




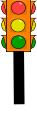






Formulary Committee Recommendations on:
a) unlicensed and off-label medicines (FAF3), and
b) medicines not considered by SMC (FAF2)



Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
5-aminolevulinic acid hydrochloride (Gliolan®) Medac To help guide resection of Glioblastomas	Added to the Additional List, for Specialist Use only. FC December 2013	N/A
N-acetylcysteine 600mg capsules  Idiopathic pulmonary fibrosis (IPF), in combination with prednisolone +/- azathioprine	Treatment to be initiated by specialists only. Patients responding to treatment at 3 months, as judged by a stable or increase in lung function, can be transferred to primary care prescribing under SCP arrangements (SCP to be developed). N-acetylcysteine 600mg capsules for the unlicensed indication, for use in combination with prednisolone and azathioprine in IPF has been categorised AMBER under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. FC December 2006	AMBER (General use with restrictions)



Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
adalimumab (Humira®) Abbott For use in Crohn's Disease for patients intolerant or allergic to infliximab	 It was agreed that adalimumab should be added to the Additional List. Adalimumab for Crohn's disease has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only. FC August 2005 SMC advice issued in November 2007 (Report No. 417/07), states that adalimumab is NOT RECOMMENDED FOR USE for this indication.	RED (Specialist Use only)
ajmaline 50mg/10ml intravenous infusion (Gilurymal®) Solvay Pharmaceuticals Diagnosis of Brugada syndrome	 Added to the Additional List, for Specialist Use only. Ajmaline for Brugada syndrome has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only. FC September 2009	RED (Specialist Use only)


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
alemtuzumab (MabCampath®) Genzyme Immunosuppression for islet cell transplant recipients 	<p>Added to the Additional List, for Specialist Use only.</p> <p>Alemtuzumab for immunosuppression for islet cell transplant recipients has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.</p> <p>FC January 2011</p>	RED (Specialist Use only)
alemtuzumab (MabCampath®) Genzyme Treatment of relapsed chronic lymphocytic leukaemia (subcutaneous administration) 	<p>Added to the Additional List, for Specialist Use only.</p> <p>Alemtuzumab for the treatment of relapsed chronic lymphocytic leukaemia has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.</p> <p>FC April 2012</p>	RED (Specialist Use only)
alfentanil (Rapifen®) injection and sublingual / buccal spray Janssen-Cilag Moderate to severe opioid responsive pain for use under specialist supervision, and incident pain 	<p>Added to the Additional List, for initiation by Specialists.</p> <p>Alfentanil (Rapifen®) has been categorised AMBER under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.</p> <p>FC March 2007</p>	AMBER (General use with restrictions)


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
amlodipine (Istin[®]) Pfizer Hypertension	Amlodipine to replace nifedipine as first choice calcium channel blocker in the LJF. FC December 2006	N/A
artesunate (Malacef[®]) Guilin Pharmaceuticals Treatment of adults and children with severe P. Falciparum malaria. 	Added to the Additional List, for Specialist Use only. Artesunate for the treatment of adults and children with severe P. Falciparum malaria has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only. FC April 2014	RED (Specialist Use only)
atomoxetine (Strattera[®]) Eli Lilly and Company Ltd. Treatment of Attention Deficit Hyperactivity Disorder in Adults (>18yr) 	Added to the Formulary as a second choice drug, and prescribed in accordance with the SCP. General use with restrictions. Atomoxetine (Strattera [®]) has been categorised AMBER under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. FC April 2012	AMBER (General Use with restrictions)


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
axitinib (Inlyta[®]) Pfizer <i>As a second-line treatment for advanced/metastatic renal carcinoma after pazaponib therapy.</i> 	<p>Added to the Additional List, for Specialist Use only.</p> <p>Axitinib as a second-line treatment for advanced/metastatic renal carcinoma after pazopanib therapy has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.</p> <p>FC April 2014</p>	RED (Specialist Use only)
baclofen (Lioresal[®]) Novartis <i>Use in maintenance treatment of alcohol abstinence in alcohol dependant patients.</i> 	<p>It was agreed that baclofen should be added to the Additional List.</p> <p>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.</p> <p>FC July 2008</p>	RED (Specialist Use only)



Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
baclofen (Lioresal®)  Novartis Adjunct to high-dose chlordiazepoxide, in gamma-butyrolactone (GBL) withdrawal and to prevent relapse in formerly GBL-dependent patients.	<p>Added to the Additional List, for Specialist Use only.</p> <p>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.</p> <p>FC December 2010</p>	RED (Specialist Use only)
bendamustine (Levact®)  NAPP In combination with rituximab for relapsed chronic lymphocytic leukaemia.	<p>Added to the Additional List, for Specialist Use only.</p> <p>Bendamustine has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.</p> <p>FC February 2014</p>	RED (Specialist Use only)


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
botulinum Toxin – A (Botox[®]) Allergan  <i>use for intractable detrusor over activity</i>	<p>It was agreed that botulinum should be added to the Additional List.</p> <p>Botulinum use for intractable overactive bladder has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.</p> <p>FC July 2008</p>	RED (Specialist Use only)
botulinum Toxin – A (Dysport[®]) Ipsen  <i>Use for severe overactive bladder with urge incontinence, with urodynamically proven detrusor activity</i>	<p>It was agreed that botulinum should be added to the Additional List.</p> <p>Botulinum use for severe overactive bladder has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.</p> <p>FC October 2008</p>	RED (Specialist Use only)


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
buprenorphine (Transtec[®])  Napp <i>Moderate to severe cancer pain & severe pain that does not respond to non-opioid analgesics (resubmission from clinicians in Lothian to the Lothian Formulary Committee following the decision of the SMC)</i>	To remain 'Not recommended' in line with SMC Report No. 116/04. FC September 2005	N/A

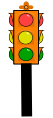
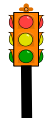

Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
<p>buprenorphine and naloxone (Suboxone®) Schering-Plough</p>  <p>Substitution treatment for opioid drug dependence as an alternative maintenance treatment when methadone is not suitable (off-label dose of 32mg daily.)</p>	<p>It was agreed that buprenorphine and naloxone should be added to the Additional List.</p> <p>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.</p> <p>FC July 2008</p> <p>See the webtable of SMC decisions – for the approval of the licensed indication</p>	<p>RED (Specialist Use only)</p>
<p>cabergoline (Dostinex®) Pharmacia</p> <p>As suppression of initiation of lactation in women over 24 weeks with a foetal loss.</p>	<p>Added to the LJF as a prescribing note, for Specialist Use only.</p> <p>FC December 2012</p>	<p>N/A</p>


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
capecitabine (Xeloda®) Roche <i>Adjuvant use following potentially curative surgery for adenocarcinoma of the pancreas to replace 5FU/folinic acid given according to the Mayo schedule</i>	Added to the LJF as first choice for use post-operatively in the treatment of adenocarcinoma of the pancreas, for Specialist Use only. FC January 2007	N/A
capecitabine (Xeloda®) Roche  Colorectal cancer	Added to the Additional List for use in secondary care only. Specialist use only. FC January 2005	RED (Specialist Use only)



Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
<p>capecitabine (Xeloda[®]) Roche </p> <p><i>Pre-operative chemoradiation in patients with locally advanced rectal cancer requiring down staging prior to definitive resection or in patients with good performance status and low volume metastatic disease requiring durable palliation for unresectable rectal cancer</i></p>	<p>Added to the Additional List, for Specialist Use only.</p> <p>capecitabine (Xeloda[®]) (for pre-operative chemoradiation in patients with locally advanced rectal cancer requiring down staging prior to definitive resection or in patients with good performance status and low volume metastatic disease requiring durable palliation for unresectable rectal cancer) has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.</p> <p>FC September 2006</p>	<p>RED (Specialist Use only)</p>
<p>capecitabine (Xelox[®]) Roche </p> <p><i>In combination with epirubicin and cisplatin (ECX) for palliative treatment of advanced oesophagogastric cancer</i></p>	<p>It was agreed that capecitabine (Xelox[®]) should be added to the Additional List. Capecitabine (Xelox[®]) in combination with epirubicin and cisplatin (ECX) for first line use as palliative treatment of advanced oesophagogastric cancer has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.</p> <p>FC September 2005</p>	<p>RED (Specialist Use only)</p>

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capecitabine/oxaliplatin (Xeloda®/Eloxatin®) Roche First choice treatment for Dukes B colorectal cancer	Added to the Additional List for Specialist Use only. FC July 2007	N/A
cefazolin sodium (Kefzol®) Sandoz Treatment of meticillin-sensitive Staph aureus (MSSA) bacteraemia in renal patients. 	Added to the Additional List, for Specialist Use only. The Alert Antibiotic Policy will be updated accordingly. Cefazolin sodium for the treatment of MSSA bacteraemia in renal patients has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only. FC January 2013	RED (Specialist Use only)
celecoxib (Celebrex®) Pharmacia Treatment of osteoarthritis and rheumatoid arthritis in patients who are in need of NASID therapy and are at high risk of gastrointestinal (GI) side effects.	Not preferred as suitable alternatives are available. FC July 2008	N/A



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chlordiazepoxide (Librium®) Meda Pharmaceuticals Adjunct to baclofen in gamma-butyrolactone withdrawal (GBL) 	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. FC December 2010	RED (Specialist Use only)
chlorhexidine gluconate 2% in 70% isopropyl alcohol cutaneous solution (ChloroPrep®) CareFusion For disinfection of the skin prior to invasive procedures.	Added to the Additional List as a first-line treatment, for Specialist Use only. FC November 2013	N/A
Complan® Shake Complan Foods Oral Nutritional Supplement	Added to section 9.4 (Oral Nutritional Supplements) of the Formulary as First Choice. FC April 2011	N/A


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
colecalciferol (Dekristol®) <i>Jenapharm/ IDIS</i> <i>Treatment of Vitamin D deficiency and osteomalacia</i> 	Added to the Additional List for use in rheumatology patients. Colecalciferol has been categorised AMBER under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian' - General use with restrictions. Prescribing should be initiated by or on the advice of specialists. FC January 2011	AMBER (General use with restrictions)
colecalciferol (Dekristol®) <i>Jenapharm/ IDIS</i> <i>Treatment of Vitamin D deficiency</i> 	Added to the Additional List for use in patients with HIV and Hepatitis C infection. Colecalciferol has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian' – Specialist use only. FC May 2011	RED (Specialist use only)
colecalciferol (Dekristol®) <i>mibe GmbH Arzneimittel/IDIS</i> <i>Treatment of Vitamin D deficiency</i> 	Added to the LJF for General Use, in line with Adult Vitamin D guidelines Colecalciferol has been categorised GREEN under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. FC October 2012	GREEN (General use)


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colecalfiferol (Dekristol®)  For vitamin D deficiency (vit D < 25nmol/L) in children and adolescents aged 12 to 18 years.	Added to the LJF (Children) as a joint first choice preparation. Colecalciferol for vitamin D deficiency in children and adolescents aged 12 to 18 years has been categorised GREEN under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. FC April 2014	GREEN (General Use)
cisplatin/ vinorelbine Adjuvant non-small cell lung cancer	Added to the Additional List, for Specialist Use only. FC October 2005	N/A
clopidogrel (Plavix®) Sanofi-Synthelabo and Bristol-Myers Squibb In combination with aspirin for secondary prevention in ST-elevation myocardial infarction (STEMI)	Added to the Formulary as a Prescribing Note - to be used for up to 1 month post ST-elevation myocardial infarction (STEMI). FC August 2006	N/A



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colistin (colistimethate sodium) 2million units for nebulisation (Colomycin®) Forest  Severe bronchiectasis after treatment failure with nebulised gentamicin	Added to the Additional List, as second choice and prescribed in accordance with Shared Care Protocol. Colistin (Colomycin®) has been categorised AMBER under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. General use with restrictions. FC November 2008	AMBER (General use with restrictions)
copper Wire IUD (surface area 380mm2) (TT380) Contraception (long-term)	Added to the Formulary as first choice copper IUD. FC May 2006	N/A
dalteparin (Fragmin®) Pharmacia  Thromboprophylaxis in patients with oesophago-gastric cancer undergoing pre-operative cisplatin-based chemotherapy prior to surgery with curative intent.	Added to the Additional List, for Specialist Use only. Dalteparin for thromboprophylaxis in patients with oesophago-gastric cancer undergoing pre-operative cisplatin-based chemotherapy prior to surgery with curative intent has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only. FC December 2013	RED (Specialist Use only)


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dalteparin sodium (Fragmin®) Pfizer Prophylaxis and treatment of venous thromboembolism.	Added to the Formulary as first choice. FC September 2010	N/A
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'. FC April 2012	AMBER (General Use with restrictions)
diclofenac sodium 3% gel (Solaraze®) Shire Pharmaceuticals Actinic keratosis	Added to the Formulary as joint first choice for patients with small non tender diffuse actinic keratoses. Care should be taken to avoid confusion with Voltarol Emulgel® (non-formulary) which contains a different concentration of diclofenac to relieve musculoskeletal pain. FC November 2005	N/A
digoxin immune fab (Digifab®) Protherics UK Limited Treatment of life threatening digoxin toxicity.	Added to the Additional List for Specialist Use only. FC January 2013	N/A


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dinoprostone pessaries (Propess®) Ferring  Outpatient Induction of labour	Added to the Additional List, for Specialist Use only. Dinoprostone for outpatient induction of labour has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only. FC September 2009	RED (Specialist Use only)
domperidone  Augmentation of lactation.	Added to the Formulary. General use with restrictions. Domperidone (Motilium®) has been categorised AMBER under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. FC April 2012	AMBER (General use with restrictions)
droperidol (Xomolix®) Prostrakan Anticipated problematic post operative nausea and vomiting (PONV)	Added to the Additional List, for Specialist Use only. FC August 2010	N/A



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Duac[®] once daily (1% clindamycin, 5% benzoyl peroxide) For the treatment of mild to moderate acne vulgaris	Added to the LJJ as a prescribing note for the treatment of mild to moderate acne vulgaris. FC November 2009 <i>See also table of SMC recommendations.</i>	N/A
dutasteride (Avodart[®]) GlaxoSmithKline Lower urinary tract symptoms due to BPH	To remain on the Additional List. FC January 2006	N/A
emulsifying ointment BP 25% w/w in coconut oil BP  Treatment of scalp dermatitis, psoriasis, keratosis.	Added to the LJJ as a prescribing note. Emulsifying ointment BP 25% w/w in coconut oil BP has been categorised GREEN under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian' FC April 2013	GREEN (General use)




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<p>epirubicin (Pharmorubicin[®]), cisplatin (Platinex[®]) and capecitabine (Xeloda[®]) (ECX) <i>Pharmacia, Bristol-Myers Squibb, Roche</i></p> <p><i>Peri-operative treatment of operable gastric and type 3 oesophagogastric junctional adenocarcinomas</i></p>	<p>Added to the LJF as first choice treatment for peri-operative treatment of operable gastric and type 3 oesophagogastric junctional adenocarcinomas, Specialist Use only.</p> <p>FC September 2007</p>	<p>N/A</p>
<p>eptotermin alfa (Osigraft[®])  <i>Stryker UK Ltd</i></p> <p><i>Treatment of non-union of long bones of at least 9 month duration, secondary to trauma, in skelletally mature patients, in cases where previous treatment with autograft has failed or use of autograft is unfeasible.</i></p>	<p>Added to the Additional List, Specialist Use only.</p> <p>Eptotermin alfa for the treatment of non-union of long bones has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'</p> <p>FC January 2011</p>	<p>RED (Specialist Use only)</p>


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ergocalciferol (Sterogyl®) Desma Pharma  For vitamin D deficiency (vit D < 25nmol/L) in children and adolescents aged 12 to 18 years.	Added to the LJF (Children) as a joint first choice preparation. Ergocalciferol for vitamin D deficiency in children and adolescents aged 12 to 18 years has been categorised GREEN under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. FC April 2014	GREEN (General Use)
ertapenem (Invanz®) Merck Sharpe and Dohme Limited  For multi-resistant infections treatment in Outpatient Parenteral Antimicrobial Treatment (OPAT) clinic.	Added to the Additional List, for Specialist Use only. The Alert Antibiotic Policy will be updated. Ertapenem has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. FC February 2014	RED (Specialist Use only)



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etanercept (Enbrel®) Wyeth <i>Treatment of adults with moderate to severe plaque psoriasis who failed to respond to, or have a contra-indication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or PUVA (photochemotherapy)</i>	<p>Added to the Additional List, for Specialist Use only.</p> <p>NICE - recommends for use (NICE technology appraisal guidance 103. Etanercept and efalizumab for adults with psoriasis. July 2006. www.nice.org.uk/page.aspx?o=TA103)</p> <p>NHS QIS www.nhshealthquality.org/nhsqis advises that this NICE appraisal is as valid for Scotland as for England and Wales and that the guidance on efalizumab supersedes the advice issued by the Scottish Medicines Consortium 10 December 2004.</p> <p>FC October 2006</p>	N/A
etonogestrel (Nexplanon®)  Organon (MSD) <i>Contraception within 72 hours postpartum</i>	<p>Added to the Additional List, for Specialist Use only.</p> <p>Etonogestrel has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.</p> <p>FC April 2012</p>	RED (Specialist Use only)


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fluconazole (oral)  (Diflucan®) Pfizer <i>Empirical treatment of breast pain (mastalgia) during breastfeeding</i>	Not preferred in Lothian. Fluconazole (Diflucan®) has been categorised BLACK under the ADTC 'Policy for the use of unlicensed (and off label use) Medicines in NHS Lothian, for the treatment of mastalgia. FC July 2007	BLACK (Not approved for use)
FOLFIRINOX combination chemotherapy (Folic acid, 5-Fluorouracil, Oxaliplatin) Various <i>For use in palliative chemotherapy for inoperable pancreatic adenocarcinoma in good performance status patients.</i>	Added to the Additional List, for Specialist Use only. FC December 2011	N/A



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fosfomycin (Monuril®) (oral) Zambon Group <i>Treatment of culture proven lower urinary tract infections caused by multiple antibiotic-resistant enterobacteriaceae.</i> 	fosfomycin (Monuril®) 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. A prescribing note will be added to the LJJ. FC September 2011	AMBER (General use with restrictions)
fosfomycin (Fosfocina®) (injection) Laboratories ERN, S.A., Barcelona <i>Treatment of multiresistant Pseudomonas aeruginosa infection in adult cystic fibrosis patients.</i> 	Added to the Additional List for Specialist Use only. Added to the Alert Antibiotic policy. fosfomycin (fosfocina®) has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian' Specialist Use only. FC June 2013	RED (Specialist Use only)

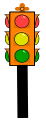
Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
gabapentin Neuropathic pain in children 	<p>Added to the Lothian Joint Formulary for Children as a prescribing 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.</p> <p>FC January 2006</p>	AMBER (General use with restrictions)
gemcitabine (Gemzar®) Eli Lilly & Co Ltd Biliary tract cancer 	<p>It was agreed that gemcitabine (Gemzar®) for biliary tract cancer should be added to the Additional List.</p> <p>Gemcitabine (Gemzar®) for biliary tract cancer has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.</p> <p>FC September 2005</p>	RED (Specialist Use only)
gemcitabine (Gemzar®) In combination with dexamethasone and cisplatin for relapsed / refractory lymphoma. 	<p>Added to the Additional List, for Specialist Use only.</p> <p>Gemcitabine (Gemzar®) for relapsed / refractory lymphoma has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.</p> <p>FC May 2014</p>	RED (Specialist Use only)



Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
gentamicin 80mg vials (40mg/ml 2ml vials) Severe bronchiectasis 	<p>Added to the Additional List, as first choice and prescribed in accordance with Shared Care Protocol.</p> <p>Gentamicin has been categorised AMBER under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. General use with restrictions.</p> <p>FC November 2008</p>	AMBER (General use with restrictions)
gliclazide 30mg modified release tablet (Diamicron® MR) Servier Type II diabetes mellitus	<p>Added to the Formulary as a prescribing note. This preparation should be reserved for patients with a demonstrated compliance problem.</p> <p>FC March 2005</p>	N/A
histidine - tryptophan - ketoglutarate (HTK) (Custodial®) Kohler Medical Ltd (1) Non heart-beating kidney - liver donors (NHBD) (2) Live donor liver transplantation (LDLT)	<p>Approved for use in all non heart-beating donation (NHBD) and live donor liver transplantation (LDLT) retrievals, for Specialist Use only. Added to the Additional List.</p> <p>FC May 2006</p>	N/A


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
ibuprofen melts 400mg <i>Pre-operative dosing where no NSAIDs have been administered in advance, and occasional post-operative use in patients unable to swallow ibuprofen tablets</i>	Added to the Additional List. FC October 2007	N/A
idebenone (Daruma[®]) Wyeth Pharmaceuticals  Mitochondrial cytopathies	Added to the Additional List. The unlicensed use of idebenone for the treatment of mitochondrial cytopathies has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian' - Specialist use only. FC January 2006	RED (Specialist Use only)
indomethacin 50mg vial containing powder and solvent for injection (Liometacin[®]) Chiesi Farmaceutici  Treatment of ventilated patients with acute liver failure and raised uncontrollable intracranial pressure	Added to the Additional List. Indomethacin has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian' - Specialist use only. FC July 2009	RED (Specialist Use only)


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
<p> infliximab (Remicade®) 100mg vial (powder for reconstitution for intravenous infusion) Schering-Plough </p>  <p> <i>Paediatric inflammatory bowel disease - induction of remission of severe abdominal or complex perianal Crohn's disease, induction of remission in severe acute ulcerative colitis, and maintenance of remission in severe abdominal or complex perianal Crohn's disease</i> </p>	<p> Added to the Additional List for use in paediatric inflammatory bowel disease. For specialist use only. </p> <p> Infliximab (Remicade®) has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. </p> <p> FC May 2007 </p>	<p> RED (Specialist Use only) </p>


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
infliximab (Remicade®) powder for reconstitution 100mg vial Schering-Plough <i>For the treatment of refractory juvenile idiopathic arthritis (JIA), uveitis associated with JIA and idiopathic uveitis in children and young people.</i> 	Added to the Additional List, for Specialist Use only. Infliximab (Remicade®) has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only. FC May 2014	RED (Specialist Use only)
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 FC April 2008	RED (Specialist Use only)



Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
ketamine injection (Ketalar®) Pfizer ketamine oral solution Martindale 'special' Specialist palliative care patients with severe neuropathic pain that is poorly responsive to opioids	 <p>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.</p> <p>FC May 2005</p>	AMBER (General use with restrictions)
levobupivacaine (Chirocaine®) Abbott As paravertebral local anaesthetic infusion for post thoracotomy (pleurodesis) pain relief.	<p>Added to the Additional List for Specialist Use only.</p> <p>FC May 2012</p>	N/A



Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
levobupivacaine and fentanyl epidural infusion Fresenius Kabi <i>For postoperative pain in patients for whom an epidural infusion is an appropriate mode of analgesia.</i> 	<p>Added to the Additional List, for Specialist Use only.</p> <p>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.</p> <p>FC November 2013</p>	RED (Specialist Use only)
levobupivacaine, sodium chloride, ketorolac and adrenaline <i>Local infiltration analgesia for total knee replacement.</i> 	<p>Not approved for use in Lothian.</p> <p>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.</p> <p>FC August 2012</p>	BLACK (Not approved for use)




Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
levofloxacin (Tavanic®) Hoechst Marion Roussel Antibiotic prophylaxis for neutropenic sepsis in lung cancer patients undergoing chemotherapy only	Not preferred as suitable alternatives exist. FC December 2006	N/A
levofloxacin (Tavanic®) Hoechst Marion Roussel Pneumococcal infection in patients with severe allergy to penicillins and cephalosporins - new use request	'Not preferred' as effective alternatives available. FC May 2005	N/A
levofloxacin (Tavanic®) Sanofi - Aventis  Treatment of lower respiratory tract infection in cystic fibrosis	Added to Additional list – Categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label) use of Medicines in NHS Lothian', for cystic fibrosis patients - Specialist use only FC May 2012	RED (Specialist Use only)

Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
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. FC November 2004	N/A
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. FC September 2007	N/A
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. FC April 2009	AMBER (General use with restrictions)



Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
macrogol 3350 and ascorbic acid (Moviprep[®]) Norgine Pharmaceuticals Ltd Bowel preparation prior to colonoscopy	Added to the Additional List. FC August 2007	N/A
magnesium sulphate, injection 5g in 10ml (50%) Martindale  Fetal neuroprotection in the context of preterm birth brain injury if delivery anticipated prior to 30 weeks gestation.	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 FC March 2012	RED (Specialist Use only)
mannitol powder (Osmohale[®]) Pharmix Diagnostic test for asthma, measuring bronchial hyperresponsiveness (BHR).	Added to the Additional List, Specialist Use Only FC April 2011	N/A

Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
methadone hydrochloride (Eptadone[®]) Dee Pharmaceuticals Ltd Treatment of opioid drug addiction (as a narcotic abstinence syndrome suppressant)	Not recommended for use in Lothian. FC March 2008 This advice relates to this particular brand of methadone.	N/A
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	AMBER (General Use with restrictions)
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'. FC April 2012	AMBER (General Use with restrictions)


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
methotrexate 50mg/ml pre-filled syringe (Metoject®) Medac <i>Inflammatory diseases eg non-classified polyarthritis</i> 	Added to the Additional List. Methotrexate 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. FC September 2009	AMBER (General Use with restrictions)
methotrexate 50mg/ml pre-filled syringe (Metoject®) Medac <i>Crohn's disease in paediatrics</i> 	Added to the Additional List. Methotrexate has been categorised AMBER for paediatrics under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian' – specialist use only. FC May 2010	AMBER (General Use with restrictions)



Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
<p>methotrexate 50mg/ml pre-filled syringe (Metoject®) Medac</p>  <p><i>Crohn's disease in adults</i></p>	<p>Added to the Additional List and prescribed in accordance with Shared Care Protocol.</p> <p>Methotrexate has been categorised AMBER for adults under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian' - General use with restrictions.</p> <p>FC April 2010</p>	<p>AMBER (General Use with restrictions)</p>
<p>micronised progesterone (Utrogestan)</p>  <p>For the unlicensed use in luteal phase support for patients undergoing IVF</p>	<p>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</p> <p>FC June 2008</p>	<p>RED (Specialist Use only)</p>
<p>midazolam oral liquid 2.5mg/mL Special Products Ltd</p>  <p><i>Sedative pre-medication prior to anaesthesia and surgery</i></p>	<p>Added to LJJ as first choice for use in children undergoing anaesthesia and surgery who are anxious and require sedative pre-medication. For specialist use only.</p> <p>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'.</p> <p>FC May 2007</p>	<p>RED (Specialist Use only)</p>


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
mometasone furoate nasal spray 50micrograms/spray (Nasonex®) Schering-Plough Prophylaxis and treatment of allergic rhinitis; nasal polyps	Added to the Formulary as second choice. Beclometasone nasal spray is first choice. The current second choice (fluticasone nasal spray) has been removed and added to the Additional List. FC January 2006	N/A
moxifloxacin (Avelox®) Bayer CF/bronchiectasis patients when therapy failed or co-amoxiclav and clarithromycin resistance - new use request	'Not Preferred' in the Children's Formulary as effective alternatives are available. FC April 2005	N/A


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
<p>moxifloxacin (Avelox®) Bayer Schering</p>  <p><i>As part of tuberculosis treatment regimen if the patient infection is resistant to one or more first line antibacterial agents and is sensitive to moxifloxacin.</i></p>	<p>Added to the Additional List, for Specialist Use only.</p> <p>moxifloxacin (Avelox®) has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.</p> <p>FC December 2012</p>	<p>RED (Specialist Use only)</p>
<p>mycophenolate mofetil (CellCept®) Roche</p>  <p><i>Management of steroid-dependent nephrotic syndrome in paediatric patients.</i></p>	<p>Added to the Additional List and prescribed in accordance with Shared Care Protocol.</p> <p>Mycophenolate mofetil has been categorised AMBER for paediatrics under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.</p> <p>FC April 2012</p>	<p>AMBER (General Use with restrictions)</p>


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
naloxone hydrochloride (Prenoxad[®]) Martindale Pharma <i>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.</i>	Added to the LJF as a prescribing note. FC November 2013	N/A
naltrexone 50mg tablets (Nalorex[®]) Bristol Myers Squibb <i>Adjunctive prophylactic therapy in the maintenance of detoxified, formerly opioid-dependent patients.</i>	Added to the Additional List for Specialist Use only, and not for GP prescribing. FC June 2005	N/A


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
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'. FC March 2009	RED (Specialist Use only)
nebivolol (Nebilet[®]) A. Menarini Pharma UK SRL Essential hypertension, angina, chronic heart failure	Added to the Additional List to be initiated by specialists only (prescribing to continue in primary care). It should be reserved for patients requiring a beta-blocker for the treatment of hypertension in situations where they are unable to tolerate LJJ first or second choice beta-blockers. It should not be used for treatment of angina or chronic heart failure for which it does not have a licence. FC May 2006 <i>Note - The Scottish Medicines Consortium does not recommend nebivolol (Nebilet[®]) for use within NHS Scotland for the treatment of stable mild and moderate chronic heart failure (CHF) in addition to standard therapies in elderly patients ≥70 years.</i> FC September 2006	N/A


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
oxaliplatin (Eloxitan®) Sanofi Aventis Oesophagogastric cancer 	<p>Added to the Additional List.</p> <p>Oxaliplatin (Eloxitan®) (for use in oesophagogastric cancer) has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.</p> <p>FC May 2006</p>	RED (Specialist Use only)
oxaliplatin (Eloxitan®) Sanofi Aventis Treatment of metastatic or locally advanced inoperable oesophagogastric carcinoma (in combination with epirubicin and capecitabine (EOX)) 	<p>Added to the Additional List - Categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.</p> <p>FC March 2009</p>	RED (Specialist Use only)



Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
oxaliplatin, 5-fluorouracil and folinic acid, a combination chemotherapy regimen  Second-line chemotherapy for patients with pancreatic cancer who have progressed after first-line gemcitabine-based chemotherapy and are of very good performance status.	Added to the Additional List for Specialist Use only. A combination chemotherapy regimen using oxaliplatin, 5-fluorouracil and folinic acid has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. FC July 2013	RED (Specialist Use only)
oxycodone 10mg/mL injection For post-operative pain.	Added to the Additional List as a third-line treatment for Specialist Use only. FC October 2013	N/A
palivizumab (Synagis®) Abbott Prevention of serious disease caused by respiratory syncytial virus	Added to the Additional List for pre-term babies or infants with particular medical conditions. FC November 2010 Note: - Already on the Additional List for paediatric cardiac patients (2004)	N/A


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
<p>paracetamol self dissolving tablets 250mg (melts)</p> <p><i>For teenage patients who cannot swallow tablets</i></p>	<p>Added to the Additional List.</p> <p>FC October 2007</p>	<p>N/A</p>
<p>perindopril (Coversyl®) Servier</p> <p><i>Heart failure, hypertension, secondary prevention in patients with established vascular (atheroma) disease</i></p>	<p>To remain as 'Not Preferred' in Lothian for the treatment of heart failure, hypertension, and secondary prevention in patients with established vascular (atheroma) disease.</p> <p>FC November 2005</p>	<p>N/A</p>
<p>piperacillin plus tazobactam </p> <p><i>For the treatment of neonates with suspected or confirmed late onset blood stream infection defined as infection arising greater than 72 hours after birth in infants currently on the neonatal unit at the RIE.</i></p>	<p>Added to the LJJ as a first-line treatment, for Specialist Use only.</p> <p>Piperacillin plus tazobactam has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.</p> <p>FC February 2014</p>	<p>RED (Specialist Use only)</p>


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
<p>piperacillin / tazobactam </p> <p><i>For the treatment of Pseudomonas or Enterobacteriaceae infections with borderline resistance (high MICs) and/or complicated source of infection in critical care within the RIE, WGH and SJH. Extended time infusion.</i></p>	<p>Added to the Additional List, for Specialist Use only.</p> <p>Piperacillin / tazobactam has been categorised RED under the ADTC 'Policy and procedures for the use of unlicensed medicines.'</p> <p>FC July 2014</p>	<p>RED (Specialist Use only)</p>
<p>pivmecillinam (Selexid®) <i>Leo Laboratories Ltd</i></p> <p><i>Treatment of culture proven lower urinary tract infections caused by multiple antibiotic-resistant enterobacteriaceae.</i></p>	<p>Added to the LJF as a prescribing note.</p> <p>FC September 2011</p>	<p>N/A</p>


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
Pollinex Tree and Pollinex Grasses & Rye Allergy Therapeutics Severe seasonal rhino-conjunctivitis with insufficient response to pharmacotherapy in children over 8 years.	Added to the Additional List, for Specialist Use only. FC December 2013	N/A
propranolol  Treatment of childhood haemangioma causing functional problems or disfigurement.	Added to the Additional List, for Specialist Use only. Propranolol for the treatment of childhood haemangioma causing functional problems or disfigurement has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only. FC January 2013	RED (Specialist Use only)


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
<p>raltegravir (Isentress®) </p> <p><i>For post exposure prophylaxis for HIV in combination with tenofovir / emtricitabine (Truvada®).</i></p>	<p>Added to the Additional List, for Specialist Use only.</p> <p>Raltegravir (Isentress®) has been categorised RED under the ADTC 'Policy and procedures for the use of unlicensed medicines.'</p> <p>FC July 2014</p>	<p>RED (Specialist Use only)</p>
<p>regadenoson (Rapiscan®) <i>Rapiscan Pharma Solutions EU Ltd.</i></p> <p><i>This medical product is for diagnostic use only. Rapiscan® is a selective coronary vasodilator for use as a pharmacological stress agent for radionuclide myocardial perfusion imaging (MPI) in adult patients unable to undergo adequate exercise stress.</i></p>	<p>Added to the Additional List, for Specialist Use only.</p> <p>FC August 2013</p>	<p>N/A</p>

Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
riboflavin (isotonic or hypotonic) eye drops Veni Vidi Treatment of keratoconus	Added to the Additional List, for Specialist Use only FC January 2011	N/A
rituximab (Mabthera®) Roche Acquired Haemophilia. 	Added to the Additional List, for Specialist Use only. Rituximab (Mabthera®) for the treatment of acquired haemophilia has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only. FC July 2012	RED (Specialist Use only)
rituximab (Mabthera®) Roche Immune Thrombocytopenia. 	Added to the Additional List, for Specialist Use only. Rituximab (Mabthera®) for the treatment of immune thrombocytopenia has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only. FC July 2012	RED (Specialist Use only)


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
rituximab (Mabthera®) Roche <i>In combination with bendamustine for first-line treatment of Chronic Lymphocytic Leukaemia.</i>	Added to the Additional List, for Specialist Use only. FC April 2014	N/A
ropivacaine hydrochloride 0.2%  <i>Local infiltration analgesia for total knee and total hip replacement.</i>	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. FC August 2012	RED (Specialist Use only)
rosuvastatin (Crestor®) AstraZeneca Hypercholesterolaemia	To remain on the Additional List, for Specialist Use only. FC August 2010	N/A



Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
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. FC September 2005	N/A
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. FC January 2012	RED (Specialist Use only)
sodium hyaluronate 1.2% (OVD®) Beaver-Visitec International Ltd Ophthalmic cataract surgery	Added to the Additional List, for Specialist Use only. FC December 2010	N/A

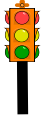
Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
sodium oxybate (Xyrem®) UCB Pharma Ltd Treatment of cataplexy in adult patients with narcolepsy	Not 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. FC January 2009	N/A
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. FC March 2009	N/A
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. FC January 2011	RED (Specialist Use only)


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
<p> tacrolimus (Protopic® / Tacrolimus in Orabase / mouthwash) Astellas/Western Infirmary Glasgow  </p> <p> For recalcitrant oral lichen planus (OLP). </p>	<p> Added to the Additional List, for Specialist Use only. </p> <p> Tacrolimus for recalcitrant OLP has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only. </p> <p> FC November 2013 </p>	<p> RED (Specialist Use only) </p>
<p> temocillin powder for injection or infusion (Negaban®) Eumedica </p> <p> Burkholderia cepacia lung infection in cystic fibrosis </p>	<p> Added to the Additional List, for Specialist Use only in cystic fibrosis patients. </p> <p> FC May 2010 </p> <p> Added to the Alert Antibiotic Policy. </p> <p> FC March 2013 </p>	<p> N/A </p>

Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
<p>temocillin 1g powder for solution for injection (Negaban®) Eumedica</p> <p><i>As an alternative to carbapenems in the treatment of septicaemia, urinary tract infection or lower respiratory tract infection where Enterobacteriaceae or Burkholderia cepacia suspected or confirmed; and Pseudomonas, anaerobes, or Gram-positive organism unlikely or covered by other agents.</i></p>	<p>Added to the Additional List, for Specialist Use only. Added to the Alert Antibiotic Policy.</p> <p>FC March 2013</p>	<p>N/A</p>


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
tenofovir / emtricitabine (Truvada®)  For post exposure prophylaxis for HIV in combination with raltegravir (Isentress®).	Added to the Additional List, for Specialist Use only. Tenofovir / emtricitabine (Truvada®) has been categorised RED under the ADTC 'Policy and procedures for the use of unlicensed medicines.' FC July 2014	RED (Specialist Use only)
ticarcillin / clavulanic acid (Timentin®) GSK For Stenotrophomonas maltophilia lung infection in cystic fibrosis.	Added to the Additional List, for Specialist Use only. FC July 2014	N/A
tinzaparin sodium (Innohep®) Leo Prevention of clotting in Extracorporeal circuits (Haemodialysis).	Added to the Additional List, for Specialist Use only by the Haemodialysis Units. FC December 2011	N/A


Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
Tisseel Kit (fibrin sealant) Baxter <i>Ophthalmic surgery involving the conjunctiva and cornea</i> 	<p>Added to the Additional List, for Specialist Use only.</p> <p>Tisseel Kit for ophthalmic surgery involving the conjunctiva and cornea has been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'. Specialist Use only.</p> <p>FC September 2009</p>	RED (Specialist Use only)
thiazolidinediones & insulin Diabetes 	<p>Rosiglitazone and pioglitazone are contra-indicated in combination with insulin due to the risk of heart failure and/or oedema. In rare circumstances, where this combination is to be used, both should be prescribed in secondary care by a diabetologist.</p> <p>They have been categorised RED under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.</p> <p>FC April 2005</p>	RED (Specialist Use only)

Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
thioridazine (Apo-thioridazine[®])  Imported via IDIS World Medicines Ltd. Manufactured by Apotex, Canada. Treatment of schizophrenia	<p>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.</p> <p>Thioridazine (Apo-thioridazine[®]) 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. A shared care protocol is to be developed for thioridazine (Apo-thioridazine[®]) for this indication.</p> <p>FC November 2005</p>	AMBER (General use with restrictions)
topotecan (Hycamtin[®]) Merck Pharmaceuticals Platinum-resistant or refractory ovarian cancer	<p>It was agreed that topotecan (Hycamtin[®]) should be added to the Additional List.</p> <p>FC September 2005</p>	N/A
topotecan (Hycamtin[®]) GlaxoSmithKline Recurrent or metastatic carcinoma cervix	<p>Added to the Formulary as recommended by SMC Advice.</p> <p>Not Preferred for use in patients, who have received cisplatin previously.</p> <p>FC November 2008</p>	N/A

Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
urofollitropin (Fostimon[®]) Pharmasure Ltd For use in IVF treatment	Added to the Formulary as second choice product. Specialist Use only. FC April 2009	N/A
valganciclovir (Valcyte[®]) Roche As pre-emptive therapy for CMV infection in recipients of allogeneic haematopoietic stem cell transplants where surveillance detects CMV reactivation before development of CMV disease 	Added to the LJF, for Specialist Use only. FC January 2008	RED (Specialist Use only)

Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
Versiva® XC dressing <i>Use in moderate to high exudating, sloughy or granulating wounds to replace the combination of Aquacel and Allevyn (adhesive or non-adhesive)</i>	Added to the LJF as a prescribing note, alternative first choice when Aquacel and Allevyn are used in combination. FC December 2010	N/A
Vitamins A & D (5000iu/400iu) capsules <i>Malabsorption in adult cystic fibrosis</i>	Added to the Additional List. FC January 2011	N/A
Vitamin E 75iu capsules <i>Malabsorption in adult cystic fibrosis</i>	Added to the Additional List. FC January 2011	N/A

Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
<p>VSL#3[®] (Lactic acid bacteria probiotic food supplement) 3g sachet Ferring Pharmaceuticals </p> <p>Maintenance of remission in chronic or relapsing inflammation of ileoanal pouch anastomosis (pouchitis)</p> <p>(VSL#3[®] is a probiotic food supplement.)</p>	<p>Added to the Additional List - Categorized AMBER under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian' - General use with restrictions.</p> <p>Only prescribable under ACBS conditions "for the maintenance of remission of ileoanal pouchitis only in adults as induced by antibiotics."</p> <p>FC December 2008</p>	<p>AMBER (General use with restrictions)</p>
<p>zoledronic acid (Zometa[®]) Novartis</p> <p>For tumour induced hypercalcaemia</p>	<p>Added to the Formulary as first choice.</p> <p>To be included in the section for tumour induced hypercalcaemia.</p> <p>FC April 2010</p>	<p>N/A</p>

Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments (following submission from clinical teams)	Category under ADTC Unlicensed Drug Policy (red/ amber/ green/ black)
zopiclone 15mg tablets  <i>Short term treatment of insomnia including difficulty in falling asleep, nocturnal awakening and/or early wakening, transient or situational insomnia</i>	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 FC January 2010	RED (Specialist use only)
zopiclone 7.5mg, 15mg tablets Short term treatment of insomnia	Added as second choice to the Formulary. FC May 2011	N/A



= Unlicensed/ off-label medicine categorised under ADTC unlicensed drugs policy

RED: Specialist use only

AMBER: General use with restrictions

GREEN: Unrestricted general use

BLACK: Not approved for use