



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

Product SMC Advice Date / Report No. <b>For more details see</b> <a href="http://www.scottishmedicines.org.uk">www.scottishmedicines.org.uk</a>	Lothian Recommendation and Indication  <b>For more details see</b> <a href="http://www.ljf.scot.nhs.uk">www.ljf.scot.nhs.uk</a>
adalimumab 40mg/0.8mL solution for injection (Humira®) 09.05.16 1143/16	<b>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 5<sup>th</sup> October 2017.</b>  <i>Treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy.</i>  FC May 2017
adalimumab (Humira®) 40mg/0.4mL pre-filled syringe and pre-filled pen adalimumab (Humira®) 40mg/0.8mL vial for paediatric use 12.06.17 1243/17 PRODUCT UPDATE (abbreviated submission)	<b>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 5<sup>th</sup> October 2017.</b>  <i>Treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic HS therapy.</i>  FC May 2017
budesonide/formoterol 100micrograms/6micrograms and 200micrograms/6micrograms inhalation powder (Symbicort® SMART®) 12.06.17 1244/17 PRODUCT UPDATE (abbreviated submission)	<b>Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.</b>  <i>The regular treatment of asthma where use of a combination (inhaled corticosteroid and a long-acting β2 adrenoceptor agonist is appropriate: patients not adequately controlled with inhaled corticosteroids and “as needed” short-acting β2 adrenoceptor agonists, or patients already adequately controlled on both inhaled corticosteroids and long-acting β2 adrenoceptor agonists.</i>  FC May 2017
buprenorphine 2mg, 8mg oral lyophilisate (Espranor®) 12.06.17 1245/17 Patient Access Scheme PRODUCT UPDATE (abbreviated submission)	<b>Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.</b>  <i>Substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. Treatment with buprenorphine oral lyophilisate is intended for use in adults and adolescents aged 15 years or over who have agreed to be treated for addiction.</i>  <i>SMC restriction: to patients in whom methadone is not suitable.</i>  FC May 2017
calcipotriol 50micrograms/g and betamethasone 0.5g/g cutaneous foam (Enstilar®) 12.09.16 1182/16 PRODUCT UPDATE (abbreviated submission)	<b>Routinely available in line with national guidance. Included on the LJF as a prescribing note, for General Use.</b>  <i>As topical treatment of psoriasis vulgaris in adults.</i>  FC May 2017
daclizumab 150mg/mL solution for injection in prefilled syringe/pen (Zinbryta®) 10.04.17 1216/17 Patient Access Scheme	<b>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.</b>  <i>In adult patients for the treatment of relapsing forms of multiple sclerosis.</i>  <i>SMC restriction: for use</i> <ul style="list-style-type: none"> <li>• in patients with rapidly evolving severe (RES) relapsing remitting multiple sclerosis (RRMS) or</li> <li>• in patients with RRMS with an inadequate response to disease modifying therapy</li> </ul> FC May 2017
deferasirox 125, 250, 500mg dispersible tablets (Exjade®) 16.01.17 347/07 RESUBMISSION	<b>Routinely available in line with national guidance. Included on the Additional List, for specialist use only.</b>  <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 anaemia.</i>  FC May 2017



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Formulary Committee Recommendations Supplement to LPB Issue No. 86



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<b>deferasirox 90mg, 180mg and 360mg film-coated tablets (Exjade<sup>®</sup>)</b> 12.06.17 1246/17 PRODUCT UPDATE (abbreviated submission)	<p>Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.</p> <ul style="list-style-type: none"> <li>Treatment of chronic iron overload due to frequent blood transfusions (<math>\geq 7\text{mL/kg/month}</math> of packed red blood cells) in patients with beta thalassaemia major aged 6 years and older.</li> <li>Treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate in the following patient groups:               <ul style="list-style-type: none"> <li>in paediatric patients with beta thalassaemia major with iron overload due to frequent blood transfusions (<math>\geq 7\text{mL/kg/month}</math> of packed red blood cells) aged 2 to 5 years,</li> <li>in adult and paediatric patients with beta thalassaemia major with iron overload due to infrequent blood transfusions (<math>&lt; 7\text{mL/kg/month}</math> of packed red blood cells) aged 2 years and older,</li> <li>in adult and paediatric patients with other anaemias aged 2 years and older.</li> </ul> </li> </ul> <p>SMC restriction: deferasirox film-coated tablets are restricted to use as for the SMC advice issued for deferasirox dispersible tablets (No.347/07)</p> <p style="text-align: right;">FC May 2017</p>
<b>emtricitabine/tenofovir disoproxil 200mg/245mg film-coated tablets (Truvada<sup>®</sup>)</b> 10.04.17 1225/17	<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 5<sup>th</sup> October 2017.</p> <p><i>In combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in adults at high risk.</i></p> <p style="text-align: right;">FC May 2017</p>
<b>ibrutinib 140mg hard capsules (Imbruvica<sup>®</sup>)</b> 08.08.16 1151/16 Patient Access Scheme	<p>Included on the Additional List, Specialist Use only, for the indication in question: Treatment of adult patients with CLL and with 17p deletion or TP53 mutation, who are unsuitable for chemo-immunotherapy, in the first-line or relapsed setting.</p> <p><i>Treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy, or in first line in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy.</i></p> <p>SMC restriction: patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy.</p> <p style="text-align: right;">FC May 2017</p>
<b>idarucizumab 2.5g/50mL solution for injection/infusion (Praxbind<sup>®</sup>)</b> 12.09.16 1178/16	<p>Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only on advice of a Haematologist.</p> <p><i>As a specific reversal agent for dabigatran. It is indicated in adult patients treated with dabigatran etexilate when rapid reversal of its anticoagulant effects is required for emergency surgery/urgent procedures or in life-threatening or uncontrolled bleeding.</i></p> <p style="text-align: right;">FC May 2017</p>
<b>ixekizumab 80mg solution for injection (Taltz<sup>®</sup>)</b> 10.04.17 1223/17 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.</p> <p><i>For moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.</i></p> <p>SMC restriction: patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contra-indication to these treatments.</p> <p style="text-align: right;">FC May 2017</p>
<b>micronised progesterone vaginal capsules 200mg (Utrogestan<sup>®</sup>)</b> 08.05.17 935/13 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.</p> <p><i>In women for supplementation of the luteal phase during Assisted Reproductive Technology (ART) cycles.</i></p> <p style="text-align: right;">FC May 2017</p>
<b>nepafenac 3mg/mL eye drops, suspension (Nevanac<sup>®</sup>)</b> 11.05.17 1228/17 PRODUCT UPDATE (abbreviated submission)	<p>Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.</p> <p><i>Reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.</i></p> <p style="text-align: right;">FC May 2017</p>



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obinutuzumab 1,000mg concentrate for solution for infusion (Gazyvaro®) 13.03.17 1219/17 Patient Access Scheme	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.  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.  FC May 2017
trastuzumab emtansine 100mg and 160mg powder for concentrate for solution for infusion (Kadcyla®) 10.04.17 990/14 RESUBMISSION Patient Access Scheme	Routinely available in line with national guidance. Included on the Additional List, for Specialist Use only.  As a single agent, for the treatment of adult patients with human epidermal growth factor type 2 (HER2)-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either received prior therapy for locally advanced or metastatic disease, or developed disease recurrence during or within six months of completing adjuvant therapy.  FC May 2017
Zarzio filgrastim 300mcg and 480mcg pre-filled syringes  Local formulary process	Routinely available in line with local or regional guidance. Included on the LJF as a first choice, for Specialist initiation.  For primary or secondary prophylaxis of neutropenia; treatment of profound neutropenia associated with sepsis and mobilisation of autologous stem cells for transplants.  FC May 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
pregabalin Local formulary process  <i>For the treatment of persistent/chronic pain in children aged 12-18 years where first line treatments amitriptyline and gabapentin are not tolerated or in-effective.</i>	 For more details see <a href="http://www.ljf.scot.nhs.uk">www.ljf.scot.nhs.uk</a> Routinely available in line with local or regional guidance. Included on the Additional List, for Specialist Use only.  Categorised as <b>RED</b> under the ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian'.  FC May 2017
silver alginate dressing (Silvercel®) Systagenix Wound Management Ltd. Local formulary process  <i>Treatment of colonised and infected wounds in adult patients at the Spittal Street Centre (Substance Misuse Directorate).</i>	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.  FC May 2017

## 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 <a href="http://www.scottishmedicines.org.uk">www.scottishmedicines.org.uk</a>	NOT RECOMMENDED for this indication
alectinib hydrochloride (Alecensa®) 150mg hard capsules 08.05.17 257/17 NON SUBMISSION	Treatment of adult patients with anaplastic lymphoma kinase positive advanced non-small cell lung cancer previously treated with crizotinib.
ibrutinib (Imbruvica®) 140mg hard capsules 12.06.17 1258/17 NON SUBMISSION	In combination with bendamustine and rituximab for the treatment of adult patients with chronic lymphocytic leukaemia who have received at least one prior therapy.



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<b>liraglutide (Saxenda<sup>®</sup>) 6mg/mL solution for injection in pre-filled pen</b> 08.05.17 1247/17 NON SUBMISSION	<i>As an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index of</i> <ul style="list-style-type: none"> <li>• <math>\geq 30\text{kg/m}^2</math> (obese), or</li> </ul> <i><math>\geq 27\text{kg/m}^2</math> to <math>&lt; 30\text{kg/m}^2</math> (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.</i>
<b>pertuzumab 30mg/mL concentrate for solution for infusion (Perjeta<sup>®</sup>)</b> 12.06.17 897/13 2 <sup>nd</sup> RESUBMISSION	<i>For use in combination with trastuzumab and docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.</i>
<b>safinamide (Xadago<sup>®</sup>) 50mg/100mg film-coated tablets</b> 12.06.17 1259/17 NON SUBMISSION	<i>Treatment of adult patients with idiopathic Parkinson's disease (PD) as add-on therapy to a stable dose of Levodopa alone or in combination with other PD medicinal products in mid-to late-stage fluctuating patients.</i>
<b>talimogene laherparepvec (Imlygic<sup>®</sup>) 10<sup>8</sup> and 10<sup>8</sup> plaque forming units (PFU)/mL solution for injection</b> 08.05.17 1248/17 NON SUBMISSION	<i>Treatment of adults with unresectable melanoma that is regionally or distantly metastatic (Stage IIIB, IIIC and IVM1a) with no bone, brain, lung or other visceral disease.</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**