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

15 – Anaesthesia

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**
chloroprocaine hydrochloride, 10mg/mL, solution for injection (Ampres®) *Mercury Pharmaceuticals Ltd* 12.08.13 *SMC Report No. 885/13*	NOT RECOMMENDED: chloroprocaine hydrochloride (Ampres®) is not recommended for use within NHS Scotland as spinal anaesthesia in adults where the planned surgical procedure should not exceed 40 minutes. In a small, single-centre, randomised, double-blind, controlled study spinal anaesthesia with chloroprocaine injection compared with a hyperbaric formulation of an amide-type local anaesthetic agent was associated with a faster resolution of sensory and motor block, resulting in a shorter time to meet eligibility criteria for discharge. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.	NOT RECOMMENDED	
dehydrated alcohol (absolute alcohol) BP for injection *Martindale Pharmaceuticals*	Percutaneous ablation of thyroid nodules. 	Routinely available in line with local or regional guidance. Included on the Additional List, for Specialist Use only, categorised 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, categorised as **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) medicines in NHS Lothian'.	January 2017
dexmedetomidine 100 micrograms/mL concentrate for solution for infusion (Dexdor®) *Orion Pharma UK* 11.06.12 *SMC Report No. 784/12*	Accepted for use: dexmedetomidine (Dexdor®) is accepted for use within NHS Scotland for sedation in adult intensive care unit (ICU) patients requiring a sedation level not deeper than arousal in response to verbal stimulation (corresponding to Richmond Agitation-Sedation Scale [RASS] 0 to -3). Dexmedetomidine was as effective as propofol and midazolam in maintaining the target depth of sedation in ICU patients. The median duration of mechanical ventilation was numerically shorter with dexmedetomidine than with propofol and significantly shorter than with midazolam.	Included on the Additional List, Specialist Use only for the indication in question.	October 2012

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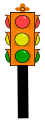
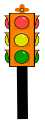
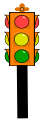
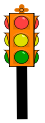
etomidate (Etomidate-Lipuro®) *B Braun Medical Ltd* 13.12.04 *SMC Report No. 143/04* PRODUCT UPDATE (abbreviated submission)	Accepted for use: Etomidate-Lipuro® 2mg/ml is accepted for use in NHS Scotland for the induction of general anaesthesia in patients aged six months and above where etomidate is an appropriate agent. Compared with high-osmolality etomidate formulations based on propylene glycol, this formulation may be associated with a reduction in adverse events, including pain on administration and the requirement for a local anaesthetic, at no additional cost.	Added to the Formulary as second choice drug, replacing standard etomidate for general anaesthesia.	January 2005
glycopyrronium 320 micrograms/mL (glycopyrronium bromide 400 micrograms/mL) oral solution (Sialanar®) *Proveca Limited* 10.07.17 *SMC Report No. 1254/17* PRODUCT UPDATE (abbreviated submission)	Symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders.	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.	July 2017
Intralipid® *Fresenius Kabi*	For the treatment of local anaesthetic toxicity 	Added to Additional list – Categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label) use of Medicines in NHS Lothian' - Specialist use only	April 2008
levobupivacaine (Chirocaine®) *Abbott*	As paravertebral local anaesthetic infusion for post thoracotomy (pleurodesis) pain relief.	Added to the Additional List for Specialist Use only.	May 2012
levobupivacaine 0.125% (200mL Infusion)	Local infiltration analgesia for total knee or hip replacement. 	Added to the Additional List, for Specialist Use only. levobupivacaine 0.125% (200mL Infusion) has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	March 2015
levobupivacaine and fentanyl epidural infusion *Fresenius Kabi*	For postoperative pain in patients for whom an epidural infusion is an appropriate mode of analgesia. 	Added to the Additional List, for Specialist Use only. Levobupivacaine and fentanyl epidural infusion has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	November 2013

Product ***Manufacturer*** **Date SMC/NICE Recommendation** ***Report number***	**Condition being treated** **For more details see www.scottishmedicines.org.uk/**	**NHS Lothian decision**	**Date of NHS Lothian decision**
levobupivacaine, sodium chloride, ketorolac and adrenaline	Local infiltration analgesia for total knee replacement. 	Not approved for use in Lothian. Levobupivacaine, sodium chloride, ketorolac and adrenaline as local infiltration analgesia for total knee replacement has been categorised **BLACK** under the ADTC 'Policy for the use of unlicensed (and off label use) Medicines in NHS Lothian.	August 2012
lidocaine patches (Versatis®) *Grünenthal*	Use in palliative care 	Additional List to be amended to include Versatis® as the named brand of lidocaine patch for off-label use in palliative care. Lidocaine patches (Versatis®) remain on the Additional List. Off-label use approved for palliative care only, with a prescribing protocol for GPs.	September 2007
lidocaine plaster (Versatis®)	Symptomatic relief of adults with focal bone pain 	Not recommended for use in Lothian. Lidocaine plaster (Versatis®) have been categorised **BLACK** under the ADTC 'Policy and procedures for the use of unlicensed medicines'.	September 2015
lidocaine plaster 5% (Versatis®) *Grunenthal Ltd.* Local formulary process	For the symptomatic relief of adults >65 years of age with musculoskeletal pain (e.g. osteoporotic vertebral fracture) in whom topical therapy is considered appropriate but are not able to use topical NSAIDs (e.g. severe renal impairment or hypersensitivity). 	Routinely available in line with local or regional guidance. Included on the Additional List, for Specialist initiation. Classified as **AMBER** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Included on the Additional List, Specialist initiation. Classified as **AMBER** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	March 2017

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lidocaine 70mg / tetracaine 70mg (Rapydan 70 mg / 70 mg medicated plaster) *EUSA Pharma (Europe) Limited* 09.06.08 *SMC Report No. 483/08* NON SUBMISSION	NOT RECOMMENDED: lidocaine 70mg / tetracaine 70mg (Rapydan 70mg / 70mg medicated plaster) is not recommended for use within NHSScotland for surface anaesthesia of the skin in connection with needle puncture and in cases of superficial surgical procedures (such as excision of various skin lesions and punch biopsies) on normal skin in adults; or for surface anaesthesia of the skin in connection with needle puncture on normal intact skin in children from 3 years of age. 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	
midazolam oral liquid 2.5mg/mL *Special Products Ltd*	Sedative pre-medication prior to anaesthesia and surgery 	Added to LJF as first choice for use in children undergoing anaesthesia and surgery who are anxious and require sedative pre-medication. For specialist use only. Midazolam oral liquid 2.5mg/mL has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.	May 2007
naloxone hydrochloride (Prenoxad®) *Martindale Pharma*	For emergency use in the home or other non-medical setting by appropriate individuals or in a health facility setting for the complete or partial reversal of respiratory depression induced by natural and synthetic opioids.	Added to the LJF as a prescribing note.	November 2013
prilocaine hydrochloride 2% hyperbaric solution for injection (Prilotekal®) *Goldshield Group* 17.01.11 *SMC Report No. 665/10*	Restricted use: prilocaine hydrochloride 2% hyperbaric solution for injection (Priloketal®) is accepted for restricted use within NHS Scotland. Indication under review: spinal anaesthesia SMC restriction: for use in spinal anaesthesia in ambulatory surgery settings such as day surgery units. Prilocaine 2% hyperbaric solution for injection was associated with faster discharge times than a hyperbaric formulation of another local anaesthetic in one small single-centre, double-blind, randomised study. Use of this preparation may allow service improvement through benefits to individual patients or service delivery.	Included on the Additional List, for Specialist Use only, for the indication in question.	October 2012
propofol 1% (10mg/mg) emulsion of long and medium chain triglycerides (MCT-LCT) (Propofol Lipuro®) *B.Braun* 09.01.04 *SMC Report No. 53/03*	Accepted for use: propofol MCT-LCT emulsion 1% is a new formulation of an existing product. It is as effective as alternative formulations of propofol. Pain on injection is significantly reduced in frequency and intensity compared with alternative formulations, though not totally eliminated. The major advantage of this formulation will be realised when co-administration of lignocaine is unnecessary. This advice is based on the assumption that the product will be available through contract at a price that is competitive with available formulations of propofol.	Added to the LJF for Children - Specialist Use only. Note: propofol MCT-LCT is not in the Adult Formulary. It is 'Not preferred' in adults as effective alternatives are available.	June 2004 January 2004

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ropivacaine hydrochloride 0.2%	Local infiltration analgesia for total knee and total hip replacement. 	Added to the Additional List, for Specialist Use only. Ropivacaine hydrochloride 0.2% as analgesia for total knee and total hip replacement has been categorised **RED** under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.	August 2012
8.4% sodium bicarbonate preservative free Minijet® *UCB Pharma*	Rapid top-up of epidural for emergency Caesarean Section 	Added to the Additional List, for Specialist Use only. 8.4% sodium bicarbonate for rapid top-up of epidural for emergency Caesarean Section 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 2012
sugammadex 100mg/ml solution for injection (Bridion®) *Schering-Plough* 09.02.09 *SMC Report No. 527/09*	Accepted for use: sugammadex (Bridion®) is accepted for restricted use within NHS Scotland for the immediate reversal of rocuronium-induced neuromuscular blockade. Sugammadex, when administered after rocuronium or vecuronium, has been shown to provide more rapid reversal of neuromuscular blockade than an anticholinesterase comparator and, when administered with rocuronium in the rapid sequence induction setting, gave a faster mean recovery time than using a depolarising neuromuscular blocking comparator. Sugammadex is accepted for restricted use in the immediate reversal of rocuronium-induced neuromuscular blockade in adults only. Sugammadex is not recommended for the routine reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults, children and adolescents as the manufacturer did not present a sufficiently robust economic case to gain acceptance by SMC.	Added to Additional List, Specialist Use only.	August 2009

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sugammadex 100mg/mL (1mL, 2mL, 5mL) solution for injection (Bridion®) *Merck, Sharp & Dohme Limited* 11.03.13 *SMC Report No. 527/09* RESUBMISSION	Restricted use: sugammadex (Bridion®) is accepted for restricted use within NHS Scotland for the routine reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults and rocuronium in children and adolescents. Indication under review: Reversal of neuromuscular blockade induced by rocuronium or vecuronium. For the paediatric population: sugammadex is only recommended for routine reversal of rocuronium induced blockade in children and adolescents. This resubmission is for the part of the indication relating to routine reversal of neuromuscular blockade. SMC restriction: only for use in the routine reversal setting in high-risk patients (e.g. morbid obesity, significant respiratory disease or reduced respiratory reserve, significant coronary disease, major abdominal/chest surgery) or where prompt reversal of neuromuscular block is required. Sugammadex, when administered after rocuronium or vecuronium, has been shown to provide more rapid reversal of moderate and profound neuromuscular blockade than an anti-cholinesterase comparator. Sugammadex is significantly more expensive than conventional treatments used to reverse neuromuscular blockade.	Sugammadex is recommended in Lothian for immediate reversal of rocuronium-induced neuromuscular blockade only. Included on the additional list, Specialist use only, for the indication in question. For use in high-risk patients only.	June 2013 April 2016
tetracaine / lidocaine (Pliaglis 70 mg/g + 70 mg/g cream®) *Galderma (UK) Ltd* 13.10.14 *SMC Report No. 1000/14* NON SUBMISSION	NOT RECOMMENDED: tetracaine / lidocaine (Pliaglis®) is not recommended for use within NHS Scotland as local dermal anaesthesia on intact skin prior to dermatological procedures 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	