

R TAYSIDE PRESCRIBER WHS



Tayside ADTC Supplement No 156 – September 2016

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

Special Points of Interest for **Primary Care**

SMC Advice - June:

Blinatumomab (Blincyto®)

Cabazitazel (Jevtana®)

Co-careldopa (Duodopa®)

Evolocumab (Repatha® PFS)

Febuxostat (Adenuric®)

Mepolizumab (Nucala®)

Naproxen (Stirlescent®)

SMC Advice - July:

Adalimumab (Humira®)

Afatainib (Giotrif®)

Azacitidine (Vidaza®)

Brivaracetam (Briviact®)

Crizotinib (Xalkori®)

Nivolumab (Opdivo®)

Ramucirumab (Cyrmaza®)

Secukinumab (Cosentyx®)

Vortioxetine (Brintellix®)

SMC Advice - August:

Alirocumab (Praluent®)

Diamorphine hydrochloride (Ayendi®)

Elotuzumab (Empliciti®)

Emtricitabine/tenofovir alafenamide (Descovy®)

Human alpha I-proteinase inhibitor (Respreeza®)

Ibrutinib (Imbruvica®)

Insulin degludec (Tresiba®)

Levofloxacin (Qunsair®)

Necitumumab (Portrazza®)

Nivolumab (Opdivo®)

Rilpivirine (Edurant®)

Secukinumab (Cosentyx®)



Drug Safety Updates

Please follow link - Drug Safety Updates 2016: June | July | August

Topical Miconazole, including Oral Gel: Reminder of **Potential for Serious Interactions with Warfarin**

The MHRA are concerned about reports of serious bleeding events, in some cases fatal, in patients taking miconazole (in particular, the oral gel) and warfarin and are considering further measures to minimise risk of potentially serious interactions between miconazole and warfarin.

Oral miconazole gel has recently been approved as formulary 1st line choice for oral thrush. It is also available on dental prescriptions or via community pharmacy (15g pack size is a Pharmacy, (P) medicine).

Nystatin may be a suitable alternative for oral thrush in patients on warfarin.

Reminder for Health Care Professionals:

- Miconazole, including the oral gel formulation, can enhance the anticoagulant effect of warfarin. If miconazole and warfarin are used concurrently, the anticoagulant effect should be carefully monitored and, if necessary, the dose of warfarin reduced.
- Patients should be advised to tell their doctor or pharmacist if they are receiving warfarin before using products that contain miconazole (including those available without prescription), and to seek medical advice if they notice signs of over anticoagulation during treatment, such as sudden unexplained bruising, nosebleeds or blood in the urine.

Absorption of miconazole from application to the skin or vaginally is minimal and clinically relevant reactions are rare for these products. However, there have been reports of increased INR and bleeding in patients on these preparations. Caution and careful monitoring of the INR is therefore advisable in patients using all available topical products containing miconazole in combination with warfarin.

Suspected drug interactions between miconazole and warfarin should be reported to the MHRA via the yellow card scheme directly or via your local medicines information centre (Tay-UHB.medinfo@nhs.net or 01382-632351).

See MHRA Drug Safety Update, Topical Miconazole, June 2016 for further information.

Inside this issue:		SMC Advice - issued June 2016	4
Drug Safety Updates	1	SMC Advice - issued July 2016	5-6
Guidelines and Protocols	2	Updates from previous SMC Advice	6
Specialist Lists Updates	2	TAF Updates	6-8
Information Technology	2	SMC Briefing Note	8
SMC Advice - issued May 2016	3	Forthcoming SMC Advice	8



Guidelines and Protocols

Melatonin Treatment Protocol

The treatment protocol on the use of melatonin for chronic sleep disturbance in children has been updated. The recommended first line formulation is now melatonin 2mg prolonged release tablets (Circadin® brand). However, it can be crushed and mixed with water/juice/food to provide an immediate-release formulation in children who are unable to swallow the tablet whole. The crushed tablets can also be administered via NG/gastrostomy tubes. Patients who are currently established on other brands of melatonin should not be switched to Circadin® unless on the advice of a specialist. Parents/carers should be given a copy of the melatonin information sheet by the initiating specialist.

CLICK HERE for a copy of the Melatonin Treatment Protocol and Patient Information Leaflet.



Specialist List Updates

Endocrinology Specialist Formulary List

The Endocrinology specialist formulary list and relevant formulary sections have been reviewed including hypoglycaemic agents for type 2 diabetes mellitus, anti-thyroid drugs, corticosteroids, and medicines used in the management and prevention of osteoporosis. Updates include: addition of prescribing information on hypoglycaemic agents and addition of prescribing information in line with SIGN 142 Management of osteoporosis and the prevention of fragility fractures, March 2015 to support prescribers and formulary users. For further information on the changes, see the TAF Update table on pages 6-8.

The Medicine for the Elderly Osteoporosis algorithm has been undergoing review and is due to be updated once approved.

The ENT specialist formulary list has also been undergoing review.



Information Technology

Medusa (Injectable Medicines Guide)

The Injectable Medicines Guide website contains monographs which give information on medicines given by IV injection/infusion in adults and includes separate monographs for paediatrics as well as individual monographs for IM injections. Each monograph describes the preparation, administration, compatibility, characteristics and storage of a given medicine. Monographs include links to the British National Formulary (BNF), the Summary of Product Characteristics (SPC) and the Patient Information Leaflet (PIL) if available. The website is restricted to use by NHS organisations who either contribute to monograph development or subscribe to the site.

A link has been added to Medusa from the home page of the Tayside Area Formulary and is only accessible from NHS Tayside computers.

BNF and BNFC Apps on Apple iOS Devices

A fault on the BNF and BNFC apps has been detected affecting some Apple iOS devices. A small amount of content may be out of date. Please delete the app and reinstall it from the App store. Android devices and all online web versions of the BNF are unaffected.

Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
Blinatumomab, 38.5 micrograms powder for concentrate and solution for solution for infusion (Blincyto®) SMC No. 1145/16 Full submission Accepted	The treatment of adults with Philadelphia chromosome negative relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL).	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. (Link to Formulary).	SMC link SPC link
Cabazitazel 60mg concentrate and solvent for solution for infusion (Jevtana®) SMC No 735/11 Resubmission under end of life process Not recommended	In combination with prednisone or prednisolone is indicated for the treatment of patients with hormone refractory metastatic prostrate cancer previously treated with docetaxel containing regimen.	Not available as not recommended for use in NHS Scotland	SMC link
Co-careldopa (levodopa 20mg/ml and carbidopa monohydrate 5mg/ml) intestinal gel (Duodopa®) SMC No 316/06 Resubmission under orphan process Accepted restricted under orphan process with PAS	Treatment of advanced levodopa responsive Parkinsons disease with severe motor fluctuations and hyper dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results. Restriction: for use in patients not eligible for deep brain stimulation.	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. (Link to Formulary)	SMC link SPC link
Evolocumab 140mg, solution for injection in pre-filled pen (Repatha® Sureclick) or pre-filled syringe (Repatha® PFS) SMC No 1148/16 Full Submission Not recommended	In adults with primary hypercholesterolaemia (heterozygous familial hypercholesterolaemia and non-familial) or mixed dyslipidaemia, as an adjunct to diet.	Not available as not recommended for use in NHS Scotland	SMC link
Febuxostat 120mg film-coated tablet (Adenuric®) SMC No 1153/16 Full submission Accepted restricted	The prevention and treatment of hyperuricaemia in adult patients undergoing chemotherapy for haematologic malignancies at intermediate to high risk of Tumour Lysis Syndrome (TLS). Restriction: prevention of hyperurucaemia in adult patients at intermediate risk of TLS in whom allopurinol is either unsuitable or contraindicated, such as those intolerant of allopurinol or those on whom allopurinol is contraindicated e.g. patients with renal impairment.	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. (Link to Formulary)	SMC link SPC link
Mepolizumab 100mg powder for solution for injection (Nucala®) SMC No 1149/16 Full submission Accepted restricted with PAS	As an add-on treatment for severe refractory eosinophilic asthma in adult patients.	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. (Link to Formulary)	SMC link SPC link
Naproxen 250mg effervescent tablets (Stirlescent®) SMC No 1154/16 Abbreviated submission Accepted restricted	Treatment of rheumatoid arthrirtis, osteoarthritis, ankylosing spondilytis, acute muskulo-skeletal disorders, dysmenorrhoea and acute gout in adults. Restriction: use in patients unable to swallow naproxen tablets	Available in line with National Guidance	SMC link SPC link

Local processes exist to allow prescribing of non-SMC approved medicines for individual patients and are available in the NHS Tayside Policy on the New Treatment Requests).

Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
Adalimumab 40mg/0.8ml solution for injection (Humira®) SMC 1173/16 In the absence of a submission Not recommended	Treatment of moderate to severe chronic plaque psoriasis on adult patients who are candidates for systemic therapy. (This licence extension relates to previous SMC advice 468/08).	Not available as not recommended for use in NHS Scotland	SMC link
Afatainib 20mg/20mg/40mg/50mg film-coated tablets (Giotrif®) SMC 1174/16 In the absence of a submission Not recommended	As monotherapy for the treatment of locally advanced or metastatic non small cell lung cancer of aquamous histology progressing on or after platinum based chemotherapy.	Not available as not recommended for use in NHS Scotland	SMC link
Azacitidine 25mg/ml powder for suspension for injection (Vidaza®) SMC 1175/16 In the absence of a submission Not recommended	Treatment of adult patients aged 65 years or older who are not eligible for haematopoietic stems cell transplantation (HSCT) with acute myeloid leukaemia (AML with >30% marrow blasts according to World Health Organisation classification).	Not available as not recommended for use in NHS Scotland	SMC link
Brivaracetam 10mg, 25mg, 75mg, 100mg film coated tablets; 10mg/ml oral solution; 10mg solution for injection/infusion (Briviact®) SMC 1160/16 Full submission Accepted Restricted	Adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy. Restriction: for use in patients with refractory epilepsy and treatment should be initiated by physicians who have appropriate experience in the treatment of epilepsy.	Not Routinely available as local implementation plans are being developed or the ADTC is waiting further advice from local clinical experts- decision expected by September 2016	SMC link SPC links: 10 mg/ml oral sol 10 mg/ml sol for injection/infusion film-coated tablets
Crizotinib 200mg and 250mg hard capsule (Xalkori®) SMC NO 1152/16 Full submission under end of life and ultra-orphan process Accepted with PAS	First line treatment of adults with anaplastic lymphoma kinase (ALK)-positive advanced non small cell lung cancer.	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. (Link to Formulary)	SMC link SPC link
Nivolumab 40mg/ml and 100mg/ml vials of concentrate for solution for infusion (Opdivo®) SMC 1144/16 Submission under end of life process Accepted with PAS	Treatment of locally advanced or metastatic squamous non small cell lung cancer after prior chemotherapy in adults.	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 (Link to Formulary).	SMC link SPC link
Ramucirumab 10mg/ml concentrate for solution for infusion (Cyramza®) SMC 1176/16 In the absence of a submission Not recommended	In combination with paclitaxel for the treatment of adults patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy. As monotherapy for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum or fluoropyramidine chemo-therapy, for whom treatment in combination with paclitaxel is not appropriate.	Not available as not recommended for use in NHS Scotland	SMC link
Secukinumab 150mg prefilled syringe, 150mg pre-filled pen (Cosentyx®) SMC 1159/16 Full submission Accepted with PAS	Treatment of active ankylosing spondilytis (AS) in adults who have responded inadequately to conventional therapy.	Available in line with national guidance Hospital Only (Rehumatology Clinic)	SMC link SPC link
Vortioxetine 5mg, 10mg, 20mg film- coated tablet (Brintellix®) SMC 1158/16 Full submission Accepted Restricted	Treatment of major depressive episodes in adults. 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.	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 (Link to Formulary)	SMC link SPC link

Autocard Sing and 150mp; solution Comments and Occide Links	Olifo Advice issued in odly 2010	(publication date 8 August 2010) Sinc	website. <u>www.scottisiii</u>	icaionics.org.uk
Security	Medicine	Condition Being Treated		
clinic in patients with heterozygous familial hypercholestreolunia (HeHr) AND either: • LDL-C > 5.0mmol/L for primary prevention of cardiovascular events OR, • LDL-C > 5.0mmol/L for primary prevention of cardiovascular events OR, • LDL-C > 5.0mmol/L for primary prevention of cardiovascular events OR, • LDL-C > 5.0mmol/L for primary prevention of cardiovascular events OR, • LDL-C > 5.0mmol/L for primary prevention of cardiovascular events Teraament of acute severe nociceptive pain in children and adolescents in a hospital setting. Diamorphone hydro-children axal strays hould be administrated in the administration of popiolis in children with appropriate or concentrate for solution for infusion (Emplicities) Flouzumab 300mg and 400mg powder for concentrate for solution for infusion (Emplicities) FMC 1183/16 Absence of a submission Not recommended In combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35kg) infected with human immunodeficiency virus type I Human alpha I-proteinase inhibitor (Obcercoy/®) FMC 1187/16 Full submission under end of life and ultra orphan medicines process Accepted or submission or protein the protein of the protein process or protein protein process and protein process and coller with obox and protein process and protei	for injection in prefilled pen (Praluent®) SMC 1147/16 Full submission with PAS	familial and non familial) or mixed dyslipidaemia, as an adjunct to diet: in combination with a statin and other lipid lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of statin or, alone or in combination with other lipid lowering therapies in patients who are statin intolerant or for whom a statin is	guidance for prescribing	
Diamorphine hydrochloride 720 microgram/actuation and 1600 microgram/actua		clinic in patients with heterozygous familial hypercholesterolaemia (HeFH) AND either:		
gazmiactuation and 1600 microgram/ actuation said spray (Ayendré) hydro-chloride said sprays should be administrated in the amergency setting by practitioners experienced in the administration of opioids in children with appropriate monitoring. Elouzumab 300mg and 400mg powder for concentrate for solution for infusion (Emplicité) monitoring. Treatment of multiple myeloma in combination with lealidomide and dexamethasone in adult patient who have received at least one prior therapy. SMC 1183/16 Absence of a submission Not recommended In combination with other antiretroviral agents for the extension addies with body weight at least 35kg) infected with human immunodeficiency virus type 1 Human alphal-proteinase inhibitor (A1-PI) deficiency. SMC 1187/16 Human alphal-proteinase inhibitor of or infusion (Respreeza®) SMC 1157/16 Elousumison under orphan equivalent process SMC 1151/16 Full submission under end of life and ultra orphan medicines process Accepted with PAS. Brutinib 140mg hard capsule for MCL (Imbruvica®) Treatment of patients with relapsed or refractory mande dura orphan medicines process Accepted with PAS. Treatment of patients with relapsed or refractory mande colinical experts do not wish to add the medicine to the formulary at this time or there for all this orbital experts do not wish to add the medicine to the formulary at this time or there for a local preference for alternative medicines process Accepted with PAS. Treatment of patients with relapsed or refractory mande colinical experts do not wish to add the medicine process a local preference for alternative medicines process Accepted with PAS. Treatment of patients with relapsed or refractory mande colinical experts do not wish to add		cardiovascular events OR, • LDL-C ≥ 3.5mmol/L, for secondary prevention		
lealdomide and dexamethasone in adult patient who have received at least one prior therapy.	gram/actuation and 1600 microgram/ actuation nasal spray (Ayendi®) SMC 1172/16 Abbreviated submission	adolescents in a hospital setting. Diamorphone hydro-chloride nasal spray should be administered in the emergency setting by practitioners experienced in the administration of opioids in children with appropriate	implementation plans are being developed or the ADTC is waiting further advice from local clinical experts - decision	SPC links: 720 microgram
Absence of a submission Not recommended Emtricitabine/tenofovir alafenamide 200mg/25mg, 200mg/10mg film coated (Descoy®). In combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with human immunodeficiency virus type 1 SMC 1169/16 Abbreviated Submission Accepted Human alphal-proteinase inhibitor 1,000mg powder and solvent for solution for infusion (Respreeza®) and 1-proteinase inhibitor (A1-P1) deficiency. SMC 1157/16 Full submission under orphan equivalent process Not recommended Ibrutinib 140mg hard capsule for CLL (Imbruvica®) and the analysis of the and ultra orphan medicines process Accepted restricted with PAS. BYC Restriction: patients with relapsed or refractory mante cell lymphoma Treatment of adult patients with relapsed or refractory mante cell lymphoma Treatment of patients with relapsed or refractory mante cell lymphoma The treatment of diabetes mellitus in adults in adults in prefilled pen or cartridge and 200units/ml solution for injection in prefilled pen or cartridge and 200units/ml solution for injection in prefilled pen or cartridge and 200units/ml solution for injection in prefilled pen or cartridge and 200units/ml solution for injection in prefilled pen or cartridge and 200units/ml solution for injection in prefilled pen or cartridge and 200units/ml solution for injection in prefilled pen or cartridge and 200units/ml solution for injection in prefilled pen or cartridge and 200units/ml solution for injection in prefilled pen or cartridge and 200units/ml solution for injection in prefilled pen or cartridge and 200units/ml solution for injection in prefilled pen or cartridge and 200units/ml solution for injection in prefilled pen or cartridge and 200units/ml solution for injection in prefilled pen or cartridge and 200units/ml solution for injection in prefiled pen or cartridge and 200units/ml solution for injection in prefiled pen or cartridge and 200units/ml solution for injection in prefiled pen or cartridge and 200units/m	for concentrate for solution for infusion	lealidomide and dexamethasone in adult patient who have	recommended for use in NHS	SMC link
200mg/15mg, 200mg/10mg film coated (Descovy®) 200mg/15mg and adolescents (aged 12 years and older with body weight at least 35kg) infected with human immunodeficiency virus type 1 200mg/10mg 200mg/10mg/10mg/10mg/10mg/10mg/10mg/10mg/	Absence of a submission			
Abbreviated Submission Accepted Human alphal-proteinase inhibitor 1,000mg powder and solvent for solution for infusion (Respreeza®) SMC 1157/16 Full submission under orphan equivalent process Not recommended Ibrutinib 140mg hard capsule for CLL (Imbruvica®) SMC 1151/16 Full submission under end of life and ultra orphan medicines process Accepted restricted with PAS. Ibrutinib 140mg hard capsule for MCL (Imbruvica®) SMC estriction: patients with relapsed or refractory mantle cell lymphoma Treatment of diabetes mellitus in adults Treatment of diabetes mellitus in adults SMC ink SMC ink SMC link SMC li	200mg/25mg, 200mg/10mg film coated (Descovy®)	treatment of adults and adolescents (aged 12 years and older with body weight at least 35kg) infected with human		SPC links: 200mg/25mg
I,000mg powder and solvent for solution for infusion (Respreeza®) SMC 1157/16 Full submission under orphan equivalent process Not recommended Ibrutinib 140mg hard capsule for CLL (Imbruvica®) Full submission under end of life and ultra orphan medicines process Accepted restricted with PAS. Ibrutinib 140mg hard capsule for MCL (Imbruvica®) Ibrutinib 140mg hard capsule for CLL (Imbruvica®) SMC 1151/16 Full submission under end of life and ultra orphan medicines process Accepted restricted with PAS. Ibrutinib 140mg hard capsule for MCL (Imbruvica®) Ibrutini	Abbreviated Submission			
Full submission under orphan equivalent process Not recommended Ibrutinib 140mg hard capsule for CLL (Imbruvica®)	1,000mg powder and solvent for solution	emphysema in adults with documented severe alpha	recommended for use in NHS	SMC link
Ieukaemia (CLL) who have received at least one prior therapy, or first line in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemotherapy. SMC 1151/16	Full submission under orphan equivalent process			
Full submission under end of life and ultra orphan medicines process Accepted restricted with PAS. Ibrutinib 140mg hard capsule for MCL (Imbruvica®) Ibrutinib 140mg hard capsule for MCL (Imbruvica®) SMC Restriction: patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy. Treatment of patients with relapsed or refractory mantle cell lymphoma Treatment of patients with relapsed or refractory mantle cell lymphoma 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 (Link to Formulary) Insulin degludec 100 units/ml solution for injection in prefilled pen or cartridge and 200 units/ml solution for injection in prefilled pen (Tresiba®) The treatment of diabetes mellitus in adults SMC link SPC links: 100 units/ml solution in prefilled pen (Tresiba®)	(Imbruvica®)	leukaemia (CLL) who have received at least one prior therapy, or first line in the presence of 17p deletion or	clinical experts do not wish to add the medicine to the	
(Imbruvica®) cell lymphoma clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (Link to Formulary) Insulin degludec 100 units/ml solution for injection in prefilled pen (Tresiba®) Clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines (Link to Formulary) Available in line with local guidance for prescribing (Link to Formulary) Insulin degludec 100 units/ml solution for injection in prefilled pen (Tresiba®)	Full submission under end of life and ultra orphan medicines process	SMC Restriction: patients with 17p deletion or TP53	is a local preference for alternative medicines	
SMC 1150/16 Full submission under end of life and ultra orphan medicines process Accepted with PAS Insulin degludec 100 units/ml solution for injection in prefilled pen (Tresiba®) The treatment of diabetes mellitus in adults The treatment of diabetes mellitus in adults Available in line with local guidance for prescribing (Link to Formulary) SMC link SPC links: 100 units/ml solution in prefilled pen (Tresiba®)			clinical experts do not wish to	
injection in prefilled pen or cartridge and 200units/ml solution for injection in prefilled pen (Tresiba®) guidance for prescribing (Link to Formulary) Link to Formulary) in prefilled pen	Full submission under end of life and ultra orphan medicines process		formulary at this time or there is a local preference for alternative medicines	
	injection in prefilled pen or cartridge and 200units/ml solution for injection in prefilled pen (Tresiba®)	The treatment of diabetes mellitus in adults	guidance for prescribing	SPC links: 100units/ml solution in prefilled pen 100units/ml solution
SMC 856/13 Second resubmission Accepted in cartridge 200units/ml solution in prefilled pen	Second resubmission			200units/ml solution

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).

Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
Levofloxacin 240mg nebuliser solution (Quinsair®) SMC 1162/16 Full submission under orphan equivalent process Accepted restricted	The management of chronic pulmonary infections due to psudomonas aeruginosa in adult patients with cystic fibrosis Restriction: for use as a third line treatment option after colisimethate sodium (first line) and tobramycin (second line)	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 (Link to Formulary)	SMC link SPC link
Necitumumab 800mg concentrate for solution for infusion (Portrazza®) SMC 1184/16 Absence of a submission Not recommended	In combination with gembitabine and cisplatin chemotherapy for the treatment of adult patients with locally advanced metastatic epidermal growth factor receptor (AGFR) expressing squamous non small cell lung cancer who have not received prior chemotherapy for this condition	Not available as not recommended for use in NHS Scotland	SMC link
Nivolumab 10mg/ml concentrate solution for infusion (Opdivo®) SMC 1120/16 Resubmission assessed under end of life and orphan medicine process Accepted restricted	As monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. Restriction: patients previously treated with ipilimumab	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 (Link to Formulary)	SMC link SPC link
Rilpivirine 25mg film-coated tablet (Edurant®) SMC 1168/16 Abbreviated submission Accepted	in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus type I (HIVI) infection in antiretroviral treatment naïve patients aged12 to 18 years of age and older with a viral load (VL)≤ 100,000 HIV-IRNA copies/mI	Available from a specialist Centre in another Board	SMC link
Secukinumab 150mg prefilled syringe, 150mg pre-filled pen (Cosentyx®) SMC 1167/16 Full submission Accepted Restricted	Alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adult patients when the response to previous disease modifying antirheimatic drug (DMARD) therapy has been inadequate. Restriction: Use in patients whose disease has not responded to adequate trials of at least two standard DMARDs either individually or in combination.	Available in line with national guidance	SMC link SPC link

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

Updates from previous SMC Advice - No updates this month



Tayside Area Formulary (TAF) Updates - August 2016

Medicines within the Tayside Area Formulary are intended to guide choice on a rational selection of medicines for **adults** which have been included on the basis of clinical efficacy, safety, patient acceptability and cost-effectiveness.

TAF Section	Drug(s)/Topic	Changes	
01.03.03	Chelates and complexes	De-Noltab® (Tripotassium Dicitratobismuthate) – no longer formulary as discontinued (Dec 2015).	
		Sucralfate tablet formulation added to formulary and <u>Gastroenterology specialist formulary list</u> as unlicensed sucralfate tablets are currently being used due to ongoing supply problems with licensed sucralfate liquid and tablets. Note added that there is a long term supply problem with sucralfate liquid and tablets and that unlicensed preparations are available.	
02.04	Beta-adrenoceptor blocking drugs	Nadolol tablets discontinued – unlicensed preparation available. Now non-formulary and unlicensed with note added – may only be used under the direction of Cardiology in patients with prolonged QT interval.	
		Propranolol – note added – adjunct for thyrotoxicosis (replaces nadolol for this indication) (M/R capsules preferred as less frequent dosing required).	
02.05.05.02	Angiotensin - II receptor antagonists	Link to <u>Sacubitril/Valsartan (Entresto) Prescribing Checklist and General Practice Information Sheet</u> added to sacubitril/valsartan formulary entry.	
02.12	Other lipid modifying agents	Alirocumab 75mg and 150mg solution for injection in prefilled pen (Praluent®) – added to formulary and Cardiology specialist formulary list as Amber traffic light for use under the direction of the Cardiovascular risk clinic (restricted use). See SMC advice on page 5.	

Cont./...



Tayside Area Formulary (TAF) Updates - August 2016

TAF Section	Drug(s)/Topic	Changes
<u>04.03.04</u>	Other antidepressant drugs	Vortioxetine 5mg, 10mg, 20mg film-coated tablet (Brintellix®) added as non-formulary. See SMC advice on page 4.
04.09.01	Levodopa	Co-careldopa (levodopa 20mg/ml and carbidopa monohydrate 5mg/ml) intestinal gel (Duodopa®) – Black traffic light removed, remains non-formulary. See SMC advice on page 3.
<u>05.01.12</u>	Quinolones	Levofloxacin 240mg nebuliser solution (Qunsair®) – added as non-formulary. See SMC advice on page 5.
05.03.01	HIV Infection	Emtricitabine/tenofovir alafenamide 200mg/25mg, 200mg/10mg film coated (Descovy®) – added to formulary as Red traffic light (Hospital Only) for prescribing by HIV clinic only. See SMC advice on page 5.
Chapter 6	Endocrine system	Links to Society for Endocrinology website added and 'You and your hormones' website (for patient information) added as Chapter links. Links to SIGN 116: Management of Diabetes March 2010 removed and replaced with links to NICE CG28 Type 2 diabetes in adults: management, Dec 2015 throughout section 06.01.
06.01.01	Insulins	Insulins changed from Green to Amber traffic light in formulary and on Endocrinology specialist formulary list. Insulin degludec 100units/ml solution for injection in prefilled pen or cartridge and 200units/ml solution for injection in prefilled pen (Tresiba®) – now formulary, but not listed in formulary as all insulins are detailed within the Tayside Diabetes MCN Handbook. See SMC advice on page 5.
06.01.02.01	Biguanides	Prescribing information added to notes section, information on use in renal or hepatic impairment and advice on stopping metformin with a dehydrating illness added to metformin entry.
06.01.02.02	Sulphonylureas	Prescribing information added to notes section. Information on renal or hepatic impairment added to gliclazide and glipizide entries. Second choice added to glipizide entry.
		Glibenclamide changed to Amber traffic light as prescribing is for gestational diabetes which is under the direction of specialists.
06.01.02.04	Dipeptidylpeptidase-4 inhibitors	Prescribing information added to notes section, information on use in renal or hepatic impairment added to alogliptin, sitagliptin, alogliptin/metformin (Vipdomet®), and sitagliptin/metformin (Janumet®) entries. Advice on stopping with a dehydrating illness added to alogliptin/metformin (Vipdomet®) and sitagliptin/metformin (Janumet®) entries.
<u>06.01.02.05</u>	Glucagon-like peptide-l receptor agonists and Glucagon-like peptide-l receptor agonists - once weekly	Prescribing information added to notes section, information on use in renal or hepatic impairment added to liraglutide entry. Information on use in renal impairment added to lixisenatide, exenatide once weekly, and dulaglutide once weekly entries.
06.01.02.06	Sodium-glucose co-transporter 2 inhibitors	Prescribing information added to notes section, information on stopping empagliflozin/metformin (Synjardy®) and dapagliflozin/metformin (Xigduo®) with a dehydrating illness added to those entries.
	innoicors	Link to Tayside Diabetes MCN Patient Information Leaflet on the risk of diabetic ketoacidosis with SGLT2 inhibitors added to all SGLT2 inhibitor drug entries.
06.02.02	Antithyroid drugs	Carbimazole – Prescribing information on bone marrow suppression added. Propylthiouracil – changed from Green to Amber traffic light and added to endocrinology specialist formulary list due to cases of severe hepatic reactions being reported. Prescribing information on hepatic reactions and agranulocytosis added.
06.03.02	Glucocortcoid therapy	Addition of information on oral glucocorticoids and risk of fracture added as per SIGN 142 Management of osteoporosis and the prevention of fragility fractures, March 2015.
06.04.01.01	Oestrogens and HRT and Raloxifene	Addition of information on HRT, tibolone and raloxifene for prevention of fractures as per SIGN 142.
06.06	Drugs affecting bone metabolism	Links to NOGG (National Osteoporosis Guideline Group) replaced with links to SIGN 142.
06.06.01	Calcitonin and parathyroid hormone	Parathyroid hormone (Preotact®) removed as discontinued. Local treatment protocol for parathyroid hormone updated to Local treatment protocol for teriparatide only.
06.06.02	Bisphosphonates and other drugs affecting bone metabolism	Link to MHRA Drug Safety Update – Bisphosponates: very rare reports of osteonecrosis of the external auditory canal, Dec 2015 added.
		Local treatment protocol for denosumab reviewed and updated.

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Tayside Area Formulary (TAF) Updates - August 2016

TAF Section	Drug(s)/Topic	Changes
07.04.02	Urinary incontinence	Oxybutynin elixir has been discontinued (January 2016) note added to entry and elixir formulation removed from formulary.
		Mirabegron M/R tablets - updated to Green traffic light as suitable for initiating in primary care. Information added on use in renal or hepatic impairment.
08.03.04.03	Somatostatin analogues	Link to Tayside Treatment Protocol for use of Somatostatin analogues in neuroendocrine and pituitary tumours updated to reviewed and updated version.
10.01.01	Non-steroidal anti-inflammatory drugs	naproxen 250mg effervescent tablets (Stirlescent®) (new formulation) – added to formulary for use in patients unable to swallow naproxen tablets.
		Dexibuprofen – note added that this non-formulary medicine has been discontinued (Feb 16).
10.01.03	Cytokine modulators	Secukinumab 150mg prefilled syringe, 150mg pre-filled pen (Cosentyx®) - added to formulary and Rheumatology specialist formulary list (Hospital Only):
		as first line biological treatment for active ankylosing spondilytis (AS) in adults who have responded inadequately to conventional therapy
		 as first line alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adult patients when the response to previous disease modifying anti-rheumatic drug (DMARD) therapy has been inadequate restricted to those patients for whom anti-TNF therapy is contra-indicated and in whom the 150mg dose is indicated, otherwise second line after failure or inadequate response to anti-TNF therapy.
10.01.04	Long-term control of gout	Febuxostat 120mg film-coated tablet (Adenuric®) (indication: the prevention and treatment of hyperuricaemia in adult patients undergoing chemotherapy for haematologic malignancies at intermediate to high risk of Tumour Lysis Syndrome (TLS)) – note added - non-formulary for this indication (120mg tablets only are licensed for this indication).
11.03.02	Antifungals	Miconazole eye drops (unlicensed) - Link to DTC supplement for article (see page I) on topical miconazole, including oral gel: reminder of potential for serious interactions with warfarin and prescribing note on this added.
12.03.02	Oropharyngeal Fungal infections	Miconazole (Daktarin®) oral gel - Link to DTC supplement for article (see page I) on topical miconazole, including oral gel: reminder of potential for serious interactions with warfarin and prescribing note on this added.
13.02.01	Creams/gels (Emollients)	Diprobase® cream replaced with Zerobase® cream as this is more cost-effective (also available as 500g pump dispenser)
13.04.01	Topical corticosteroids – Compound preparations – with antimicrobials (Potency: Mild)	Hydrocortisone 1% with miconazole Nitrate 2% (Daktacort®) cream, ointment – Link to DTC supplement article (see page 1) on topical miconazole, including oral gel: reminder of potential for serious interactions with warfarin and prescribing note on this added.
13.10.02	Antifungal preparations	Miconazole 2% cream - Link to DTC supplement article (see page 1) on topical miconazole, including oral gel: reminder of potential for serious interactions with warfarin and prescribing note on this added.
13.12	Hyperhidrosis	Aluminium salts (zeaSORB®) – discontinued September 2015. Non-formulary but note added.
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SMC Monthly Briefing Notes 2016

Forthcoming SMC Advice

Local implementation of SMC recommendations is taken forward by the Tayside Prescribing Support Unit (PSU). This bulletin is based on evidence available to Tayside PSU at time of publication and is covered by the Disclaimer and Terms & Conditions of Use.

<u>CLICK HERE</u> for access to the Medicines Governance section of the Pharmacy Staffnet site. 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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