiterates advice issued by SMC in January 2003 following the extension of the licence for transdermal fentanyl (Durogesic®) patch to include non-malignant pain. SMC has not assessed transdermal fentanyl in its original indication for intractable pain due to cancer. Note that, although the new formulation is the same price as the previous patches, it remains significantly more expensive than oral therapy.	New formulation of an existing product already approved for use in chronic intractable pain.	October 2007
fentanyl (Durogesic D Trans®) transdermal patches 12micrograms/hour *Janssen-Cilag Ltd* 08.05.06 *SMC Report No. 250/06* PRODUCT UPDATE (abbreviated submission)	Restricted use: Transdermal fentanyl (Durogesic D Trans® patches) 12micrograms/hour is accepted for restricted use within NHS Scotland for patients with chronic intractable pain due to non-malignant conditions. It should be considered as a second-line alternative, reserved for patients whose pain has initially been controlled by oral means, the pain being stable. Its use should focus on patients who have difficulty swallowing or have problems with opiate-induced constipation. The new strength allows greater flexibility in dose titration without a substantial impact on price compared with the range of patches previously available. However, it remains significantly more expensive than oral therapy. SMC has not assessed transdermal fentanyl in its original indication for intractable pain due to cancer.	New formulation of an existing product already approved for use in chronic intractable pain.	October 2007
fentanyl 50 micrograms/dose, 100 micrograms/dose, 200 micrograms/dose nasal spray (Instanyl®) *Nycomed UK Ltd.* 09.11.09 *SMC Report No: 579/09*	Restricted use: fentanyl nasal spray (Instanyl®) is accepted for restricted use within NHS Scotland for the management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain. In an open-label comparative study intranasal fentanyl was superior to another fentanyl formulation used in the treament of breakthrough pain in terms of time to onset of pain relief, although more episodes using the intranasal formulation required a second dose. Use of fentanyl nasal spray should be restricted to patients who are unsuitable for other short-acting oral opioids (e.g. oral morphine) as an alternative to other buccal and sublingual fentanyl preparations. It should be noted that the doses of fentanyl nasal spray are significantly lower than doses of fentanyl given by other routes of administration for this indication.	'Not preferred' in Lothian as suitable alternatives exist.	December 2009

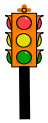
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
fentanyl 50, 100, 200 microgram single dose nasal spray (Instanyl®) *Nycomed UK Ltd* 16.01.12 *SMC Report No 750/11* PRODUCT UPDATE *(abbreviated Submission)*	Restricted use: fentanyl single dose nasal spray (Instanyl®) is accepted for restricted use in NHS Scotland for the management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain. Breakthrough pain is a transitory exacerbation of pain that occurs on a background of otherwise controlled persistent pain. Patients receiving maintenance opioid therapy are those who are taking at least 60 mg of oral morphine daily, at least 25 micrograms of transdermal fentanyl per hour, at least 30 mg oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer. SMC restriction: to patients who are unsuitable for other short-acting oral opioids (e.g. oral morphine) as an alternative to other buccal and sublingual fentanyl preparations. It should be noted that the doses of fentanyl nasal spray are significantly lower than doses of fentanyl given by other routes of administration for this indication. In a pharmacokinetic study in healthy volunteers, this single dose fentanyl nasal spray presentation was shown to be bioequivalent to the multi-dose nasal spray presentation and is available at equivalent cost per dose.	'Not preferred' in Lothian as suitable alternatives exist.	January 2012
fentanyl, 100, 200, 400, 600 and 800 microgram buccal tablet (Effentora®) *Cephalon UK Ltd.* 09.02.09 *SMC Report No. 510/08*	Restricted use: fentanyl buccal tablets (Effentora®) are accepted for restricted use within NHS Scotland for the treatment of breakthrough pain (BTP) in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain. When compared with placebo, the tablets showed an improvement in patient assessment of the intensity of breakthrough pain. Use of fentanyl buccal tablets should be restricted to patients who are unsuitable for other short-acting opioids e.g. oral morphine. Prescribers should be aware of the differing absorption and elimination characteristics of available buccal fentanyl preparations; doses are not interchangeable.	'Not preferred' in Lothian as suitable alternatives exist.	December 2009
fentanyl 100, 200, 300, 400, 600 and 800 microgram sublingual tablets (Abstral®) *ProStrakan* 09.02.09 *SMC Report No. 534/09* PRODUCT UPDATE *(abbreviated Submission)*	Restricted use: fentanyl sublingual tablets (Abstral®) are accepted for restricted use in NHS Scotland for the management of breakthrough pain in adult patients using opioid therapy for chronic cancer pain. Use of sublingual fentanyl tablets should be restricted to patients who are unsuitable for other short-acting opioids e.g. oral morphine. This product offers an alternative to buccal administration at a reduced cost per administration. Prescribers should be aware of the differing absorption and elimination characteristics of available oral fentanyl preparations; doses are not interchangeable.	Added to the Additional List, for Specialist initiation.	May 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**
fentanyl 100microgram/dose and 400microgram/dose nasal spray solution (PecFent®) *Archimedes Pharma* 17.01.11 *SMC Report No. 663/10*	Restricted use: fentanyl nasal spray (PecFent®) is accepted for restricted use within NHS Scotland. Indication under review: management of breakthrough pain in adults who are already receiving maintenance opioid therapy for chronic cancer pain. SMC restriction: restricted to use in patients unsuitable for short-acting oral opioids, as an alternative to other fentanyl preparations. Fentanyl pectin nasal spray offers an advantage in the time to onset of pain relief and reduction in pain intensity of breakthrough pain compared with placebo and immediate release morphine sulphate. Indirect comparison indicates broadly comparable efficacy to an oral transmucosal fentanyl formulation and an existing fentanyl nasal spray. Prescribers should be aware of the differing absorption and elimination characteristics of the available nasal fentanyl preparations; doses are not interchangeable.	Added to the Additional List, for Specialist initiation.	August 2011
fentanyl citrate (Breakyl®) 200mcg, 400mcg and 800mcg buccal film *Meda Pharmaceuticals* 13.01.14 *SMC Report No 947/13* NON SUBMISSION	NOT RECOMMENDED: fentanyl citrate (Breakyl®) is not recommended for use within NHS Scotland for the treatment of breakthrough pain (BTP) in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain. 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	
fentanyl (Ionsys®) 40 micrograms per dose transdermal system *The Medicines Company UK Ltd* 12.12.16 *SMC Report No 1207/16* NON SUBMISSION	NOT RECOMMENDED: fentanyl transdermal system (Ionsys®) is not recommended for use within NHS Scotland for management of acute moderate to severe post-operative pain in adult patients 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	
frovatriptan (Migard®) *A Menarini UK* 09.02.04 *SMC Report No. 49/03* RESUBMISSION	Accepted for use: frovatriptan (Migard®) is accepted for use within NHS Scotland for treatment of the headache phase of migraine attacks with or without aura. It is the seventh 5-HT_1 agonist to be marketed in the UK for this indication. It is less effective at rapidly relieving migraine when compared with the most commonly prescribed drug in this class, but has a similar duration of effect. It is also less expensive than other 5-HT_1 agonists.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	May 2007

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
gabapentin	Neuropathic pain in children 	Added to the Lothian Joint Formulary for Children as a prescribing note. The unlicensed use of gabapentin for the treatment of neuropathic pain in children has been categorised **AMBER** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian' - General use with restrictions. Prescribing should be initiated by specialists and transferred to primary care after 3 months, and only when the patient is stabilised.	January 2006
galantamine hydrobromide (Reminyl XL®) *Shire Pharmaceuticals* 13.06.05 *SMC Report No. 139/04* PRODUCT UPDATE (abbreviated submission)	Accepted for use: galantamine hydrobromide as Reminyl XL® prolonged-release capsules is accepted for use in NHS Scotland for the treatment of mild-to-moderately severe dementia in Alzheimer's disease in patients for whom therapy with galantamine is appropriate. It allows the reduction of dosing frequency to once daily and, at a given dose, involves no additional cost compared with immediate-release formulations of galantamine.	Added to the Formulary for initiation by Specialist only (new formulation of existing therapy). The shared care protocol for galantamine will be updated with these changes.	April 2006
guanfacine, 1mg, 2mg, 3mg and 4mg prolonged-release tablets (Intuniv®) *Shire Pharmaceuticals Contracts Ltd* 08.02.16 *SMC Report No. 1123/16*	Accepted use: guanfacine (Intuniv®) is accepted for use within NHS Scotland. Indication under review: treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6 to 17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective. Treatment must be used as part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures. Two phase III studies in children and adolescents aged 6 to 17 years with ADHD demonstrated that guanfacine improved the symptoms of ADHD compared with placebo.	Included on the LJF as a prescribing note, specilialist initiation.	March 2016
ketamine injection (Ketalar®) *Pfizer* ketamine oral solution Martindale 'special'	Specialist palliative care patients with severe neuropathic pain that is poorly responsive to opioids 	Added to the Additional List, and prescribed in accordance with the SCP. Ketamine 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.	May 2005
lacosamide, 50mg, 100mg,150mg and 200mg tablets, 15mg/ml syrup and 10mg/ml solution for intravenous infusion (Vimpat®) *UCB Pharma Limited* 09.02.09 *SMC Report No. 532/09*	Restricted use: lacosamide (Vimpat®) is accepted for restricted use within NHS Scotland as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy aged 16 years and older. The proportion of responders was significantly greater with adjunctive lacosamide treatment compared to placebo. Lacosamide use is restricted to patients with refractory epilepsy and treatment should be initiated by physicians who have appropriate experience in the treatment of epilepsy.	Added to the Additional List. Treatment to be initiated by, or on the advice of, a specialist and to be prescribed in primary care.	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**
lacosamide (Vimpat®) 50mg / 100mg / 150mg / 200mg film-coated tablets / 10mg/mL solution for infusion / 10mg/mL syrup *UCB Pharma Limited* 13.03.17 *SMC Report No. 1231/17* NON SUBMISSION	As monotherapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent (16-18 years) patients with epilepsy.	NOT RECOMMENDED	April 2017
levetiracetam (Keppra®) 750mg film-coated tablets *UCB Pharma Limited* 10.01.05 *SMC Report No. 150/04* PRODUCT UPDATE (abbreviated submission)	Restricted use: levetiracetam 750mg film-coated tablets are accepted for restricted use in NHS Scotland as an additional dosage form for adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in patients for whom therapy is appropriate. Its use should be initiated by physicians who have appropriate experience in the treatment of epilepsy. The budget impact for NHS Scotland is likely to be small.	Added to the Formulary with other additional anti-epilepsy agents.	March 2005
levetiracetam (Keppra®) 100mg/ml oral solution *UCB Pharma Limited* 10.01.05 *SMC Report No. 151/04* PRODUCT UPDATE (abbreviated submission)	Restricted use: levetiracetam 100 mg/ml oral solution is accepted for restricted use in NHS Scotland as an additional dosage form for adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in patients for whom therapy is appropriate. Its use should be initiated by physicians who have appropriate experience in the treatment of epilepsy. The budget impact for NHS Scotland is likely to be small.	Added to the Formulary with other additional anti-epilepsy agents.	March 2005
levetiracetam 500mg/5ml concentrate for infusion (Keppra®) *UCB Pharma Ltd* 09.10.06 *SMC Report No. 311/06* PRODUCT UPDATE (abbreviated submission)	Accepted for use: levetiracetam 500mg/5ml concentrate for infusion (Keppra®) is accepted for use in NHS Scotland as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in adults and children from 4 years of age with epilepsy. It is an alternative when oral administration is temporarily not feasible in patients for whom levetiracetam is an appropriate anticonvulsant. Intravenous infusion is associated with a greater cost per dose.	Added to the Additional List. Treatment to be initiated by, or on the advice of, a specialist and to be prescribed in primary care.	January 2010
levetiracetam, 250, 500, 750 and 1000mg tablets and levetiracetam oral solution 100mg/mL (Keppra®) *UCB Pharma Limited* 11.02.08 *SMC Report No. 394/07* RESUBMISSION	Accepted for use: levetiracetam (Keppra®) is accepted for use within NHS Scotland as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in children from 4 years of age with epilepsy. In the pivotal study, addition of levetiracetam to existing anticonvulsant therapy achieved a greater reduction in partial seizure frequency than addition of placebo.	Added to the Additional List. Treatment to be initiated by, or on the advice of, a specialist and to be prescribed in primary care.	January 2010

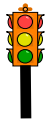
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
levetiracetam, 250, 500, 750 and 1000mg tablets and levetiracetam oral solution 100mg/mL (Keppra®) *UCB Pharma Limited* 11.02.08 *SMC Report No. 395/07* RESUBMISSION	Accepted for use: levetiracetam (Keppra®) is accepted for use within NHS Scotland as adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. In the pivotal study, addition of levetiracetam to existing anticonvulsant therapy was more effective than addition of placebo in reducing the number of days on which myoclonic seizures occurred.	Added to the Additional List. Treatment to be initiated by, or on the advice of, a specialist and to be prescribed in primary care.	January 2010
levetiracetam, 250, 500, 750 and 1000mg tablets and levetiracetam oral solution 100mg/mL (Keppra®) *UCB Pharma Limited* 11.02.08 *SMC Report No. 396/07* RESUBMISSION	Accepted for use: levetiracetam (Keppra®) is accepted for use within NHS Scotland as adjunctive therapy in the treatment of primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with generalised idiopathic epilepsy. In the pivotal study, addition of levetiracetam to existing anticonvulsant therapy achieved a significantly greater reduction in the frequency of primary generalised tonic-clonic seizures than addition of placebo.	Added to the Additional List. Treatment to be initiated by, or on the advice of, a specialist and to be prescribed in primary care.	January 2010
levetiracetam, 250, 500, 750 and 1000mg tablets and levetiracetam oral solution 100mg/mL (Keppra®) *UCB Pharma Limited* 11.02.08 *SMC Report No. 397/07* RESUBMISSION	Restricted use: levetiracetam (Keppra®) is accepted for restricted use within NHS Scotland as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in patients from 16 years of age with newly diagnosed epilepsy. Levetiracetam has been shown to be non-inferior to an older first choice anti-epileptic drug for partial seizures. Levetiracetam is significantly more expensive than traditional drugs so its use is restricted to patients for whom the range of traditional drugs normally used for first-line treatment are ineffective or unsuitable.	Added to the Additional List. Treatment to be initiated by, or on the advice of, a specialist and to be prescribed in primary care.	January 2010
levetiracetam 100mg/ml oral solution (Keppra®) *UCB Pharma Ltd* 17.01.11 *SMC Report No. 661/10* PRODUCT UPDATE (abbreviated submission)	Restricted use: levetiracetam 100mg/ml oral solution (Keppra®) is accepted for restricted use within NHS Scotland. Indication under review: adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in children and infants from 1 month of age to 4 years with epilepsy. SMC restriction: to initiation and management under the supervision of a paediatric neurologist. The Scottish Medicines Consortium has previously accepted this product for use within NHS Scotland as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in children from 4 years of age with epilepsy. Addition of levetiracetam to existing anticonvulsant therapy has shown a greater reduction in partial seizure frequency than addition of placebo. Levetiracetam is listed in the British National Formulary for Children 2010-2011 for adjunctive treatment for partial seizures with or without secondary generalisation from 1 month old. Smaller syringe sizes of 1 and 3 ml have been made available to accommodate the smaller volumes for younger children.	Added to the Additional List. Treatment to be initiated by, or on the advice of, a specialist and to be prescribed in primary care.	January 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**
levodopa, carbidopa and entacapone (Stalevo®) *Orion Pharma (UK) Ltd* 09.01.04 *SMC Report No. 85/03* PRODUCT UPDATE (abbreviated submission)	Accepted for use: Stalevo® is accepted for use in NHSScotland for the treatment of patients with Parkinson's disease and end of dose motor fluctuations not stabilised on levodopa/dopa decarboxylase inhibitor treatment. This combination preparation allows administration of a single tablet incorporating ingredients that are routinely combined for the indication described above. This may improve convenience to the patient. Depending on the doses and formulations being replaced, conversion to the combination may result in a modest increase in cost or (less commonly) a cost saving.	Added to the Additional List, for general use. Should be beneficial to patients receiving the three drugs contained in this combination product. Should be reserved for patients already stable on three individual drugs at stated doses.	March 2004
lidocaine 5% patch (Lidoderm® patch) *Endo Pharmaceuticals*	Neuropathic and localised bone pain	Added to Additional List. Unlicensed product approved for palliative care only, with a prescribing protocol for GPs. Note: Not recommended for use in chronic pain clinic.	November 2004
lidocaine 5% plaster (Versatis®) *Grunenthal GmbH* 11.08.08 *SMC Report No. 334/06* RESUBMISSION	Restricted use: lidocaine 5% medicated plaster (Versatis®) is accepted for restricted use within NHS Scotland for the treatment of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia). There are only limited comparative data available for lidocaine plasters, the comparative clinical effectiveness remains unclear. It is restricted to use in patients who are intolerant of first-line systemic therapies for post-herpetic neuralgia or where these therapies have been ineffective.	Added to the Formulary as a 'Prescribing Note'.	December 2008
lidocaine plaster (Versatis®) *Grünenthal*	Second line treatment for persistent neuropathic pain in children not responding to gabapentin and amitriptyline 	Added to the Additional List, and prescribed in accordance with the SCP. Lidocaine 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.	April 2009
lidocaine with methylprednisolone (Depo-medrone®) lidocaine with levo-bupivacaine (Chirocaine®)	For refractory chronic migraine, cluster headache and other trigeminal autonomic cephalgias. 	Added to the Additional List, for Specialist Use only. Lidocaine with methylprednisolone (Depo-medrone®) and lidocaine with levo-bupivacaine (Chirocaine®) have been categorised **RED** under the ADTC 'Policy and procedures for the use of unlicensed medicines'.	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**
lisdexamfetamine dimesylate, 30mg, 50mg & 70mg capsules (Elvanse®) *Shire Pharmaceutical Contracts Ltd* 13.05.13 *SMC Report No: 863/13*	Accepted for use: lisdexamfetamine dimesylate (Elvanse®) is accepted for use within NHS Scotland as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children aged 6 years of age and over when response to previous methylphenidate treatment is considered clinically inadequate. In a multi-centre, randomised, double-blind, controlled study in children and adolescents with ADHD, treatment with lisdexamfetamine was associated with a shorter time to first response compared with a non-stimulant, centrally-acting sympathomimetic agent. A greater proportion of lisdexamfetamine treated patients achieved improvements in symptom scores and functioning than those treated with the active comparator.	Included on the Additional List and as a prescribing note, for the indication in question.	July 2013
lisdexamfetamine dimesylate, 30mg, 50mg and 70mg hard capsules (Elvanse Adult®) *Shire Pharmaceuticals Ltd.* 07.09.15 *SMC Report No: 1079/15*	Accepted: lisdexamfetamine dimesylate (Elvanse Adult®) is accepted for use within NHS Scotland. Indication under review: as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in adults. Based on clinical judgement, patients should have ADHD of at least moderate severity. Three phase III and two phase IV clinical studies in adults with ADHD demonstrated that lisdexamfetamine improves the symptoms of ADHD compared with placebo.	Included on the LJF as second choice, specialist intiiation, for the indication in question.	October 2015
lurasidone, 18.5mg, 37mg, 74mg film-coated tablets (Latuda®) *Sunovion* 13.10.14 *SMC Report No. 994/14*	Restricted use: lurasidone (Latuda®) is accepted for restricted use within NHS Scotland for the treatment of schizophrenia in adults aged 18 years and over. SMC Restriction: as an alternative treatment option in patients in whom it is important to avoid weight gain and metabolic adverse effects. Lurasidone demonstrated benefit over placebo in mean change from baseline in Positive and Negative Syndrome Scale (PANSS) total score after six weeks of treatment and was non-inferior to another second generation antipsychotic medicine for time to relapse over 12 months.	Included on the Additional List, for Specialist Initiation, for the indication in question.	March 2015
melatonin 2mg prolonged-release tablets (Circadin®) *Lundbeck Limited* 11.08.08 *SMC Report No. 500/08* NON SUBMISSION	NOT RECOMMENDED: melatonin prolonged-release tablets (Circadin®) are not recommended for use within NHS Scotland as monotherapy for the short-term treatment of primary insomnia characterized by poor quality of sleep in patients who are aged 55 or over. 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 NHS Scotland	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**
memantine (Ebixa®) *Lundbeck Ltd* 23.03.11 Multiple Technology Appraisal No. 217	NICE (Multiple Technology Appraisal Guidance No. 217 – Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease (review of NICE technology appraisal guidance 111). The review and re-appraisal of donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease has resulted in a change in the NICE guidance. Specifically: · donepezil, galantamine and rivastigmine are now recommended as options for managing mild as well as moderate Alzheimer's disease, and · memantine is now recommended as an option for managing moderate Alzheimer's disease for people who cannot take AChE inhibitors, and as an option for managing severe Alzheimer's disease. SMC has previously issued advice for the following drugs and indications however, the NICE appraisal, published on 23 March 2011, has been considered by NHS Quality Improvement Scotland through its revised procedure of processing of NICE appraisals. No important differences were identified for this NICE appraisal and NHS Quality Improvement Scotland advises that the recommendations are as valid for Scotland as for England and Wales therefore the NICE MTA supersedes previous SMC advice. NHS Scotland should take account of the NICE appraisal and ensure that recommended drugs or treatments are made available to meet clinical need.	Added to the Formulary as second choice. For community based patients only.	September 2011
methadone hydrochloride (Eptadone®) *Dee Pharmaceuticals Ltd*	Treatment of opioid drug addiction (as a narcotic abstinence syndrome suppressant)	Not recommended for use in Lothian. This advice relates to this particular brand of methadone.	March 2008
methadone tablets (Physeptone®)	Treatment of opioid dependence as a short term treatment for patients travelling abroad. 	Added to the Formulary as a Prescribing Note – Categorised **AMBER** under the ADTC 'Policy for the use of unlicensed (and off-label) use of Medicines in NHS Lothian'. FC	March 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**
methylphenidate modified release (Equasym XL®) *Celltech* 09.05.05 *SMC Report No. 99/04*	Restricted use: methylphenidate modified release (Equasym XL®) is accepted for restricted use within NHS Scotland for the treatment of attention deficit/hyperactivity disorder (ADHD) as part of a comprehensive treatment programme, when remedial measures alone prove insufficient. Like other modified release methylphenidate formulations, it should be considered second line and used only in exceptional circumstances where the supervising clinician has clear evidence that administration of a midday dose is problematic or inappropriate. As for other methylphenidate preparations, initiation of treatment should be by a specialist in childhood behaviour disorders. The pharmacokinetic profile of Equasym XL® differs from that of other modified release formulations of methylphenidate. Equasym XL® would be suitable for patients who do not require therapy in the evening or could have been managed on morning and lunchtime immediate release methylphenidate.	Added to the LJF, for use in exceptionally problematic patients/circumstances only, where the supervising clinician has clear evidence that administration of a midday dose is problematic or inappropriate. Concerta® XL (methylphenidate modified release) is already included in the LJF. Equasym XL® increases the range of formulations and strengths available. Use of m/r formulations reduces flexibility of dosage which can be a disadvantage for many children and parents.	June 2005
methylphenidate prolonged-release capsule (Medikinet XL®) *Flynn Pharma Ltd* 09.07.07 *SMC Report No. 388/07* PRODUCT UPDATE (abbreviated submission)	Restricted use: methylphenidate prolonged-release capsule (Medikinet XL®) is accepted for restricted use within NHS Scotland as part of a comprehensive treatment programme for attention deficit hyperactivity disorder (ADHD) in children over 6 years of age when remedial measures alone prove insufficient. Like other modified release methylphenidate formulations, it should be considered second line and used for patients requiring methylphenidate in the morning and afternoon when administration of a midday dose is problematic or inappropriate. Treatment should be under the supervision of a specialist in childhood behaviour disorders. The pharmacokinetic profile of Medikinet XL® differs from those of other modified release formulations of methylphenidate.	New formulation of a drug already included in the Formulary.	October 2007
methylphenidate sustained release OROS formulation (Concerta® XL) *Janssen-Cilag* 05.07.02 *SMC Report No. 04/02*	Restricted use: Treatment with methylphenidate should be part of a comprehensive treatment programme for attention-deficit hyperactivity disorder (ADHD) when remedial measures alone prove insufficient (under specialist supervision). Because of its substantially greater costs, methylphenidate OROS should be restricted to second line therapy and used only in exceptional circumstances where the supervising clinician has clear evidence of compliance problems. As for other methylphenidate preparations, initiation should be on the recommendation of a specialist in childhood behaviour disorders.	Approved for use - added to the LJF as a Prescribing Note.	
methylphenidate	Treatment of Attention Deficit Hyperactivity Disorder in Adults (>18yr) 	Added to the Formulary as a first choice drug, and prescribed in accordance with the SCP. General use with restrictions. Methylphenidate has been categorised **AMBER** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	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**
midazolam, 5mg/mL, oromucosal solution (Buccolam®) *ViroPharma Ltd* 13.02.12 *SMC Report No. 757/12*	Accepted for use: midazolam oromucosal solution (Buccolam®) is accepted for use within NHS Scotland for the treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents (from 3 months to <18 years). Midazolam given via the buccal route was considered at least non-inferior to rectally administered benzodiazepine in terminating acute prolonged seizures. The economic case was demonstrated for midazolam oromucosal solution (Buccolam®) compared to rectal diazepam.	Not included on the LJF because clinicians do not support the formulary inclusion. FC October 2012	
midazolam 40mg/mL and lidocaine 2mg/mL intra-nasal solution	For sedation in special care patients in dental clinics, who do not tolerate cannulation and refuse or are unable to drink oral midazolam. 	Included on the additional list for the indication in question. 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.	April 2016
mirtazapine (Zispin SolTab®) *Organon Laboratories Ltd* 13.10.03 *SMC Report No. 66/03*	Zispin SolTab® (mirtazapine) is an orodispersible tablet formulation which is less expensive than mirtazapine tablets of the same dose and is therefore a suitable alternative preparation in patients receiving this drug for the treatment of depressive illness.	Remains on the Additional List. Zispin SolTab® is a new formulation of mirtazapine very occasionally used to treat depression when first and second choice drugs are ineffective, not tolerated or contra-indicated.	January 2004
modafinil 100mg and 200mg tablets (Provigil®) *Cephalon* 13.03.06 *SMC Report No. 63/03*	NOT RECOMMENDED The licence was amended in 2010, therefore the SMC advice was withdrawn. Please visit the SMC website for more information – modafinil (Provigil®)	NOT RECOMMENDED	
modafinil 100mg and 200mg tablets (Provigil®) *Cephalon* 13.06.05 *SMC Report No. 183/05.*	NOT RECOMMENDED The licence was amended in 2010, therefore the SMC advice was withdrawn. Please visit the SMC website for more information – modafinil (Provigil®)	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**
nalmefene 18mg film-coated tablets (Selincro®) *Lundbeck Limited* 07.10.13 *SMC Report No. 917/13*	Accepted for use: nalmefene 18mg film-coated tablets (Selincro®) are accepted for use within NHS Scotland for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL), without physical withdrawal symptoms and who do not require immediate detoxification. Nalmefene should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption. Nalmefene should be initiated only in patients who continue to have a high DRL two weeks after initial assessment. In a post hoc analysis of two pivotal phase III studies representing the licensed population, nalmefene was shown to significantly reduce alcohol intake compared with placebo, measured as a reduction in heavy drinking days and total alcohol consumption over a six month period.	Not included on the LJF because clinicians do not support the formulary inclusion.	January 2015
naltrexone 50mg tablets (Nalorex®) *Bristol Myers Squibb*	Adjunctive prophylactic therapy in the maintenance of detoxified, formerly opioid-dependent patients.	Added to the Additional List for Specialist Use only, and not for GP prescribing.	June 2005
naltrexone 50mg tablets (Nalorex® /Opizone®) *Bristol Myers Squibb/ Britannia*	Treatment of alcohol dependence. 	Added to the Additional List - Categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	March 2009
Nicotinell TTS 10 (7mg/24hrs), 20 (14mg/24hrs) and 30 (21mg/24hrs) patch Local formulary process	Replacement therapy for Nicotine.	Routinely available in line with local or regional guidance. Included on the LJF as first choice for General Use. Included on the LJF as first choice, for General Use, for the indication in question.	March 2017
Nicotinell 2mg lozenge Local formulary process	Replacement therapy for Nicotine.	Routinely available in line with local or regional guidance. Included on the LJF as first choice for General Use. Included on the LJF as first choice, for General Use, for the indication in question.	March 2017

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
olanzapine (Zyprexa®) *Eli Lilly and Co Ltd* 06.06.03 *SMC Report No. 44/03*	Restricted use: olanzapine is the first atypical antipsychotic to be licensed for the treatment of acute mania and is at least as effective as comparator treatments. Oral: Treatment of moderate to severe manic episode Intramuscular: Rapid control of agitation and disturbed behaviours in patients with schizophrenia, or manic episodes when oral therapy is not appropriate. It was associated with fewer extrapyramidal side effects than haloperidol and was similar to placebo in the rate of Parkinson-like effects. The management of mania is complex due to the variable presentation of the condition, the wide range of treatment options and a lack of clear guidance on their optimum use. The use of olanzapine in the treatment of acute mania should be restricted to patients under the overall supervision of clinicians experienced in managing this complex disorder.	Approved for use - added to the Additional List, for Specialist Use only.	September 2003
olanzapine (Zyprexa®) *Eli Lilly & Company Ltd* 10.05.04 *SMC Report No. 98/04*	Accepted for use: olanzapine (Zyprexa®) is accepted for use within NHS Scotland for the prevention of recurrence in patients with bipolar disorder whose manic episode has responded to olanzapine treatment. Olanzapine has been shown to be significantly superior to placebo in delaying symptomatic relapse of mania or depression and of mania alone. Apart from weight gain, somnolence and treatment-emergent depression, most significant differences between olanzapine and active competitors favoured olanzapine.	Added to the Additional List. To be initiated in secondary care for the prevention of recurrence.	November 2004
olanzapine (Zyprexa®) 10mg powder for solution for injection *Eli Lilly & Co* 12.07.04 *SMC Report No. 106/04*	Accepted for use: olanzapine for intramuscular use is accepted for use within NHS Scotland for the control of agitation and disturbed behaviours in patients with schizophrenia or manic episode, when oral therapy is not appropriate. Intramuscular olanzapine has been shown to be at least as clinically and cost effective as haloperidol or lorazepam in treating agitation and other symptoms associated with acute schizophrenia and bipolar disorder. Both the clinical and the economic case are limited by the entry criteria for trials, which effectively restricted entry to moderately agitated patients and excluded those who were severely agitated. However, the difficulties in conducting research in this clinical situation are recognised.	Added to the Additional List, for use in specified circumstances and by Specialists only.	October 2005
olanzapine 210mg, 300mg, 405mg powder and solvent for prolonged release suspension for injection (ZypAdhera®) *Eli Lilly and Company Limited* 09.08.10 *SMC Report No. 624/10*	NOT RECOMMENDED: olanzapine long acting injection (ZypAdhera®) is not recommended for use within NHS Scotland. Indication under review: Maintenance treatment of adult patients with schizophrenia sufficiently stabilised during acute treatment with oral olanzapine. The pivotal study showed comparable efficacy of olanzapine long-acting injection to oral olanzapine in preventing relapse in stabilised patients over 24 weeks. Supervision requirements in relation to the risk of post injection syndrome may limit the benefit of decreased frequency of administration. The manufacturer did not present a sufficiently robust economic case to gain acceptance by SMC.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
oxycodone prolonged release tablets 5, 10, 20, 40 and 80mg (OxyContin®) *Napp Pharmaceuticals Limited* 12.09.05 *SMC Report No. 197/05*	Restricted use: oxycodone prolonged release (OxyContin®) is accepted for restricted use within NHS Scotland for the treatment of severe non-malignant pain requiring a strong opioid analgesic. Oxycodone prolonged release is restricted to use in patients in whom controlled release morphine sulphate is ineffective or not tolerated.	Added to the Formulary as a Prescribing Note. To be initiated on Specialist advice for patients with severe non-malignant pain in whom controlled release morphine sulphate is ineffective or not tolerated.	January 2006
oxycodone (OxyNorm®) injection *Napp Pharmaceuticals Limited* 08.05.06 *SMC Report No. 266/06* NON SUBMISSION	NOT RECOMMENDED: oxycodone (OxyNorm®) injection is not recommended for use within NHSScotland for the treatment of post-operative pain. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this formulation. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	
oxycodone 10mg/mL injection	For post-operative pain.	Added to the Additional List as a third-line treatment for Specialist Use only.	October 2013
oxycodone/naloxone 10mg/5mg and 20mg/10mg prolonged release tablets (Targinact®) *Napp Pharmaceuticals Ltd* 09.03.09 *SMC Report No. 541/09*	NOT RECOMMENDED: oxycodone/naloxone prolonged release tablets (Targinact®) are not recommended for use within NHS Scotland for the treatment of severe pain which can be adequately managed only with opioid analgesics. The addition of naloxone to oxycodone did not impair analgesia and improved bowel function when patients were not receiving regular laxative therapy. However the clinical benefit in patients receiving regular laxative therapy is uncertain and the manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
paliperidone 3, 6 and 9mg prolonged release tablets (Invega®) *Janssen-Cilag* 07.04.08 *SMC Report No. 453/08*	NOT RECOMMENDED: paliperidone (Invega®) is not recommended for use within NHS Scotland for the treatment of schizophrenia. Paliperidone has been shown to be superior to placebo in reducing symptoms of schizophrenia. However, there are limited statistical comparative data versus other atypical antipsychotics. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
paliperidone 1.5mg, 3mg, 6mg, 9mg, 12mg prolonged release tablets (Invega ®) *Janssen-Cilag Ltd* 11.04.11 *SMC Report No; 702/11* NON SUBMISSION	NOT RECOMMENDED: paliperidone (Invega®) is not recommended for use within NHS Scotland. Indication under review: For the treatment of psychotic or manic symptoms of schizoaffective disorder. Effect on depressive symptoms has not been demonstrated. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
paliperidone palmitate 50mg, 75mg, 100mg and 150mg prolonged release suspension for injection (Xeplion) *Janssen-Cilag Ltd* 07.11.11 *SMC Report No. 713/11* RESUBMISSION	Accepted for use: paliperidone palmitate prolonged release suspension for injection (Xeplion) is accepted for use within NHS Scotland. Indication under review: maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone. In selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, it may be used without prior stabilisation with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed. Paliperidone prolonged release suspension for injection was non-inferior to another atypical antipsychotic depot injection in terms of control of schizophrenia symptoms over a 3-month period and was more effective than placebo in preventing relapse of schizophrenia.	Added to the Formulary as second choice drug.	January 2012
paliperidone palmitate 175mg, 263mg, 350mg, 525mg prolonged release suspension for injection (Trevicta®) *Janssen-Cilag Ltd* 12.09.16 *SMC Report No. 1181/16* PRODUCT UPDATE (abbreviated submission).	Accepted for use: paliperidone palmitate (Trevicta®) is accepted for use within NHS Scotland paliperidone palmitate (Trevicta®), a three-monthly injection, is indicated for the maintenance treatment of schizophrenia in adult patients who are clinically stable on one-monthly paliperidone palmitate injectable product. This new formulation of paliperidone palmitate is administered every three months and is available at pro-rata cost to the monthly formulation.	Included on the Additional List, for Specialist Use only, for the indication in question.	October 2016
paracetamol infusion (Perfalgan®) *Bristol-Myers Squibb* 13.12.04 *SMC Report No. 137/04*	Accepted for use: paracetamol 1g/100mL infusion (Perfalgan®) is accepted for use within NHS Scotland for the short-term treatment of moderate pain following surgery and fever, when administration by intravenous route is clinically justified.	Added to the Formulary, for Specialist Use only.	February 2005
paracetamol 500mg/50ml intravenous infusion (Perfalgan®) *Bristol Myers Squibb* 09.05.05 *SMC Report No. 172/05* PRODUCT UPDATE (abbreviated submission).	Accepted for use: paracetamol 500mg/50ml intravenous infusion (Perfalgan®) is accepted for use in children weighing less than 33kg but more than 10kg for the short-term treatment of moderate pain following surgery, and short-term treatment of fever, when administration by the intravenous route is clinically justified. This updates SMC advice No. 137/04 which covered other patient groups.	Already in the Formulary.	
paracetamol self dissolving tablets 250mg (melts)	For teenage patients who cannot swallow tablets.	Added to the Additional List.	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**
parecoxib (Dynastat®) *Pharmacia* 10.01.03 SMC Report No. 27/02	NOT RECOMMENDED: parecoxib is not recommended for use within NHS Scotland. For treatment of post-operative pain There is no evidence that the parenteral COX-2 selective non-steroidal anti-inflammatory drug (NSAID), parecoxib, is associated with a reduction in clinically significant post-operative haemorrhagic or gastro-intestinal complications compared with the non-selective NSAIDs. Parecoxib is substantially more expensive than non selective NSAIDs and should therefore not replace these drugs. The license holder has indicated their decision to resubmit in light of additional information.	NOT RECOMMENDED	
perampanel, 2mg, 4mg, 6mg, 8mg, 10mg, 12mg film-coated tablets (Fycompa®) *Eisai Ltd* 10.12.12 *SMC Report No. 819/12* Patient Access Scheme	Restricted use: perampanel (Fycompa®) is accepted for restricted use within NHS Scotland as adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older. SMC restriction: use as a second-line adjunctive treatment in patients with refractory partial onset epilepsy. Treatment should be initiated only by physicians who have appropriate experience in the treatment of epilepsy. In three placebo-controlled studies in patients with uncontrolled partial-onset seizures, perampanel was superior to placebo in terms of the proportion of patients experiencing a ≥50% reduction in partial seizure frequency per 28 days. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of perampanel. This SMC advice is contingent upon the continuing availability of the patient access scheme or a list price that is equivalent or lower.	Included on the Additional List, specialist initiation, for the indication in question.	April 2013
perampanel (Fycompa®) 2mg, 4mg, 6mg, 8mg, 10mg and 12mg film-coated tablets *Eisai Ltd* 10.10.16 *SMC Report No. 1200/16* NON SUBMISSION	NOT RECOMMENDED: perampanel (Fycompa®) is not recommended for use within NHS Scotland as adjunctive treatment of primary generalised tonic-clonic seizures in adult and adolescent patients from 12 years of age with idiopathic generalised epilepsy. 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	
pirenzepine 50mg tablets (Gatrozepin®) *Boehringer Ingelheim* Local formulary process	Treatment of clozapine induced hypersalivation. 	Routinely available in line with local or regional guidance. Included on the Additional List, for Specialist Use only, classified as **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Included on the Additional List, for Specialist Use only, classified as **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	April 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**
pitolisant (Wakix®) 4.5mg/18mg film-coated tablets *Lincoln Medical Limited* 13.02.17 *SMC Report No. 1229/17* NON SUBMISSION	NOT RECOMMENDED: pitolisant (Wakix®) is not recommended for use within NHS Scotland for the treatment of narcolepsy with or without cataplexy in 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	March 2017
pramipexole salt 0.125mg, 0.250mg, 1.0mg tablets (Mirapexin®) *Boehringer-Ingelheim* 08.05.06 *SMC Report No. 247/06*	Accepted for use: pramipexole (Mirapexin®) is accepted for use within NHS Scotland for the symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome (RLS). It should only be used in patients with a baseline score of 15 points or more on the International Restless Legs Scale (IRLS). In three double blind placebo-controlled studies pramipexole was associated with a 4 to 9-point improvement on the patient-administered 40-point IRL scale in comparison with placebo based on the core clinical features of the syndrome.	'Not preferred' in Lothian. A submission has not been made to FC regarding this product for this indication.	October 2007
pramipexole dihydrochloride monohydrate prolonged release tablets 0.375mg, 0.75mg, 1.5mg, 3.0mg, 4.5mg (equivalent to 0.26mg, 0.52mg, 1.05mg, 2.1mg, 3.15mg pramipexole) (Mirapexin®) *Boehringer-Ingelheim* 07.12.09 *SMC Report No. 580/09* PRODUCT UPDATE (abbreviated submission)	Accepted for use: pramipexole dihydrochloride monohydrate prolonged release tablets 0.375mg, 0.75mg, 1.5mg, 3.0mg, 4.5mg (equivalent to 0.26mg, 0.52mg, 1.05mg, 2.1mg, 3.15mg pramipexole) (Mirapexin®) are accepted for use in NHS Scotland for: treatment of the signs and symptoms of idiopathic Parkinson's disease, alone (without levodopa) or in combination with levodopa, i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or "on off" fluctuations). In patients for whom the use of pramipexole is appropriate, the prolonged-release formulation can provide the same daily dose as existing immediate release formulations, with the benefit of once-daily rather than thrice-daily dosing, at an equivalent cost.	New formulation of a product already included in the Formulary.	December 2009
pregabalin (Lyrica®) *Pfizer Ltd* 11.12.06 SMC Report No. 339/06 NON SUBMISSION	NOT RECOMMENDED: pregabalin (Lyrica®) is not recommended for use within NHSScotland for generalised anxiety disorder in 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	
pregabalin 25mg, 50mg, 75mg, 100mg,150mg, 200mg and 300mg capsules (Lyrica®) *Pfizer* 07.02.05 *SMC Report No. 145/04*	Restricted use: pregabalin (Lyrica®) is accepted for restricted use within NHS Scotland as adjunctive therapy in adults with partial seizures with or without secondary generalisation. It should be initiated only by physicians who have appropriate experience in the treatment of epilepsy and should be used principally in patients who have not benefited from treatment with an older anti-convulsant drug such as carbamazepine or sodium valproate, or for whom these drugs are unsuitable because of contra-indications, interaction or poor tolerance.	Added to the Additional List.	August 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**
pregabalin 25mg, 50mg, 75mg, 100mg, 150mg, 200mg and 300mg capsules (Lyrica®) *Pfizer* 11.05.09 *SMC Report No. 157/05* 2nd RESUBMISSION	Restricted use: pregabalin (Lyrica®) is accepted for restricted use within NHS Scotland for the treatment of peripheral neuropathic pain in adults. The clinical evidence of efficacy in patients with peripheral neuropathic pain who are refractory to treatment was based on open-label, uncontrolled, non-randomised studies, with small patient numbers and different methodologies. Pregabalin is restricted to use in patients who have not achieved adequate pain relief from, or have not tolerated, conventional first and second line treatments for peripheral neuropathic pain. Treatment should be stopped if the patient has not shown sufficient benefit within 8 weeks of reaching the maximally tolerated therapeutic dose.	Added to the LJF as a prescribing note.	August 2009
pregabalin 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg capsules (Lyrica®) *Pfizer Limited* 13.08.07 *SMC Report No.389/07*	NOT RECOMMENDED: pregabalin (Lyrica®) is not recommended for use within NHS Scotland for the treatment of central neuropathic pain in adults. In a randomised controlled trial pregabalin was superior to placebo in terms of the primary efficacy variable, the weekly mean pain score. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by the SMC.	NOT RECOMMENDED	
pregabalin oral solution (Lyrica®) *Pfizer Ltd* 11.06.12 *SMC Report No.765/12* PRODUCT UPDATE (abbreviated submission)	Restricted use: pregabalin oral solution (Lyrica®) is accepted for restricted use in NHS Scotland for the treatment of peripheral and central neuropathic pain in adults, as adjunctive therapy in adults with partial seizures with or without secondary generalization and the treatment of Generalised Anxiety Disorder (GAD) in adults. SMC restriction: pregabalin oral solution should be prescribed only for patients who find it difficult to or are unable to swallow tablets. The following SMC restrictions to the use of pregabalin apply: • Pregabalin is restricted to use in patients with peripheral neuropathic pain who have not achieved adequate pain relief from, or have not tolerated, conventional first and second line treatments for peripheral neuropathic pain. Treatment should be stopped if the patient has not shown sufficient benefit within 8 weeks of reaching the maximally tolerated therapeutic dose. • Pregabalin is restricted to use as adjunctive therapy in adults with partial seizures with or without secondary generalisation. It should be initiated only by physicians who have appropriate experience in the treatment of epilepsy and should be used principally in patients who have not benefited from treatment with an older anti-convulsant drug such as carbamazepine or sodium valproate, or for whom these drugs are unsuitable because of contra-indications, interaction or poor tolerance. Pregabalin is not recommended for use in the treatment of Generalised Anxiety Disorder in adults as the company have not made a submission to SMC for use in this indication. Pregabalin oral solution has been shown to be bioequivalent to pregabalin capsules.	Included on the LJF for the indication in question. For patients who find it difficult or are unable to swallow tablets Added to the LJF as a prescribing note.	May 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**
pregabalin Local formulary process	For the treatment of persistent/chronic pain in children aged 12-18 years where first line treatments amitryptiline and gabapentin are not tolerated or in-effective.	Routinely available in line with local or regional guidance. Included on the Additional List, for Specialist Use only, classified as **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	May 2017
promethazine injection 25mg/mL Local formulary process	For the management of acute behavioral disturbance in mental health.	Routinely available in line with local or regional guidance. Included on the LJF as a third choice (after a benzodiazepine and haloperidol), for Specialist Use only.	July 2017
quetiapine 50mg, 200mg, 300mg and 400mg prolonged-release tablet (Seroquel XL®) *AstraZeneca UK Ltd* 10.11.08 *SMC Report No. 433/07* PRODUCT UPDATE (abbreviated Submission)	Accepted for use: quetiapine prolonged-release tablet (Seroquel XL®) is accepted for use within NHS Scotland for the treatment of schizophrenia and manic episodes associated with bipolar disorder. It is suitable for patients in whom quetiapine is an appropriate choice of antipsychotic. For equivalent doses it has similar or lower costs compared to immediate-release quetiapine.	Added to the Formulary.	November 2008
quetiapine (Seroquel®) *AstraZeneca* 12.07.04 SMC Report No. 104/04	Accepted for use: quetiapine (Seroquel®) is accepted for use within NHS Scotland for the treatment of manic episodes associated with bipolar disorder as monotherapy or as adjunct therapy to mood stabilisers. Active comparators were included in the monotherapy trials but the studies were not designed to show differences between active comparator and quetiapine. It has not been compared to other atypical antipsychotics in this indication. Economic data suggest that quetiapine (Seroquel®) is at least cost neutral, compared to other licensed approaches using atypical antipsychotics in this indication, either as adjunctive therapy or monotherapy.	Already included in the Formulary.	June 2008

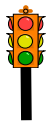
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
quetiapine, 25mg, 100mg, 150mg, 200mg, 300mg tablets (Seroquel), quetiapine, 50mg, 150mg, 200mg, 300mg, 400mg sustained release tablets (Seroquel XL) *AstraZeneca* 09.05.11 *SMC Report No. 549/09* RESUBMISSION	NOT RECOMMENDED: quetiapine (Seroquel/Seroquel XL) is not recommended for use within NHS Scotland. Indication under review: Treatment of major depressive episodes in bipolar disorder. In monotherapy studies quetiapine was superior to placebo and compared favourably with two active comparators. Efficacy relative to current practice for the management of depression in the framework of bipolar disorder in NHS Scotland involving combination therapy with a mood stabiliser or an atypical antipsychotic plus an antidepressant was not demonstrated. The manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC. Quetiapine (Seroquel/Seroquel XL) is also licensed for preventing recurrence in bipolar disorder in patients whose manic, mixed or depressive episode has responded to quetiapine treatment. The manufacturer's submission related only to use in the treatment of major depressive episodes in bipolar disorder. Therefore, SMC cannot recommend its use for preventing recurrence in bipolar disorder in patients whose manic, mixed or depressive episode has responded to quetiapine treatment.	NOT RECOMMENDED	
quetiapine (Seroquel XL®) 50 mg, 150 mg, 200 mg, 300mg 400 mg prolonged-release tablets *AstraZeneca* 10.10.11 *SMC Report No. 744/11* NON SUBMISSION	NOT RECOMMENDED: quetiapine (Seroquel XL®) is not recommended for use within NHS Scotland. Add-on treatment of major depressive episodes in patients with Major Depressive Disorder (MDD) who have had sub-optimal response to antidepressant monotherapy. 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	
rasagiline 1mg tablet (Azilect®) *Lundbeck Ltd / Teva Pharmaceuticals Ltd* 11.12.06 *SMC Report No. 243/06* RESUBMISSION	NOT RECOMMENDED: rasagiline (Azilect®) is not recommended within NHS Scotland for the treatment of idiopathic Parkinson's disease as monotherapy (without levodopa). Rasagiline provides modest symptomatic improvement for patients with early Parkinson's disease. The economic case has not been demonstrated.	NOT RECOMMENDED	
rasagiline 1mg tablet (Azilect®) *Lundbeck Ltd / Teva Pharmaceuticals Ltd* 11.12.06 *SMC Report No. 255/06* RESUBMISSION	NOT RECOMMENDED: rasagiline (Azilect®) is not recommended within NHS Scotland for the treatment of idiopathic Parkinson's disease as adjunct therapy (with levodopa) in patients with end of dose fluctuations. Rasagiline reduces off-time in patients with Parkinson's disease and end of dose fluctuations on levodopa, similar to reductions shown with the less effective of two currently marketed catechol-O-methyl transferase inhibitors. The economic case has not been demonstrated.	NOT RECOMMENDED	

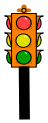
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
retigabine, 50mg, 100mg, 200mg, 300mg and 400mg film-coated tablets (Trobalt®) *GlaxoSmithKline* 11.07.11 *SMC Report No. 712/11*	Restricted use: retigabine (Trobalt®) is accepted for restricted use within NHS Scotland. Indication under review: Adjunctive treatment of partial onset seizures with or without secondary generalisation in adults aged 18 years and above with epilepsy. SMC restriction: patients with refractory epilepsy. Treatment should be initiated only by physicians who have appropriate experience in the treatment of epilepsy. In two placebo-controlled studies in patients with refractory epilepsy retigabine was superior to placebo in terms of the proportion of patients experiencing ≥ 50% reduction in partial seizure frequency per 28 days. An indirect comparison indicates that retigabine has similar efficacy to two other antiepileptic drugs used as adjunctive therapy.	Added to the Additional List.	January 2012
risperidone (Risperdal®) *Janssen-Cilag* 09.08.04 *SMC Report No. 113/04*	Accepted for use: risperidone (Risperdal®) is accepted for use within NHS Scotland for the treatment of episodes of mania in bipolar disorder. Risperidone has similar efficacy to haloperidol in improving symptom scores, with fewer extrapyramidal side effects. In an economic model based on indirect comparison, monotherapy with risperidone appears to be cost effective. No evidence is submitted on its cost effectiveness profile in co-therapy.	Already included in the formulary.	June 2008
risperidone orodispersible tablets (Risperdal Quicklet®) *Janssen-Cilag Ltd* *Treatment of acute and chronic schizophrenia and other similar psychotic conditions.* 09.05.03 *SMC Report No. 41/03*	Restricted use: Use of Risperdal Quicklet®, for the treatment of acute and chronic schizophrenia and other similar psychotic conditions, should be reserved for those patients in whom rapid oral absorption is indicated.	Approved for use - added to the Formulary. Reserved for the treatment of acute episodes of schizophrenia in patients who are unco-operative or wary of taking oral medication. Not intended for long-term use.	May 2003
risperidone prolonged release injection (Risperdal Consta®) *Janssen-Cilag Ltd* 06.12.02 SMC Report No. 22/02	Restricted use: Risperdal Consta® may be considered as a treatment option for patients who require an atypical antipsychotic and for whom depot injection is the preferred route of administration. Its use should be under the overall supervision of a consultant psychiatrist.	Approved for use - added to the Additional List. Specialist prescribing only, not primary care.	March 2003
risperidone 3mg, 4mg orodispersible tablets (Risperdal Quicklet®) *Janssen-Cilag Ltd* 10.09.07 *SMC Report No. 403/07* PRODUCT UPDATE (Abbreviated submission)	Restricted use: risperidone 3mg, 4mg orodispersible tablets (Risperdal Quicklet®) are accepted for restricted use within NHS Scotland for treatment of acute and chronic schizophrenia and similar psychosis and treatment of mania in bipolar disorder. These new strengths of risperidone orodispersible tablets should be used in patients for whom risperidone is an appropriate choice of antipsychotic and an orodispersible tablet is an appropriate formulation.	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**
rivastigmine (Exelon®) *Novartis Pharmaceuticals UK Ltd* 07.08.06 *SMC Report No. 310/06* NON SUBMISSION	NOT RECOMMENDED: rivastigmine (Exelon®) is not recommended for use within NHSScotland for the treatment of mild to moderately severe dementia in patients with idiopathic Parkinson's disease. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	
rivastigmine 4.6mg/24h and 9.5mg/24h transdermal patch (Exelon®) *Novartis Pharmaceuticals UK Limited* 12.11.07 *SMC Report No. 414/07* PRODUCT UPDATE (abbreviated submission)	Restricted use: rivastigmine transdermal patch (Exelon®) is accepted for restricted use within NHS Scotland for symptomatic treatment of moderately severe Alzheimer's dementia only. It should be used in accordance with guidance from NHS Quality Improvement Scotland on the application of the National Institute for Health and Clinical Excellence (NICE) technology appraisal number 111. Within this context it is suitable for patients in whom rivastigmine is an appropriate choice of acetylcholinesterase inhibitor and in whom a transdermal patch is an appropriate choice of formulation.	Added to the LJF as a 'new formulation of a drug already in the formulary'.	December 2007
ropinirole tablets (Adartrel®) *GlaxoSmithKline* 10.07.06 *SMC Report No. 165/05* RESUBMISSION	Restricted use: ropinirole (Adartrel®) is accepted for restricted use within NHS Scotland for the treatment of moderate to severe idiopathic restless legs syndrome (RLS). Its use should be restricted to patients with a baseline score of 24 points or more on the International Restless Legs Scale (IRLS). Compared with placebo, ropinirole was associated with a 4-point improvement on the 40-point IRLS in a pooled analysis restricted to patients with IRLS score of 24 points.	'Not preferred' in Lothian. A submission has not been made to Formulary Committee regarding this product for this indication.	August 2010
ropinirole 2 mg, 4 mg or 8 mg prolonged-release tablets (Requip® XL) *GlaxoSmithKline* 08.09.08 *SMC Report No. 491/08* PRODUCT UPDATE (abbreviated submission)	Accepted for use: ropinirole 2 mg, 4 mg, 8 mg prolonged-release tablets (Requip® XL) are accepted for use in NHS Scotland for the treatment of idiopathic Parkinson's disease in patients already taking ropinirole immediate release tablets and in whom adequate symptomatic control has been established. Substitution of ropinirole prolonged release tablets for ropinirole immediate release tablets may be used as: Monotherapy, alone (without levodopa) in idiopathic Parkinson's disease, or as: Adjunctive therapy in addition to levodopa to control 'on-off' fluctuations which might permit a reduction in the total daily dose of levodopa. Substitution of prolonged-release ropinirole for ropinirole immediate release tablets should be supervised by appropriate specialists in Parkinson's disease.	Added to the Formulary as a Prescribing Note, for Specialist Use only.	August 2008
rotigotine 2mg/24 hours, 4mg/24 hours, 6mg/24 hours, 8mg/24 hours transdermal patch (Neupro®) *Schwarz Pharma Ltd* 09.07.07 *SMC Report No. 289/06* RESUBMISSION	Accepted for use: rotigotine (Neupro®) is accepted for use within NHS Scotland for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease as monotherapy (i.e. without levodopa). Rotigotine was superior to placebo in two randomised controlled trials. However, in one active comparator study it was less effective than a non-ergolinic dopamine agonist comparator. Rotigotine transdermal patch offers an alternative non-ergolinic dopamine agonist at a lower cost in a formulation that does not have to be taken by mouth.	Added to the LJF as a Prescribing Note, Specialist Initiation	April 2011

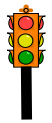
Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
rotigotine 2mg/24 hours, 4mg/24 hours, 6mg/24 hours, 8mg/24 hours transdermal patch (Neupro®) *Schwarz Pharma Ltd* 13.08.07 *SMC Report No. 392/07*	Restricted use: rotigotine (Neupro®) is accepted for restricted use within NHS Scotland for the treatment of the signs and symptoms of advanced idiopathic Parkinson's disease in combination with levodopa; i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or "on-off" fluctuations). Rotigotine increased the proportion of patients achieving □ 30% reduction in "off" time compared with placebo, but appeared to be less effective than another non-ergolinic dopamine agonist. Rotigotine trans-dermal patch offers an alternative non-ergolinic dopamine agonist at a lower cost in a formulation that does not have to be taken by mouth. It is restricted to patients where this route would facilitate treatment.	Added to the LJF as a Prescribing Note, Specialist Initiation	April 2011
rotigotine, 1mg, 2mg and 3mg per 24 hours transdermal patch (Neupro®) *UCB Pharma Ltd* 10.08.09 *SMC Report No. 548/09*	Accepted for use: rotigotine (Neupro®) is accepted for use within NHS Scotland for the symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome (RLS) in adults. It should only be used in patients with a baseline score of 15 points or more on the International Restless Legs Scale (IRLS). Compared with placebo, rotigotine was associated with improvements on a patient-administered scale based on the core clinical features of the syndrome and on the incidence of periodic limb movements during time in bed. Other dopamine agonists licensed for use in RLS are available at a lower cost.	'Not preferred' in Lothian. A submission has not been made to Formulary Committee regarding this product for this indication.	August 2010
rufinamide 100mg, 200mg and 400mg tablets (Inovelon®) *Eisai Limited* 10.11.08 *SMC Report No. 416/07* RESUBMISSION	Restricted use: rufinamide (Inovelon®) is accepted for restricted use within NHS Scotland as adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients four years and older. Adjunctive rufinamide significantly reduced the frequency of total seizures and tonic-atonic seizures and significantly improved seizure severity when compared to placebo in patients with LGS. Rufinamide is restricted to use in patients who have failed treatment with or are intolerant of alternative traditional antiepileptic drugs.	Added to the Additional List. Patients should be seen to respond to treatment prior to transferring the prescribing to primary care.	May 2009
rufinamide 40mg/mL oral suspension (Inovelon®) *Eisai Ltd* 03.07.12 *SMC Report No. 795/12* PRODUCT UPDATE (abbreviated submission)	Restricted use: rufinamide 40mg/mL oral suspension (Inovelon®) is accepted for restricted use within NHS Scotland as an adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 4 years of age or older. SMC restriction: restricted to use in patients who have failed treatment with or are intolerant of other antiepileptic drugs. Adjunctive rufinamide significantly reduced the frequency of total seizures and tonic-atonic seizures and significantly improved seizure severity when compared to placebo in patients with LGS. The oral suspension is bioequivalent to the tablets and provides an alternative formulation for patients who have difficulty swallowing. Depending on the dose it may be more expensive than the tablets but any overall budget impact is likely to be small.	Included on the Additional List for the indication in question. As an alternative formulation for patients who have difficulty swallowing.	July 2012

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
safinamide (Xadago®) 50mg / 100mg film-coated tablets *Zambon S.p.A.* 12.06.17 *SMC Report No: 1259/17* NON SUBMISSION	Treatment of adult patients with idiopathic Parkinson's disease (PD) as add-on therapy to a stable dose of Levodopa alone or in combination with other PD medicinal products in mid-to late-stage fluctuating patients.	Not routinely available as not recommended for use in NHSScotland.	May 2017
semi-sodium valproate (Depakote®) *Sanofi-Aventis*	Acute treatment of mania in bipolar disorder	It was agreed that semi-sodium valproate (Depakote®) should be added to the Additional List for Specialist Use only in acute cases, where patients cannot tolerate or do not respond to first choice drugs.	September 2005
sertraline (Lustral®) *Pfizer Ltd* 10.11.03 *SMC Report No. 68/03*	NOT RECOMMENDED: sertraline has demonstrated some benefit in treating post-traumatic stress disorder (PTSD) in two of four 12-week double blind treatment studies, and in extension studies for up to 64 weeks. The product licence restricts its use to women only; a narrower indication than for the other drug currently licensed for treating PTSD, and against which no comparative trials have been conducted. The manufacturer submitted no evidence to demonstrate the cost effectiveness of their drug.	NOT RECOMMENDED	
sodium oxybate 500mg/mL oral solution (Xyrem®) *UCB Pharma Ltd* 10.09.07 *SMC Report No. 246/06* RESUBMISSION	NOT RECOMMENDED: sodium oxybate (Xyrem®) is not recommended for use within NHS Scotland for the treatment of cataplexy in adult patients with narcolepsy. The manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.	NOT RECOMMENDED	
sodium oxybate (Xyrem®) *UCB Pharma Ltd*	Treatment of cataplexy in adult patients with narcolepsy	Not recommended. SMC rejected submissions on two occasions. Individual cases for the use of non approved drugs should be reviewed approved through local non-approved medicine route or by the Exceptional Cases Panel.	January 2009
sodium valproate (Episenta®) Beacon	Epilepsy	Added to the paediatric Formulary as a prescribing note. For use in children who cannot tolerate large volumes of liquid or swallow tablets.	March 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**
stiripentol 250mg and 500mg hard capsule, 250mg and 500mg powder for oral suspension in sachet (Diacomit®) *Biocodex* 11.09.17 *SMC Report No. 524/08* *RESUBMISSION*	Accepted for use within NHS Scotland. Indication under review: in conjunction with clobazam and valproate as adjunctive therapy of refractory generalised tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (SMEI; Dravet's syndrome) whose seizures are not adequately controlled with clobazam and valproate. Adjunctive treatment with stiripentol, compared with placebo, significantly reduced seizure frequency in children aged at least three years with SMEI who had at least four seizures per month despite treatment with clobazam and valproate. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.	Formulary classification not yet decided – waiting for information from clinicans.	
sucrose 33% *Tayside Pharmaceuticals*	Analgesia for acute painful procedures 	Added to the Additional List, for Specialist Use only. Sucrose 33% as analgesia for acute painful procedures 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 2011
sufentanil citrate 15 micrograms sublingual tablets (Zalviso®) *Grunenthal Ltd* 07.08.17 *SMC Report No: 1270/17* NON SUBMISSION	NOT RECOMMENDED Management of acute moderate to severe post-operative pain in adult patients.	NOT RECOMMENDED	
sumatriptan succinate 50mg and 100mg tablets (Imigran Radis®) *GlaxoSmithKline UK Pharmaceuticals* 11.10.04 *SMC Report No. 127/04* PRODUCT UPDATE (abbreviated submission)	Accepted for use: Imigran Radis® film-coated tablets are accepted for use within NHS Scotland for acute relief of migraine attacks, with or without aura, provided there is a clear diagnosis of migraine. They offer a fast disintegrating oral formulation of sumatriptan succinate. No increased cost is associated with this product compared to prescribing conventional Imigran® tablets.	New formulation of a drug already included in the Formulary.	
tafamidis meglumine (Vyndaqel®) 20mg soft capsules *Pfizer Limited* 13.05.13 *SMC Report No: 877/13* NON SUBMISSION	NOT RECOMMENDED: tafamidis meglumine (Vyndaqel®) is not recommended for use within NHS Scotland for the treatment of transthyretin amyloidosis in adult patients with stage 1 symptomatic polyneuropathy to delay peripheral neurologic impairment, The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
tapentadol, 50, 100, 150, 200 and 250mg prolonged-release tablets (Palexia® SR) *Grünenthal Ltd* 13.06.11 *SMC Report No. 654/10* RESUBMISSION	Restricted use: tapentadol prolonged-release (Palexia® SR) is accepted for restricted use within NHS Scotland for the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics. SMC restriction: patients in whom morphine sulphate modified release has failed to provide adequate pain control or is not tolerated. Results of a meta-analysis of three, 12-week studies suggest that tapentadol prolonged release has improved gastrointestinal tolerability and similar efficacy compared to another long-acting opioid included as an active control. The manufacturer's submission related only to the use of tapentadol prolonged release in severe chronic pain. SMC has not yet received a submission for tapentadol immediate release tablets for the relief of moderate to severe acute pain in adults, which can be adequately managed only with opioid analgesics. Tapentadol immediate release tablets are not recommended for use in NHS Scotland.	Added to Formulary as Second choice drug after morphine for severe chronic pain. Note that the immediate release tapentadol tablets are not approved for use.	January 2012
tapentadol (Palexia®) 50 mg film-coated tablets *Grunenthal Ltd* 13.02.12 *SMC Report No. 773/12* NON SUBMISSION	NOT RECOMMENDED: tapentadol (Palexia®) is not recommended for use within NHS Scotland as a relief of moderate to severe acute pain in adults, which can be adequately managed only with opioid analgesics. 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	
thioridazine (Apo-thioridazine®) *Imported via IDIS World Medicines Ltd. Manufactured by Apotex, Canada.*	Treatment of schizophrenia 	Added to Additional List as second-line treatment of schizophrenia to allow continuation of therapy in patients who have been unable to withdraw from thioridazine on previous attempts. Thioridazine (Apo-thioridazine®) has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian' – Specialist Use only.	July 2017
topiramate (Topamax®) *Janssen Cilag* 09.01.04 *SMC Report No. 75/03*	Restricted use: topiramate (Topamax®) is accepted for restricted use within NHS Scotland for its extended (monotherapy) indication. It should be initiated only by physicians who have appropriate experience in the treatment of epilepsy. Topiramate should be used principally in patients who have not benefited from treatment with an older anti-convulsant drug such as carbamazepine or sodium valproate, or for whom these drugs are unsuitable because of contraindications, interactions or poor tolerance. Its use for second-line therapy in epilepsy is unaffected by this recommendation.	'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**
topiramate 25, 50mg tablets, 25, 50mg sprinkle capsules (Topamax®) *Janssen-Cilag Limited* 11.09.06 *SMC Report No. 297/06*	Restricted use: topiramate (Topamax®) is accepted for restricted use within NHS Scotland for the prophylaxis of migraine headache in adults. It should be restricted to initiation by specialists and treatment should be managed under specialist supervision or shared care arrangements in patients who have not responded to prophylactic treatment with at least one other agent.	Added to Formulary as prescribing note – to be initiated following specialist advice.	June 2008
tramadol 37.5mg/paracetamol 325mg tablet (Tramacet®) *Janssen-Cilag* 13.02.06 *SMC Report No. 236/06*	NOT RECOMMENDED: tramadol 37.5mg/paracetamol 325mg tablet (Tramacet®) is not recommended for use within NHS Scotland for the symptomatic treatment of moderate to severe pain. Tramacet had similar efficacy to another combination analgesic in clinical studies, though the dose of paracetamol in the other analgesic preparation was lower than that usually used in the UK. Tramacet costs significantly more than its individual components prescribed separately.	NOT RECOMMENDED	
varenicline 1mg tablets (Champix®) *Pfizer Ltd* 15.01.07 *SMC Report No. 336/06*	Accepted for use: varenicline tablets (Champix®) is accepted for use within NHS Scotland for smoking cessation in adults. It should be used only as a component of a smoking cessation support programme. The benefits of an additional treatment course in those who have stopped smoking after the initial 12 weeks of therapy appear modest. Efficacy and safety in patients with significant co-morbidity are uncertain.	Added to the LJF as a prescribing note.	April 2007
venlafaxine (Efexor® XL) *Wyeth Pharmaceuticals* 11.08.08 *SMC Report No. 501/08* NON SUBMISSION	NOT RECOMMENDED: venlafaxine extended release capsules (Efexor XL) are not recommended for use within NHSScotland for the treatment of moderate to severe generalised social anxiety disorder/social phobia in 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	
vortioxetine 5mg, 10mg, 20mg film-coated tablet (Brintellix®) *Lundbeck Ltd.* 11.07.16 *SMC Report No. 1158/16*	Restricted use: vortioxetine 5mg, 10mg, 20mg film-coated tablet (Brintellix®) is accepted for restricted use within NHS Scotland for the treatment of major depressive episodes in adults. SMC restriction: patients who have experienced an inadequate response (either due to lack of adequate efficacy and/or safety concerns/intolerability) to two or more previous antidepressants. In two phase III, randomised, double-blind studies in adults with major depressive disorder, vortioxetine was non-inferior to two alternative antidepressants at reducing the Montgomery-Åsberg Depression Rating Scale (MADRS) total score from baseline to week 8.	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.	April 2017
ziconotide, 100micrograms/mL solution for intrathecal infusion (Prialt®) *Eisai Ltd* 08.10.07 SMC Report No. 405/07	NOT RECOMMENDED: ziconotide (Prialt®) is not recommended for use within NHS Scotland for the treatment of severe, chronic pain in patients who require intrathecal analgesia. Ziconotide, compared to placebo, improved pain scores in patients with chronic severe intractable pain despite treatment with systemic and/or intrathecal analgesia. However, the manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
zonisamide hard capsules 25mg, 50mg, 100mg (Zonegran®) *Eisai Ltd* 12.12.05 *SMC Reprt No. 216/05*	Restricted use: zonisamide (Zonegran®) is accepted for restricted use within NHS Scotland as adjunctive therapy in adult patients with partial seizures, with or without secondary generalisation. It should be initiated only by physicians who have appropriate experience in the treatment of epilepsy and should be used principally in patients who have not benefited from treatment with an older ant-convulsant drug such as carbamazepine or sodium valproate, or for whom these drugs are unsuitable because of contra-indications, interaction or poor tolerance.	Added to the Additional List, for specialist initiation or on specialist advice.	April 2008
zonisamide (Zonegran®) 25, 50, 100mg Hard Capsules *Eisai Ltd* 08.10.12 *SMC Report No. 817/12* NON SUBMISSION	NOT RECOMMENDED: zonisamide (Zonegran®) is not recommended for use within NHS Scotland as monotherapy for the treatment of partial seizures (with or without secondary generalization) in adults with newly diagnosed epilepsy. 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	
zonisamide 25mg, 50mg and 100mg capsules (Zonegran®) *Eisai Limited* 10.03.14 *SMC Report No. 949/14* PRODUCT UPDATE (abbreviated submission)	Restricted use: zonisamide (Zonegran®) is accepted for restricted use within NHS Scotland as adjunctive therapy in the treatment of partial seizures, with or without secondary generalisation, in adolescents, and children aged 6 years and above. SMC restriction: on advice from specialists (paediatric neurologists or paediatricians with an expertise in epilepsy). The Scottish Medicines Consortium has previously accepted zonisamide for restricted use in adult patients with partial seizures, with or without secondary generalisation. It was restricted to initiation by physicians with appropriate experience in the treatment of epilepsy and should be used principally in patients who have not benefited from treatment with an older anti-convulsant drug such as carbamazepine or sodium valproate, or for whom these drugs are unsuitable because of contra-indications, interaction or poor tolerance.	Included on the Additional List, for Specialist Use only, for the indication in question.	February 2014
zopiclone 15mg tablets	Short term treatment of insomnia including difficulty in falling asleep, nocturnal awakening and/or early wakening, transient or situational insomnia 	Added to the Additional List, categorised **RED** under the ADTC 'Policy for the use of unlicensed medicines (and off-label use) Medicines in the NHS Lothian'. Specialist Use only. For use at LEAP services only.	January 2010
zopiclone 7.5mg, 15mg tablets	Short term treatment of insomnia	Added as second choice to the Formulary.	May 2011