



Tayside DTC Supplement No 147 – April/May 2015

Produced by NHS Tayside Drug and Therapeutics Committee Medicines Advisory Group (MAG)

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Special Points of Interest for Primary Care

SMC Advice - April

- Acclidinium/formoterol fumarate dihydrate (Duaklir Genuair®)
- Fingolimod (Gilenya®)
- Infliximab (Inflectra®)
- Infliximab (Remsima®)
- Levonorgestrel (Jaydess®)
- Nintedanib (Vargatef®)
- Ponatinib (Iclusig®)
- Regorafenib (Stivarga®)
- Sucroferric oxyhydroxide (Velporo®)
- Tacrolimus (Envarsus®)



Specialist Lists - Progress

The General Surgery Specialist Formulary List is due to be discussed at the Medicines Advisory Group meeting in May.



Drug Safety Updates

Please follow link - [Drug Safety Update Download - April 2015](#)

SMC Advice issued in March 2015 (publication date 13th April 2015)

SMC website: www.scottishmedicines.org.uk

Medicine	Indication	Local recommendation category	Comments and useful links
Acclidinium/formoterol fumarate dihydrate 340/12 micrograms inhalation powder (Duaklir Genuair®) No. (1034/15) <i>Full submission</i>	Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease.	Formulary	SMC Advice SPC Link
Fingolimod 0.5mg hard capsules (Gilenya®) No. (1038/15) <i>Full submission</i>	A single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for the following adult patient groups: - Patients with high disease activity despite treatment with at least one disease modifying therapy.	Non-formulary absence of clinician demand Supplied via a Patient Access Scheme	SMC Advice SPC Link
Infliximab, 100mg, powder for concentrate for solution for infusion (Inflectra®) No. (1007/14) <i>Deferred submission</i>	Rheumatoid arthritis: in combination with methotrexate, for the reduction of signs and symptoms as well as improvement in physical function in: - adult patients with active disease when the response to disease-modifying antirheumatic drugs (DMARDs), including methotrexate has been inadequate; - adult patients with severe, active and progressive disease not previously treated with methotrexate or other DMARDs. Infliximab (Inflectra®) is also indicated in the following conditions: adult and paediatric Crohn's disease and ulcerative colitis; adult ankylosing spondylitis, psoriatic arthritis and psoriasis. SMC restriction: Infliximab (Inflectra®) is accepted for use in line with the current SMC and Healthcare Improvement Scotland advice for the reference product infliximab [Remicade®].	Hospital Use Only	SMC Advice SPC Link

Medicine	Indication	Local recommendation category	Comments and useful links
<p>Infliximab, 100mg, powder for concentrate for solution for infusion (Remsima®) No. (1006/14)</p> <p><i>Deferred submission</i></p>	<p>Rheumatoid arthritis: in combination with methotrexate, for the reduction of signs and symptoms as well as improvement in physical function in:</p> <ul style="list-style-type: none"> - adult patients with active disease when the response to disease-modifying antirheumatic drugs (DMARDs), including methotrexate has been inadequate; - adult patients with severe, active and progressive disease not previously treated with methotrexate or other DMARDs. <p>Infliximab (Remsima®) is also indicated in the following conditions: adult and paediatric Crohn's disease and ulcerative colitis; adult psoriatic arthritis, psoriasis and ankylosing spondylitis.¹</p> <p>SMC restriction: Infliximab (Remsima®) is accepted for use in line with the current SMC and Healthcare Improvement Scotland advice for the reference product infliximab [Remicade®].</p>	<p>Non-formulary absence of clinician demand</p>	<p>SMC Advice</p> <p>SPC Link</p>
<p>Levonorgestrel 13.5mg intrauterine delivery system (Jaydess®)</p> <p>No. (1036/15)</p> <p><i>Full submission</i></p>	<p>Contraception for up to 3 years.</p>	<p>Formulary - 2nd line choice</p>	<p>SMC Advice</p> <p>SPC Link</p>
<p>Nintedanib 100mg and 150mg soft capsules (Vargatef®)</p> <p>No. (1027/15)</p> <p><i>Full submission</i></p>	<p>In combination with docetaxel for the treatment of adult patients with locally advanced, metastatic or locally recurrent non-small cell lung cancer (NSCLC) of adenocarcinoma tumour histology after first-line chemotherapy.</p>	<p>Non Formulary - Absence of clinician demand</p> <p>Supplied via a Patient Access Scheme</p>	<p>SMC Advice</p> <p>SPC Link 100mg</p> <p>SPC Link 150mg</p>
<p>Ponatinib 15mg, 45mg film-coated tablets (Iclusig®)</p> <p>No. (1032/15)</p> <p><i>Full submission</i></p>	<p>Adult patients with:</p> <ul style="list-style-type: none"> - Chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation. - Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ALL) who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation. 	<p>Non Formulary - Absence of clinician demand</p>	<p>SMC Advice</p> <p>SPC Link</p>
<p>Regorafenib 40mg film-coated tablet (Stivarga®) No. (1031/15)</p> <p><i>Full submission</i></p>	<p>Treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumors (GIST) who progressed on or are intolerant to prior treatment with imatinib and sunitinib.</p>	<p>Non Formulary - Absence of clinician demand</p> <p>Supplied via a Patient Access Scheme</p>	<p>SMC Advice</p> <p>SPC Link</p>

Medicine	Indication	Local recommendation category	Comments and useful links
Sucroferric oxyhydroxide 500mg chewable tablets (Velphoro®) No. (1035/15) <i>Full submission</i>	For the control of serum phosphorus levels in adult chronic kidney disease (CKD) patients on haemodialysis (HD) or peritoneal dialysis (PD).	Non formulary - absence of clinician demand Pending further local discussions	SMC Advice SPC Link
Tacrolimus (as monohydrate) 0.75mg, 1mg and 4mg prolonged-release tablets (Envarsus®) No. (1041/15) <i>Abbreviated submission</i>	Prophylaxis of transplant rejection in adult kidney or liver allograft recipients and treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients.	Non formulary - absence of clinician demand This may change once a decision has been made by tertiary transplant centres	SMC Advice SPC Link 0.75mg SPC Link 1mg SPC Link 4mg

Updates from previous SMC Advice

Medicine	Indication	Local recommendation category	Comments and useful links
Nalmefene 18mg film-coated tablets (Selincro®) (917/13) - <i>Full submission</i>	<p>The reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL), without physical withdrawal symptoms and who do not require immediate detoxification.</p> <p>Nalmefene should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption.</p> <p>Nalmefene should be initiated only in patients who continue to have a high DRL two weeks after initial assessment.</p>	Formulary GPs should sign post patients to appropriate services offering psychosocial support, such as: Tayside Council on Alcohol (TCA) Addaction (Dundee) Dundee Drug, Alcohol & Blood Borne Virus (BBV) team Perth & Kinross Alcohol & Drug Team Angus Alcohol & Drug Partnership (ADP)	SMC advice SPC link

* 'pending' means that no local recommendation to support use is in place at the current time

Local processes exist to allow prescribing of non-SMC approved medicines for individual patients and are available in the [NHS Tayside Policy on the Prescribing of Medicines that are Non-formulary \(including Individual Patient Treatment Requests\)](#).

Tayside Area Formulary (TAF) Updates - Apr/May 2015

TAF Section	Drug(s)/topic	Changes
03.01.04	Compound bronchodilator preparations	Acclidinium/formoterol fumarate dihydrate 340/12 micrograms inhalation powder (Duaklir Genuair [®] ▼) added to formulary as a combined (long-acting beta ₂ agonist) LABA/(long-acting muscarinic antagonist) LAMA option for use in management of COPD. See SMC advice on page 1. Indacaterol/glycopyrronium (Ultibro [®] Breezhaler▼) changed from first choice LABA/LAMA combination inhaler to standard formulary as choice of combined LABA/LAMA also depends on individual inhalers prescribed previously.
04.01.02	Benzodiazepines	Link to Tayside guidelines for management of delirium in adults and older in-patients replaced with new guideline - The Diagnosis and Management of Delirium in adults and older people, December 2014 within the oral lorazepam entry.
04.02.01	Antipsychotic Drugs	Link to Tayside guidelines for management of delirium in adults and older in-patients replaced with new guideline - The Diagnosis and Management of Delirium in adults and older people, December 2014 within sub-section links, oral haloperidol entry and quetiapine entry.
04.10.01	Alcohol dependence	Nalmefene 18mg film-coated tablets (Selincro [®]) added to formulary (Green traffic light) as per SMC advice, see page 3. Links to local agencies offering psychosocial support added, see also page 3. Links to the following NICE guidance added: NICE Pathways Alcohol-use disorders, June 2014 ; NICE CG115 Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence, Feb 2011 ; and NICE CG100 Alcohol-use disorders: diagnosis and clinical management of alcohol-related physical complications, June 2010 . Naltrexone tablets added to formulary (Amber traffic light) as an intervention for moderate/severe alcohol dependence in line with the NICE pathway .
05.01.13	Antibiotics	Fosfomycin 40mg/mL powder for solution for intravenous infusion (Fomicyt [®]) added to formulary as Hospital-Only (Red traffic light) and added to Alert Antibiotic List - on Infectious Diseases/ Microbiology recommendation only.
05.03.03.02 Gastroenterology Specialist Formulary List	Chronic hepatitis C	Ledipasvir/sofosbuvir 90mg/400mg tablets (Harvoni [®] ▼) added to formulary (Hospital-Only, Red traffic light) and Gastroenterology Specialist Formulary List for treatment of chronic hepatitis C in adult patients, restricted to genotype 1 and 4 chronic hepatitis C.
07.03.02.03	Intra-uterine progestogen-only contraceptives	Levonorgestrel 13.5mg intrauterine delivery system (Jaydess [®] ▼) added to formulary (Green traffic light) as a second choice progestogen-only intra-uterine contraceptive. See SMC advice on page 2.
09.02	Fluids and electrolytes	Links to the following NHS Tayside policies added for information: NHS Tayside Food, Fluid and Nutritional Care Policy: Protocol for the assessment and management of hydration in adults, September 2014 NHS Tayside Food, Fluid and Nutritional Care Policy: Fluid Balance Monitoring, February 2015

SMC Briefing Note:

[Click here](#) for April Briefing Note

Forthcoming SMC Advice

This bulletin is produced by the Medicines Advisory Group (MAG), which is a sub-group of the NHS Tayside Drug and Therapeutics Committee.

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