



Special Points of Interest for Primary Care

- Statin Update (page 2)

SMC Advice - February:

- Abiraterone acetate (Zytiga®)
- Bosutinib (Bosulif®)
- Colestilan (BindRen®)
- Follitropin alfa (Bemfol®)
- Paclitaxel formulated as albumin bound nanoparticles (Abraxane®)
- Umeclidinium / vilanterol (Anoro®)

SMC Advice - March:

- Apixaban (Eliquis®)
- Cabozantinib (Cometriq®)
- Dabrafenib (Tafinlar®)
- Fosfomycin (Fomicyt®)
- Idelalisib (Zydelig®)
- Ledipasvir/sofosbuvir (Harvoni®)
- Ruxolitinib (as phosphate) (Jakavi®)

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Drug Safety Updates

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

Drug Driving

The Drug Driving (Specified Limits)(England and Wales) Regulations 2014 came into effect in England and Wales on 2nd March 2015. Similar legislation will be apply in Scotland, but the date on which it comes into effect has still to be set by the Scottish Parliament. It should be noted that patients may travel in England and Wales and be subject to the regulations at present. These regulations set maximum blood levels for several prescription medicines including diazepam, lorazepam, methadone, morphine, ketamine, and temazepam.

The BNF already specifies the cautionary labels recommended for inclusion with the dispensed medicine.

The BNF specifies that patients should be advised if the treatment is likely to affect their ability to drive (although it is not specified if this is the prescriber or pharmacist).

Further information is available using the links below:

Information for Healthcare Professionals:

<https://www.gov.uk/government/publications/drug-driving-and-medicine-advice-for-healthcare-professionals>

Information for patients:

<https://assets.digital.cabinet-office.gov.uk/media/5473080ee5274a1303000037/con437439.pdf>



Prescribing Changes

Emollient and Barrier Preparations and Sunscreens - Formulary Update

Sections [13.01 - Management of skin conditions](#), [13.02 - Emollient and barrier preparations](#) and [13.08.01 - Sunscreens](#) of Chapter 13: Skin within the Tayside Area Formulary have been reviewed and updated. These sections are now fully integrated into the netFormulary platform and their contents are therefore now searchable.

Emollient preparations have been listed in the formulary on the basis of cost and consensus of acceptability. See [Primary Care emollient price chart \(January 2015\)](#) for information.

See page 2 for further information on prescribing sunscreens.

Work is ongoing to review the remaining sections of Chapter 13. As sections are reviewed, they will be transferred over to the netFormulary platform.



Prescribing Changes

Sunscreen Prescribing - Reminder

Sunscreen preparations have been reviewed within the [Tayside Area Formulary](#). Formulary sunscreens are now in line with sunscreen preparations listed in the BNF.

Sunscreens can be useful to complement other photoprotection measures. Sunscreens included within the formulary are prescribable for skin protection in a range of abnormal photosensitivity disorders, including vitiligo, those resulting from radiotherapy, and chronic or recurrent herpes simplex labialis. Preparations with SPF less than 30 should not normally be prescribed.

Sunscreens are not prescribable on the NHS for those with skin cancers and 'pre-cancers' except when there is an underlying genetic disease such as xeroderma pigmentosum or albinism.

When prescribing sunscreens; endorse as ACBS (Advisory Committee on Borderline Substances).

Statin Update

Atorvastatin has now replaced simvastatin as first choice statin in the Tayside Area Formulary. This is in line with [NICE CG 181: Lipid modification: cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease \(July 2014\)](#).

NICE recommends using a high intensity statin with low acquisition cost for both primary and secondary prevention.

For primary prevention atorvastatin 20mg should be prescribed.

Atorvastatin has fewer drug interactions than simvastatin but is also metabolised by cytochrome P450 (CYP3A4) system and temporary withdrawal of statin should be considered if prescribing strong CYP3A4 inhibitors for short time periods.

Please see page 2 of [Tayside Prescriber](#) (2012) and [SPC](#) for further information.

Simvastatin will remain as 2nd formulary choice for patients already stable on simvastatin.

High dose simvastatin 80mg has an increased risk of myopathy and should not be prescribed. See [Drug Safety Update May 2010](#) for further information. **Simvastatin 80mg is non formulary in NHS Tayside.**

Medicine	Indication	Local Recommendation Category	Comments and Useful Links
Abiraterone acetate, 250mg tablets (Zytiga®) (873/13) - Full submission	With prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.	Not recommended	SMC advice
Bosutinib 100mg, 500mg film-coated tablets (Bosulif®) (910/13) - Resubmission considered under the ultra-orphan medicine process	Treatment of adult patients with chronic phase (CP), accelerated phase (AP), and blast phase (BP) Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+ CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.	Non Formulary - absence of clinician demand Supplied via a Patient Access Scheme	SMC advice SPC link
Colestilan 1g film-coated tablets, 2g and 3g granules sachets (BindRen®) (939/14) - Following an Independent Review Panel	Treatment of hyperphosphataemia in adult patients with chronic kidney disease (CKD) stage 5 receiving haemodialysis or peritoneal dialysis.	Not recommended	SMC advice
Follitropin alfa 75 units, 150 units, 225 units, 300 units, 450 units pre-filled pen for subcutaneous injection (Bemfola®) (1025/15) - Full submission	In adult women for: <ul style="list-style-type: none"> anovulation (including polycystic ovarian syndrome) in women who have been unresponsive to treatment with clomiphene citrate. stimulation of multi-follicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilisation (IVF), gamete intra-fallopian transfer and zygote intra-fallopian transfer. in association with a luteinising hormone (LH) preparation for the stimulation of follicular development in women with severe LH and follicle-stimulating hormone (FSH) deficiency. In clinical trials these patients were defined by an endogenous serum LH level <1.2 units/L. 	HOSPITAL ONLY - (Assisted Conception Unit) Obstetrics & Gynaecology Specialist List	SMC advice SPC link
Paclitaxel formulated as albumin bound nanoparticles 5mg/mL powder for suspension for infusion (Abraxane®) (968/14) - Resubmission considered under the end of life / orphan medicine process	In combination with gemcitabine for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas.	Non Formulary - absence of clinician demand	SMC advice SPC link
Umeclidinium / vilanterol, 55/22 micrograms, inhalation powder (Anoro®) (978/14) - Resubmission	As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease.	Non Formulary - lack of clinician demand	SMC advice SPC link

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

Medicine	Indication	Local Recommendation Category	Comments and Useful Links
Apixaban, 2.5mg & 5mg, film-coated tablets (Eliquis [®]) (1029/15) - Full submission	Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of recurrent DVT and PE in adults.	Formulary - Amber 2nd line choice for DVT/PE as an alternative to rivaroxaban	SMC advice SPC link (2.5mg) SPC link (5mg)
Cabozantinib 20mg and 80mg hard capsules (Cometriq [®]) (1022/15) - Full submission	For the treatment of adult patients with progressive, unresectable locally advanced or metastatic medullary thyroid carcinoma.	Not recommended	SMC advice
Dabrafenib, 50mg and 75mg hard capsules (Tafinlar [®]) (1023/15) - Full submission	Monotherapy treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. SMC restriction: for use in patients with unresectable or metastatic BRAFV600 mutation-positive metastatic melanoma who have received no prior therapy.	HOSPITAL ONLY - (Oncology) Supplied via a Patient Access Scheme	SMC advice SPC link
Fosfomycin 40mg/mL powder for solution for intravenous infusion (Fomicyt [®]) (1033/15) - Abbreviated submission	For the treatment of the following infections in adults and children including neonates: - Acute osteomyelitis - Complicated urinary tract infections - Nosocomial lower respiratory tract infections - Bacterial meningitis - Bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.	HOSPITAL ONLY (Infectious Diseases/Microbiology recommendation only) Alert antibiotic list	SMC advice SPC link
Idelalisib 100mg and 150mg tablets (Zydelig [®]) (1026/15) - Full submission	In combination with rituximab for the treatment of adult patients with chronic lymphocytic leukaemia (CLL): • who have received at least one prior therapy, or • as first line treatment in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy. SMC restriction: patients with relapsed CLL who are unsuitable for chemotherapy and treatment naïve patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy.	HOSPITAL ONLY - (Haematology) Supplied via a Patient Access Scheme	SMC advice SPC link (100mg) SPC link (150mg)
Ledipasvir/sofosbuvir, 90mg/400mg, film-coated tablet (Harvoni [®]) (1030/15) - Full submission	Treatment of chronic hepatitis C (CHC) in adults. SMC restriction: genotype 1 and 4 CHC only.	HOSPITAL ONLY - (Hep C clinic)	SMC advice SPC link
Ruxolitinib (as phosphate), 5mg, 15mg, & 20mg tablets (Jakavi [®]) (867/13) - Full submission	The treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.	HOSPITAL ONLY - (Haematology) Supplied via a Patient Access Scheme	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 \(including Individual Patient Treatment Requests\)](#).

Updates from previous SMC Advice

No updates this month.



Tayside Area Formulary (TAF) Updates - March 2015

TAF Section	Drug(s)/Topic	Changes
01.03	Antisecretory drugs and mucosal protectants	Link to NICE CG184: Dyspepsia, GORD, or both, Sept 2014 added.
02.08.02 Cardiology Specialist List	VTE treatment	Apixaban 2.5mg & 5mg, film-coated tablets (Eliquis [®]) added to formulary (Amber traffic light) and Cardiology specialist formulary list as second line choice for treatment of confirmed uncomplicated DVT or PE. See SMC advice on page 4.
02.12	Statins	Atorvastatin now formulary first choice statin. Atorvastatin primary prevention dose (20mg daily) added as prescribing note. Simvastatin is now formulary second choice statin. Note added that simvastatin 80mg daily is non-formulary. Link to NICE CG 181: Lipid modification: cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease (July 2014) added. See article on page 2 for further information.
03.01.04	Compound bronchodilator preparations	Umeclidinium / vilanterol, 55/22 micrograms, inhalation powder (Anoro [®]) - changed from SMC not recommended to non-formulary. See SMC advice on page 3.
06.05.01 Obstetrics & Gynaecology Specialist List	Anterior pituitary hormones	Follitropin alfa 75 units, 150 units, 225 units, 300 units, 450 units pre-filled pen for subcutaneous injection (Bemfola [®]) added to formulary (Hospital Only) (Red traffic light) and Obstetrics & Gynaecology specialist formulary list (under specialist supervision - Assisted Conception Unit). See SMC advice on page 3.
08.02.01	Mycophenolate mofetil and mycophenolate sodium	Links to MHRA Drug Safety Update article - mycophenolate mofetil and mycophenolic acid: risk of hypogammaglobulinaemia and risk of bronchiectasis, Jan 2015 added.
10.01.03	Mycophenolate mofetil and ustekinumab	Links to MHRA Drug Safety Update article - mycophenolate mofetil and mycophenolic acid: risk of hypogammaglobulinaemia and risk of bronchiectasis, Jan 2015 and MHRA Drug Safety Update article - ustekinumab: risk of exfoliative dermatitis, Jan 2015 added.
10.03.02	Topical NSAIDs	Ibuprofen 5% topical gel now first choice topical NSAID. Piroxicam 0.5% gel now non-formulary as no longer cost-effective in primary care.
12.03.01 Oncology & Haematology (non-chemo drugs) Specialist List	Drugs for oral ulceration and inflammation	Caphosol [®] oral rinse (medical device), now Amber traffic light (can be prescribed by GPs under specialist direction) and added to the Oncology & Haematology (non-chemo drugs) specialist formulary list.
13.01	Management of skin conditions	Links to BNF - Excipients and sensitisation and MIMS - potential skin sensitisers as ingredients of emollients added under heading– Excipients and sensitisation.

Continued over...



Tayside Area Formulary (TAF) Updates - Mar 15 cont.

TAF Section	Drug(s)/topic	Changes
13.02.01	Emollients	<p>Prescribing advice on use of emollients updated. All emollients in the BNF should be considered suitable for prescribing as appropriate, however specific preparations have been listed in order to provide further guidance. Cost and patient acceptability should be considered when prescribing.</p> <p>Link to Primary Care emollient price chart (January 2015) added.</p> <p>Layout of formulary section split up into: Ointments; Creams/gels; Lotions; Preparations containing urea; Spray emollients; Soap Substitutes; and Emollient bath and shower preparations.</p> <p>Preparations changed from formulary to non-formulary: Aqueous cream; Epaderm[®] ointment; E45[®] cream; Oilatum[®] shower emollient; Oilatum[®] emollient bath additive; Balneum[®] Plus bath oil; Dermo[®] 200 shower emollient; Dermo[®] 600 bath emollient; and Oilatum[®] Plus bath additive.</p> <p>Preparations added to the formulary: Hydromol[®] ointment; QV[®] Intensive ointment; Diprobase[®] ointment; QV[®] lotion; Diprobase[®] lotion; QV[®] cream; Hydromol[®] Intensive cream; Eucerin[®] Intensive lotion; Emollin[®] spray; Dermamist[®] spray; QV[®] gentle wash; and Hydromol[®] Bath and shower emollient.</p>
13.02.02	Barrier preparations	<p>Preparations changed from formulary to non-formulary: Drapolene[®]; Sudocrem[®]; and Zinc and Castor Oil Ointment.</p> <p>Preparations added to the formulary: Metanium[®] ointment and Zinc Paste Compound BP.</p>
13.5.3	Mycophenolate mofetil and ustekinumab	<p>Links to MHRA Drug Safety Update article - mycophenolate mofetil and mycophenolic acid: risk of hypogammaglobulinaemia and risk of bronchiectasis, Jan 2015 and MHRA Drug Safety Update article - ustekinumab: risk of exfoliative dermatitis, Jan 2015 added.</p>
13.08.01	Sunscreen preparations	<p>Delph[®] lotion SPF 30 non-formulary as discontinued.</p> <p>Uvistat[®] cream SPF 30, Uvistat[®] lipscreen SPF 50 and Anthelios[®] XL SPF 50+ Melt-in cream added to formulary.</p> <p>Prescribing advice on sunscreens updated.</p> <p>See article on page 2 for further information.</p>
Chapter 20	Continence products	<p>Links to NHS Tayside Continence Skin Care Leaflet & Product Guidelines and NATVNS Excoriation & Moisture Related Skin Damage Tool added.</p>

SMC Briefing Note:

[Click here](#) for February Briefing Note

[Click here](#) for March 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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