



**Recommendations on NEW DRUGS from the LOTHIAN FORMULARY COMMITTEE (FC)
following Scottish Medicines Consortium (SMC) recommendations**

Product SMC Advice Date / Report No. For more details see www.scottishmedicines.org.uk	Lothian Recommendation and Indication For more details see www.ljf.scot.nhs.uk
beclometasone with formoterol 100/6 micrograms/dose (Fostair[®] NEXThaler[®]) January 2015 NICE ESNM53	Routinely available in line with national guidance. Included on the LJF as second choice, for General Use, subject to clarification of the place in therapy by the Working Group. Included on the LJF as second choice, for General Use, for the indication in question, subject to clarification of the place in therapy by the Working Group. <i>Treatment of asthma in adults where MDI formulation is not suitable.</i> FC March 2017
botulinum toxin A, 50 Allergan units, 100 Allergan units, 200 Allergan units, powder for solution for injection (Botox[®]) 13.02.17 692/11 2 nd RESUBMISSION	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. <i>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).</i> <i>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.</i> FC April 2017
buprenorphine 5, 10, 15 and 20 microgram/hour transdermal patch (Butec[®]) 16.01.17 1213/17	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. <i>Treatment of chronic non-malignant pain of moderate intensity when an opioid is necessary for obtaining adequate analgesia.</i> <i>SMC restriction: for use in elderly patients (over 65 years).</i> FC March 2017
cabazitaxel 60mg concentrate and solvent for solution for infusion (Jevtana[®]) 12.12.16 735/11 2 nd RESUBMISSION Patient Access Scheme	Routinely available in line with national guidance. Included on the Additional List, Specialist Use only. Included on the Additional List, Specialist Use only, for the indication in question. <i>In combination with prednisone or prednisolone is indicated for the treatment of adult patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen.</i> <i>SMC restriction: for use in patients who have received at least 225mg/m² (three cycles) of docetaxel and have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.</i> FC April 2017
dalbavancin 500mg powder for concentrate for solution for infusion (Xydalba[®]) 16.01.17 1105/15	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. <i>Treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults.</i> <i>SMC restriction:</i> <ul style="list-style-type: none"> • for second-line use or when methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) infection is suspected, or on the advice of local microbiologists or specialists in infectious disease, and • the patient is initially hospitalised due to ABSSSI, requires intravenous antibiotics, but is eligible for early discharge as soon as their medical condition does not require further inpatient treatment. FC March 2017



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deferasirox 125mg, 250mg, 500mg dispersible tablets (Exjade [®]) 16.01.17 347/07 RESUBMISSION	<p>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.</p> <p><i>Treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate, in adult and paediatric patients aged 2 years and older with rare acquired or inherited anaemias. The current advice relates only to use in the myelodysplastic syndrome (MDS) population.</i></p> <p><i>SMC restriction: use in patients with MDS with an International Prognostic Scoring System (IPSS) score of low or intermediate -1 risk.</i></p> <p style="text-align: right;">FC March 2017</p>
everolimus 2.5mg, 5mg and 10mg tablets (Afinitor [®]) 13.02.17 1215/17 Patient Access Scheme	<p>Routinely available in line with national guidance. Included on the Additional List, Specialist Use only. Included on the Additional List, Specialist Use only, for the indication in question.</p> <p><i>Treatment of unresectable or metastatic, well-differentiated (Grade 1 or Grade 2) non-functional neuroendocrine tumours of gastrointestinal or lung origin in adults with progressive disease.</i></p> <p style="text-align: right;">FC April 2017</p>
evolocumab 140mg, solution for injection in pre-filled pen (Repatha [®] Sureclick) or pre-filled syringe (Repatha [®] PFS) 13.02.17 1148/16 RESUBMISSION Patient Access Scheme	<p>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.</p> <p><i>In adults with primary hypercholesterolaemia (heterozygous familial hypercholesterolaemia and non-familial) or mixed dyslipidaemia, as an adjunct to diet:</i></p> <ul style="list-style-type: none"> • <i>in combination with a statin or statin with other lipid lowering therapies in patients unable to reach low density lipoprotein-cholesterol (LDL-C) goals with the maximum tolerated dose of a statin or,</i> • <i>alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.</i> <p><i>SMC restriction: for specialist use only, when administered at a dose of 140mg every two weeks, in patients at high cardiovascular risk as follows:</i></p> <ul style="list-style-type: none"> • <i>patients with heterozygous familial hypercholesterolaemia (HeFH) and LDL-C ≥ 5.0mmol/L for primary prevention of cardiovascular events or,</i> • <i>patients with HeFH and LDL-C ≥ 3.5mmol/L for secondary prevention of cardiovascular events or,</i> • <i>patients at high risk due to previous cardiovascular events and LDL-C ≥ 4.0mmol/L or</i> • <i>patients with recurrent/polyvascular disease and LDL-C ≥ 3.5mmol/L</i> <p style="text-align: right;">FC April 2017</p>
insulin aspart (Fiasp [®]) 100 units/mL solution for injection in vial; solution for injection in cartridge (Penfill [®]); solution for injection in pre-filled pen (FlexTouch [®]) 10.04.17 1227/17 PRODUCT UPDATE (abbreviated submission)	<p>Not routinely available as local implementation plans are being developed or the FC is waiting for further advice from local clinical experts – decision expected by 1 September 2017. Not included on the LJF, pending protocol.</p> <p><i>Treatment of diabetes mellitus in adults.</i></p> <p style="text-align: right;">FC April 2017</p>
iron (III) isomaltoside 1000 (contains 50mg iron per mL) (Diafer [®]) solution for injection 13.02.17 1177/16 RESUBMISSION Patient Access Scheme	<p>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 do not support the formulary inclusion.</p> <p><i>Treatment of iron deficiency in adults with chronic kidney disease (CKD) on dialysis, when oral iron preparations are ineffective or cannot be used.</i></p> <p style="text-align: right;">FC March 2017</p>
mepolizumab 100mg powder for solution for injection (Nucala [®]) 13.06.16 1149/16 Patient Access Scheme	<p>Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only. Included on the Additional List, for Specialist Use only, for the indication in question.</p> <p><i>As an add-on treatment for severe refractory eosinophilic asthma in adult patients.</i></p> <p><i>SMC restriction: patients who have eosinophils of at least 150 cells per microlitre (0.15 x 10⁹/L) at initiation of treatment and have had at least four asthma exacerbations in the preceding year or are receiving maintenance treatment with oral corticosteroids</i></p> <p style="text-align: right;">FC March 2017</p>



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obinutuzumab 1,000mg concentrate for solution for infusion (Gazyvaro[®]) 13.03.17 1219/17 Patient Access Scheme	Not routinely available as local implementation plans are being developed or the FC is waiting for further advice from local clinical experts – decision expected by 1 September 2017. Not included on the LJF, pending protocol. <i>In combination with bendamustine followed by obinutuzumab maintenance is indicated for the treatment of patients with follicular lymphoma who did not respond or who progressed during or up to six months after treatment with rituximab or a rituximab-containing regimen.</i> FC April 2017
osimertinib 40mg and 80mg film-coated tablets (Tagrisso[®]) 13.02.17 1214/17 Patient Access Scheme	Routinely available in line with national guidance. Included on the Additional List, Specialist Use only. Included on the Additional List, Specialist Use only , for the indication in question. <i>Treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small-cell lung cancer (NSCLC).</i> <i>SMC Restriction: in patients who have received previous treatment with an EGFR tyrosine kinase inhibitor.</i> FC April 2017
pembrolizumab 50mg powder for concentrate for solution for infusion (Keytruda[®]) 16.01.17 1204/17 Patient Access Scheme	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 do not support the formulary inclusion. <i>Treatment of locally advanced or metastatic non-small cell lung carcinoma (NSCLC) in adults whose tumours express programmed death ligand 1 (PD-L1) and who have received at least one prior chemotherapy regimen.</i> <i>SMC restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule.</i> FC March 2017
trifluridine/tipiracil (as hydrochloride) 15mg/6.14mg and 20mg/8.19mg film-coated tablets (Lonsurf[®]) 13.02.17 1221/17 Patient Access Scheme	Routinely available in line with national guidance. Included on the Additional List, Specialist Use only. Included on the Additional List, Specialist Use only , for the indication in question. <i>Treatment of adult patients with metastatic colorectal cancer (CRC) who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-vascular endothelial growth factor agents, and anti-epidermal growth factor receptor agents.</i> FC April 2017
vortioxetine 5mg, 10mg, 20mg film-coated tablet (Brintellix[®]) 11.07.16 1158/16	Routinely available in line with national guidance. Included on the Additional List, Specialist Use only. Included on the Additional List, Specialist Use only , for the indication in question. <i>Treatment of major depressive episodes in adults.</i> <i>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.</i> FC April 2017

Recommendations on OTHER DRUGS from the LOTHIAN FORMULARY COMMITTEE (FC) (including unlicensed/off-label use)

Product Manufacturer Indication	Lothian Recommendation and Formulary Committee Comments
bendamustine 2.5mg/mL powder for concentrate for solution for infusion vials (Levact[®]) (available as 25mg and 100mg vials) Napp Pharmaceuticals Local formulary process <i>Relapsed and refractory multiple myeloma.</i>	 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'. FC April 2017



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<p>lidocaine plaster 5% (Versatis®) Grunenthal Ltd. Local formulary process</p> <p><i>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).</i></p>		<p>Routinely available in line with local or regional guidance. Included on the Additional List, for Specialist initiation.</p> <p>Categorised as AMBER under the ADTC 'Policy for the use of unlicensed (and off-label use) medicines in NHS Lothian'.</p> <p style="text-align: right;">FC March 2017</p>
<p>miconazole 2% cream (Daktarin®) Cilag Ltd and McNeil Products Ltd Local formulary process</p> <p><i>For the treatment of breast and nipple thrush in lactating women.</i></p>		<p>Routinely available in line with local or regional guidance. Included on the LJJ as a prescribing note, for General Use.</p> <p>Categorised as GREEN under the ADTC 'Policy for the use of unlicensed (and off-label use) medicines in NHS Lothian'.</p> <p style="text-align: right;">FC March 2017</p>
<p>miconazole oral 2% gel (Daktarin®) Cilag Ltd and McNeil Products Ltd Local formulary process</p> <p><i>For the treatment of oral thrush in breastfed infant ≤4 months of age as well as those > 4months of age.</i></p>		<p>Routinely available in line with local or regional guidance. Included on the LJJ as a prescribing note, for General Use.</p> <p>Categorised as GREEN under the ADTC 'Policy for the use of unlicensed (and off-label use) medicines in NHS Lothian'.</p> <p style="text-align: right;">FC March 2017</p>
<p>pirenzepine 50mg tablets (Gatrozepin®) Boehringer Ingelheim Local formulary process</p> <p><i>Treatment of clozapine induced hypersalivation.</i></p>		<p>Routinely available in line with local or regional guidance. Included on the Additional List, for Specialist Use only.</p> <p>Categorised as RED under the ADTC 'Policy for the use of unlicensed (and off-label use) medicines in NHS Lothian'.</p> <p style="text-align: right;">FC April 2017</p>
<p>PCV – procarbazine 50mg capsules, lomustine (CCNU) “medac” 40mg capsules and vincristine sulphate 1mg/mL injection vials / pre-filled infusion Local formulary process</p> <p><i>As adjuvant treatment for patients with grade II glioma following radiotherapy.</i></p>		<p>Routinely available in line with local or regional guidance. Included on the Additional List, for Specialist Use only.</p> <p>Categorised as RED under the ADTC 'Policy for the use of unlicensed (and off-label use) medicines in NHS Lothian'.</p> <p style="text-align: right;">FC April 2017</p>
<p>rituximab, methotrexate, cytarabine and thiotepa (MATRIX) Local formulary process</p> <p><i>Treatment of central nervous system lymphoma.</i></p>		<p>Routinely available in line with local or regional guidance. Included on the Additional List, for Specialist Use only.</p> <p>Categorised as RED under the ADTC 'Policy for the use of unlicensed (and off-label use) medicines in NHS Lothian'.</p> <p style="text-align: right;">FC April 2017</p>

Products **NOT RECOMMENDED** by the LOTHIAN FORMULARY COMMITTEE (FC) following Scottish Medicines Consortium (SMC) recommendations

Product SMC Advice Date / Report No. For more details see www.scottishmedicines.org.uk	NOT RECOMMENDED for this indication
<p>abatacept (Orencia®) 125mg solution for injection (pre-filled syringe) 125mg solution for injection in pre-filled pen 250mg powder for concentrate for solution for infusion 13.03.17 1230/17 NON SUBMISSION</p>	<p><i>Treatment of highly active and progressive disease in adult patients with rheumatoid arthritis not previously treated with methotrexate.</i></p>
<p>lacosamide (Vimpat®) 50mg / 100mg / 150mg / 200mg film-coated tablets / 10mg/mL solution for infusion / 10mg/mL syrup 13.03.17 1231/17 NON SUBMISSION</p>	<p><i>As monotherapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent (16-18 years) patients with epilepsy.</i></p>



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liposomal irinotecan hydrochloride trihydrate (as irinotecan sucrosfate salt), 5mg/mL concentrate for solution for infusion (Onivyde [®]) 13.03.17 1217/17	<i>Treatment of metastatic adenocarcinoma of the pancreas, in combination with fluorouracil (5-FU) and leucovorin (folinic acid), in adult patients who have progressed following gemcitabine based therapy.</i>
tenofovir alafenamide (Vemlidy [®]) 25mg film-coated tablets 10.04.17 1238/17 NON SUBMISSION	<i>Treatment of chronic hepatitis B in adults and adolescents (aged 12 years and older with body weight at least 35 kg).</i>
ticagrelor 60mg film-coated tablets (Brilique [®]) 10.04.17 1224/17	<i>Co-administered with acetylsalicylic acid for the prevention of atherothrombotic events in adult patients with a history of myocardial infarction and a high risk of developing an atherothrombotic event.</i>
ofatumumab (Arzerra [®]) 100mg & 1000mg concentrate for solution for infusion 10.04.17 1237/17 NON SUBMISSION	<i>Treatment of adult patients with relapsed CLL in combination with fludarabine and cyclophosphamide.</i>

Please refer to the LJF website, [New Drug Decisions](#) for classification of decisions.

Unlicensed medicines - 'Traffic light' system as set out in the ADTC NHS Lothian 'Policy and procedures for the Use of unlicensed medicines':



- RED: Specialist use only**
- AMBER: General use with restrictions**
- GREEN: Unrestricted general use**
- BLACK: Not approved for use**