TAYSIDE PRESCRIBER

NHS Tayside

Tayside DTC Supplement No 155 – JUNE 2016

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

Special Points of Interest for Primary Care

SMC Advice - April:

- alendronic acid (Binosto®)
- ataluren (Translarna®)
- camellia sinensis (Catephen®)
- eculizumab (Soliris®)
- everolimus (Afinitor®)
- isavuconazole (Cresemba®)
- nivolumab (Opdivo®)

SMC Advice - May:

- adalimumab (Humira®)
- bevacizumab (Avastin®)
- ceftolozane-tazobactam (Zerbaxa®)
- certolizumab pegol (Comzie®)
- elvitegravir 150mg/cobicistat 150mg/emtricitabine 200mg/ tenofovir alafenamide 10mg (Genvoya®)
- ivacaftor (Kalydeco®)
- lumacaftor 200mg/ivacaftor 125mg (Orkambi®)
- ramicurinab (Cyrmaza®)

Drug Safety Updates

Please follow link – Drug Safety Update Downloads: April 2016 | May 2016

Mycophenolate: New Pregnancy Prevention Advice for Women and Men

Mycophenolate is an immunosuppressive agent used in combination with ciclosporin and corticosteroids for the prevention of acute transplant rejection in patients who have received kidney, heart, or liver transplants.

In Tayside, it is also used off label by renal, dermatology and rheumatology.
See mycophenolate entries in the Tayside Area formulary for further information.

Mycophenolate is associated with a high rate of serious birth defects and increased risk of spontaneous abortion.

A review of worldwide cases of congenital malformations after exposure during pregnancy has confirmed mycophenolate as a powerful human teratogen, and showed evidence of an increased rate of congenital malformations and spontaneous abortions compared with other immunosuppressants.

For further information see: Drug Safety Update 14 December 2015 and Dear Healthcare professional letter, 5th November 2015.

Risk minimisation material for mycophenolate and teratogenicity is available from the electronic medicines compendium for healthcare providers and patients for CellCept® brand. Similar material via the electronic medicines compendium is available for healthcare providers and patients for generic brands.

If healthcare professionals have any concerns regarding the MHRA advice contact the specialist involved with the patients care for guidance.

A patient information leaflet for mycophenolate regarding the new pregnancy prevention advice for women and men has been developed for Scottish transplant patients.

Inside this issue:

Prescribing Changes

Discontinuation of Orphenadrine

Disipal (orphenadrine) was discontinued on 1st December 2015. There is a generic alternative, with stock currently available, but long term manufacturing problems mean that continuity of supply is not assured and alternatives need to be considered. The following guidance is adapted from information produced by Cheshire and Wirral Partnership NHS Foundation Trust on how to manage patients currently using orphenadrine for side effects associated with antipsychotic medication.

The need for ongoing treatment should be reviewed, many patients have been on this for a long period and may longer require it. If required, discontinuation should be slow and gradual, over 1-2 weeks. High doses should be withdrawn more gradually over several weeks. Possible withdrawal symptoms may include:

- Feeling and being sick
- Flu-like symptoms
- Stomach cramps
- Runny nose
- Watery eyes
- Hypersalivation
- Indigestion
- Sweating
- Vivid dreams
- Insomnia

If an alternative anticholinergic is required then TAF choice would be procyclidine, with a review after three to four months as per the SPC. Anticholinergic naive patients should be started at 2.5mg three times a day, with the dose increased by 2.5-5mg daily at intervals of 2-3 days. The maintenance dose is 15-30mg daily with younger patients tending to need doses at the higher end of this range.

Suggested dose ranges	
orphenadrine	50-100mg up to three times a day (maximum 400mg daily)
procyclidine	5-10mg up to three times a day (maximum 30mg daily). Do not give last dose at bedtime as it is stimulating

Acknowledgement: adapted from Cheshire and Wirral Partnership NHS Foundation Trust.

Prescribing for Yourself, Friends or Family

The professional bodies linked to medicine, dentistry, pharmacy, and nursing and midwifery have all issued standards or guidance on prescribing. They all recommend that practitioners should not prescribe for themselves or anyone with whom they have a close personal relationship. This is because it can be difficult to remain objective and so prescribers risk overlooking serious problems, tolerating unsuitable behaviour, or interfering with care or treatment provided by other healthcare professionals.

The Nursing and Midwifery Council advises within *Standards of proficiency for nurse and midwife prescribers* that nurses and midwives must not prescribe for themselves and, other than in exceptional circumstances, should not prescribe for anyone with whom they have a close personal or emotional relationship.

The GMC guidance says that wherever possible doctors must avoid prescribing for themselves or anyone with whom they have a close personal relationship. Any doctor who does prescribe in these situations must be prepared to justify the decision to do so and;

- make a clear record at the time or as soon as possible afterwards. Include the relationship with the patient and the reason it was necessary to prescribe.
- tell the patient's own GP what has been prescribed and any other information necessary for continuing care unless the patient objects.

Controlled drugs must not be prescribed in these situations unless no other person with the legal right to prescribe is available to assess and prescribe without a delay which would put the patient's life or health at risk or cause unacceptable pain or distress, and the treatment is immediately necessary to:

- save a life
- avoid serious deterioration in health, or
- alleviate otherwise uncontrollable pain or distress.

Advice for pharmacist prescribers is broadly similar to that issued for doctors.

Thanks to NHS Greater Glasgow and Clyde for permission to reproduce this article, originally published in Medicines Update.

SGLT2 Inhibitors and Diabetic Ketoacidosis

Rare (affecting up to 1 in 1,000 patients) but serious and life-threatening cases of DKA have been reported in some patients with Type 2 Diabetes taking SGLT2 inhibitors (canagliflozin, dapagliflozin or empagliflozin). Most cases occurred in patients also on insulin therapy. Half of the cases occurred during the first 2 months of treatment. Some cases occurred shortly after stopping the SGLT2 inhibitor. This complication may be more likely in those who are slimmer and so for whom reduced insulin secretion is more predominant. In several cases, blood glucose levels were only moderately elevated (eg atypical for DKA). This atypical presentation could delay diagnosis and treatment.

N.B. Therefore inform patients commencing an SGLT2 inhibitors of the signs and symptoms of DKA (eg nausea, vomiting, anorexia, abdominal pain, excessive thirst, difficulty breathing, confusion, unusual fatigue or sleepiness) and **test for raised ketones in patients with these signs and symptoms.**

When treating patients who are taking an SGLT2 inhibitor (canagliflozin, dapagliflozin or empagliflozin):

- test for raised ketones in patients with symptoms of acidosis, even if blood sugar levels are not high; omitting this test could delay diagnosis of DKA.
- if you suspect DKA, stop SGLT2 inhibitor treatment.
- if DKA is confirmed, take appropriate measures to correct the DKA and to monitor glucose levels – seek specialist advice and probable admission.
- in such cases, SGLT2 inhibitors should not normally be re-started.
- inform patients of the symptoms and signs of DKA (see above); advise them to get immediate medical help if these occur.
- temporarily stop SGLT2 inhibitors in patients who are undergoing major surgery or are in hospital due to serious illness.
- be aware that SGLT2 inhibitors are not approved for treatment of type 1 diabetes.

Please continue to report suspected side effects to SGLT2 inhibitors or any other medicines on a Yellow Card.

The benefits of these medicines continue to outweigh the risks in the treatment of type 2 diabetes.

Click here for a local information leaflet which can be given to patients on SGLT2 Inhibitors and DKA.
Click here for the European Medicines Agency (EMA) recommendations to minimise the risk of DKA in patients taking SGLT2 inhibitor

Produced by Tayside Diabetes Network

Stickers for BNF70 and BNF *for Children* 2015-2016

A small number of errors have been highlighted in BNF 70 and BNF for Children 2015/16 and communication was sent out locally via Tayside Prescriber 137, November 2015. Use of the electronic version of the BNF and BNFC are encouraged as they contain the most updated information. The BNF can also be accessed from individual drug entries in the Tayside Area Formulary.

The Publishers of the BNF have made a standardised sticker available to users of both publications, summarising the known errors in the paper copies of BNF 70 and BNF for Children 2015/16 . Electronic versions have been updated. Stickers have been distributed directly to recipients of the BNF Publications, following the same pathway used for distributing the September editions. All end users of the BNF 70 and BNF for Children 2015/16 should now have received stickers to put on the front page of the September 2015 paper editions. If they have not they should contact whoever distributes their BNF locally.

Further information can be found from the home page of the BNF under Using your new BNF

As of September 2015, hard copies of the BNF are only issued annually to eligible NHS healthcare professionals in NHS Scotland. This means that staff in NHS Scotland will no longer receive a paper copy of the BNF in March of each year. The next paper copies to be issued will be BNF 72 (September 2016 to March 2017) and BNF for Children 2016/17 (September 2016-17) in September 2016. However, community pharmacy contractors should have received paper copies of BNF 71 (March to September 2016) as part of their Medicines Complete package. See NHS Circular: PCA (P) (2015) 23 for further information.

Specialist List Updates

The Rheumatology specialist formulary list and the Drugs used in rheumatic diseases and gout section of the Tayside Area Formulary (TAF) have been reviewed. Changes made are outlined in the TAF Update table on page 7 under TAF section 10.01.

The Dementia specialist formulary list and Drugs for dementia section of the TAF has also been reviewed. Changes made are outlined in the TAF Update table on page 6 under TAF section 04.11.

The Diabetes section of the formulary and part of the Endocrinology specialist formulary list have recently been reviewed and changes are currently being made to the TAF and some further minor amendments to the Diabetes MCN Handbook are also anticipated before final publication of the changes.

The Endocrine sections of the formulary and remaining parts of the Endocrinology specialist formulary list are currently under review.

Dermatology Formulary Updates

Acne and Rosacea

A review of Chapter 13: Skin of the Tayside Area Formulary (TAF) is ongoing with sections completed so far: Emollient and barrier preparations, sunscreens and camouflagers, preparations for warts and calluses, shampoos and other preparations for scalp and hair conditions, and most recently, acne and rosacea.

The acne and rosacea sections have been significantly updated with guidance on management of acne updated, and new guidance on management of rosacea developed.

A first line treatments algorithm has also been developed for the management of acne. More detailed prescribing advice has been added throughout the formulary section and links to the most recent national guidance have been added.

Of note, the formulary updates reflect current guidance including:

With regard to acne:

- Topical antibiotic preparations for acne have only been included as combination products with a topical benzoyl peroxide or a topical retinoid to avoid topical antibiotics being applied as sole treatment. Bacterial resistance is a growing concern and treatment with topical or oral antibiotics should be limited to 12 weeks duration if possible. For further information see SMC/SAPG guidance (November 2015) on long term antibiotic use for acne, rosacea and other dermatology conditions.

- There is less emphasis on the use of co-cyprindiol (Dianette®) in women with acne unless particularly indicated (moderate to severe acne where other treatments have failed), as second and third generation Combined oral contraceptives (COCs) are generally preferred. If co-cyprindiol is prescribed it should be discontinued 3 months after acne has been controlled. Co-cyprindiol is not licensed for the sole purpose of contraception. Previous MHRA advice (June 2013) summarises the prescribing advice for co-cyprindiol.

With regard to rosacea:

- Topical azelaic acid added as a treatment option for erthematotelangiectatic or papulopustular rosacea.

Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
alendronic acid 70mg effervescent tablet (Binosto®) SMC 1137/16 Abbreviated submission Accepted for Restricted Use	Treatment of postmenopausal osteoporosis. SMC Restriction: for use in patients who are unable to swallow tablets where alendronic acid is the appropriate treatment choice.	Available in line with National Guidance	SMC Advice SPC Link
ataluren 125mg, 250mg, 1,000mg granules for oral suspension (Translarna®) SMC 1131/16 Full submission considered under the ultra-orphan process Not Recommended	Treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged 5 years and older.	Not available as not recommended for use in NHS Scotland	SMC Advice
camellia sinensis (green tea) leaf extract 10% ointment (Catephen®) SMC 1133/16 Full submission Accepted for Restricted Use	Cutaneous treatment of external genital and perianal warts (*condylomata acuminata*) in immunocompetent patients from the age of 18 years. SMC Restriction: for use in patients not suitable for podophyllotoxin or who have not responded to treatment with podophyllotoxin.	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	SMC advice
eculizumab 300mg/30mL vial concentrate for solution for infusion (Soliris®) SMC 1130/16 Full submission assessed under the ultra orphan process Not Recommended	In adults and children, for the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH). Evidence of clinical benefit is demonstrated in patients with haemolysis with clinical symptom(s) indicative of high disease activity, regardless of transfusion history.	Not available as not recommended for use in NHS Scotland	SMC advice
everolimus 2.5mg, 5mg and 10mg tablets (Afinitor®) SMC 872/13 Second resubmission assessed under the end of life process Accepted with PAS	For the treatment of hormone receptor-positive, HER2/neu negative advanced breast cancer, in combination with exemestane, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor.	Not routinely available as local clinical experts do not with to add the medicine to the formulary at this time or there is a local preference for alternative medicines	SMC advice
isavuconazole, 200mg powder for concentrate for solution for infusion and 100mg hard capsules (Cresemba®) SMC 1129/16 Full submission considered under the orphan process Accepted with PAS	In adults for the treatment of: invasive aspergillosis mucormycosis in patients for whom amphotericin B is inappropriate	Available in line with national guidance	SMC advice SPC Links: 200mg powder 100mg hard caps Hospital use only, Restricted to ID/ Micro approval
nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) SMC 1120/16 Amended advice - full submission assessed under the end of life and orphan equivalent process Not Recommended	As monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults.	Not available as not recommended for use in NHS Scotland	SMC advice

Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
adalimumab 40mg/0.8ml solution for injection (Humira®) SMC 1143/16 Full submission Accepted	Treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adult patients with inadequate response to conventional HS therapy	Available in line with National guidance	SMC Link SPC Link Hospital Only (Dermatology)
bevacizumab 25mg/mL concentrate for solution for infusion (Avastin®) SMC 1135/16 Full submission Accepted restricted with PAS	In combination with paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy, for treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix. SMC Restriction: for use with cisplatin and aclitaxel	Available in line with National guidance	SMC Link SPC Link Hospital Only (Oncology)
ceftolozane-tazobactam 1g/0.5g powder for concentrate for solution for infusion (Zerbaxa®) SMC 1146/16 Full submission Not recommended	Treatment of following infections in adults: complicated intra-abdominal infections, acute pyelonephritis, complicated Urinary Tract Infections	Not available as not recommended for use in NHS Scotland	SMC Link
certolizumab pegol 200mg solution for injection (Comzie®) SMC 1155/16 Non submission Not recommended	Treatment of severe, active and progressive RA in adults not previously treated with MTX or other DMARDS	Not available as not recommended for use in NHS Scotland	SMC Link
elvitegravir 150mg, cobicistat 150mg, emtricitabine 200mg, tenofovir alafenamide 10mg film coated tablet (Genvoya®) SMC 1142/16 Full submission Accepted with PAS	The treatment of adults and adolescents (aged 12 year and older with body weight at least 35kg) infected with human immunodeficiency virus-1 (HIV-1) without any known mutations associated with resistance to the integrase inhibitor class emtricitabine or tenofovir	Available in line with National Guidance	SMC Link SPC Link Hospital Only (HIV Clinic Only)
ivacaftor 50mg and 75 mg granules in sachet (Kalydeco®) SMC 1134/16 Full submission assessed under the ultra orphan medicine process Not recommended	Treatment of children with cystic fibrosis (CF aged 2 years and older and weighing less than 25kg who have one of the following gating (class III) mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R	Not available as not recommended for use in NHS Scotland	SMC Link
lumacaftor 200mg, ivacaftor 125mg film coated tablets (Orkambi®) SMC 1136/16 Full submission considered under the orphan medicine process Not recommended	Treatment of cystic fibrosis (CF) in patients aged 12 years and older who are homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene	Not available as not recommended for use in NHS Scotland	SMC Link
ramucirumab 10mg concentrate for solution for infusion (Cyramza®) SMC 1156/16 Non submission Not recommended	In combination with FOLFIRI (irinotecan, folinic acid and 5-fluorouracil) for the treatment of adult patients with metastatic colorectal cancer with disease progression on or after prior therapy with bevacizumab, oxaliplatin and a fluoropyrimidine	Not available as not recommended for use in NHS Scotland	SMC 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 Prescribing of Medicines that are Non-formulary (including Individual Patient Treatment Requests).

Updates from previous SMC Advice

Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
golimumab 50mg/0.5mL solution for injection in pre-filled pen or syringe and 100mg/mL solution for injection in pre-filled pen (Simponi®) SMC 1124/16 Full submission Accepted	treatment of adults with severe, active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).	Not routinely available as local clinical experts do not with to add the medicine to the formulary at this time or there is a local preference for alternative medicines	SMC advice

Tayside Area Formulary (TAF) Updates - Apr-Jun 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
01.01.01	Antacid preparations containing dimeticone or local anaesthetics	Antacid and oxetacaine suspension [unlicensed] added to formulary and Oncology & Haematology specialist formulary list as Amber traffic light (GPs may prescribe under specialist direction for radiotherapy induced oesophagitis).
Chapter 2	Heart failure	Links to SIGN 147 Management of chronic heart failure, March 2016 added throughout Chapter 2. SIGN 147 supersedes previous local guidance on Management of heart failure. Links to Flowchart for sequence of therapy for chronic heart failure (adapted from SIGN 147) added throughout Chapter 2.
02.02.03	Aldosterone antagonists	Link to MHRA Drug Safety Update article: Spironolactone and renin-angiotensin system drugs in heart failure– risk of potentially fatal hyperkalaemia, February 2016 added to spironolactone entry. Recommendations from SIGN 147 regarding use of spironolactone and eplerenone in heart failure added as a prescribing note to section. Link to Annex 5: Practical guidance - Use of mineralocorticoid receptor antagonist in patients with heart failure reduced ejection fraction from SIGN 147 added to section notes.
02.05.05	Drugs affecting the renin-angiotensin system	Link to MHRA Drug Safety Update article: Spironolactone and renin-angiotensin system drugs in heart failure– risk of potentially fatal hyperkalaemia, February 2016 added to section.
03.04.01	Sedating antihistamines	Hydroxyzine - syrup formulation removed from formulary as discontinued by manufacturer.
04.02.03 04.07.04.02 04.08.01 04.08.02	Valproate	Link to Tayside Prescriber Issue 142 - Valproate and Risk of Abnormal Pregnancy Outcomes: New Communication Materials, June 2016 added. Link to MHRA Drug Safety Update - Medicines related to valproate: risk of abnormal pregnancy outcomes, Jan 2015 added (already linked to section 04.08.01).
04.07.04.01	5HT1 agonists	Acute treatment of cluster headache added as additional indication for sumatriptan subcutaneous injection and zolmitriptan nasal spray [off-label].
04.07.04.03	Cluster headache	New formulary section. Prescribing notes for acute treatment of cluster headache added.
04.09.01	Dopamine receptor agonists	Link to MHRA Drug Safety Update article: Apomorphine with domperidone - minimising risk of cardiac side effects, April 2016 added to apomorphine entry.
04.11	Dementia	Dementia formulary and Dementia specialist formulary list review undertaken. The following changes have been made: Wording within formulary and specialist list changed from 'BPSD (Behavioural and Psychological Symptoms of Dementia)' to 'symptoms of stress and distress in people with dementia'. Anticholinesterases and memantine Amber traffic light for all areas across Tayside. Link to outdated Shared Care Agreement removed. Links to Tayside Guidance on antipsychotics in older people with dementia (after excluding delirium), Rationalisation of Antipsychotics in Dementia - Good Practice Guide for Reduction/Cessation of treatment and Good Practice Guide for initiation of treatment updated to new versions. Links to SIGN 86 Management of patients with dementia removed as withdrawn by SIGN as over 10 years old.

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Tayside Area Formulary (TAF) Updates - Apr-Jun 2016 (cont.)

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
05.02.01	Triazole antifungals	Isavuconazole (Cresemba®▼) intravenous infusion and capsules added to formulary as Hospital-Only (Red traffic light) Restricted to ID/Micro approval. See SMC advice on page 5.
05.03.01	Nucleoside reverse transcriptase inhibitors	Elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide film coated tablet (Genvoya®▼) added to formulary as Hospital-Only (Red traffic light) Restricted to HIV clinic. See SMC advice on page 6.
06.01.02.06	Sodium-glucose co-transporter 2 inhibitors	Links to MHRA Drug Safety Update article: SGLT2 inhibitors - updated advice on the risk of diabetic ketoacidosis, April 2016 added to each drug entry.
06.06.02	Bisphosphonates	Alendronic acid 70mg effervescent tablet (Binosto®) added to formulary as Green traffic light for use in patients who are unable to swallow standard tablets. See SMC advice on page 5.
07.03.02.03	Intra-uterine progestogen-only contraceptive	Link to MHRA Drug Safety Update article: Levonorgestrel-releasing intrauterine systems - prescribe by brand name, January 2016 added to section.
08.02.01	Mycophenolate mofetil and mycophenolate sodium	Link to MHRA Drug Safety Update - Mycophenolate mofetil, mycophenolic acid: new pregnancy-prevention advice for women and men, Dec 2015 added. Link to patient information leaflet regarding new pregnancy prevention advice for Scottish transplant patients added.
09.01.02	Folic acid	Information on folic acid supplementation before and during pregnancy in particular patient groups highlighted. Link to CMACE/RCOG guideline - Management of Women with Obesity in Pregnancy, March 2010 added as this provides advice on folic acid supplementation in women with BMI ≥ 30 before and during pregnancy.
10.01	Drugs used in rheumatic diseases and gout	Rheumatology formulary and Rheumatology specialist formulary list review undertaken. The following changes have been made: Etanercept (Enbrel®) now non-formulary. Biosimilar etanercept (Benepali®▼) now formulary first choice cytokine modulator for Rheumatology (tocilizumab remains alternative first choice) and added to the Rheumatology specialist formulary list. Addition of statement on use of biosimilars added. Certolizumab pegol (Cimzia®) now standard formulary (replaced as first choice by biosimilar etanercept). SMC approved indication severe axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and/or MRI, despite NSAID therapy or when intolerance to NSAIDs added to certolizumab pegol formulary entry and Rheumatology specialist list. Sulfasalazine no longer listed as a first choice DMARD. Mycophenolate mofetil - link added to MHRA Drug Safety Update - Mycophenolate mofetil, mycophenolic acid: new pregnancy-prevention advice for women and men, Dec 2015. Link to NICE MTA130 replaced with NICE (Multiple) TA375: Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed, January 2016. Link to NICE MTA143 replaced with NICE (Multiple) TA383: TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis, Feb 2016. Link to NICE Key Therapeutic Topic (KTT) 13: Non-steroidal anti-inflammatory drugs, updated Feb 2016 added.
11.05	Antimuscarinics	Atropine sulphate 0.5% eye drops removed from formulary as discontinued by manufacturer.
13.02.01	Emollients	Link to MHRA Drug Safety Update article: Paraffin-based skin emollients on dressings or clothing– fire risk, April 2016 added to section.
13.05.03	Drugs affecting the immune response	Adalimumab 40mg/0.8ml solution for injection (Humira®) for the indication treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adult patients with inadequate response to conventional HS therapy added to formulary (Hospital Only) and Dermatology specialist formulary list as per SMC advice. Link to MHRA Drug Safety Update - Mycophenolate mofetil, mycophenolic acid: new pregnancy-prevention advice for women and men, Dec 2015 added to mycophenolate mofetil entry. Etanercept (Enbrel®) now non-formulary. Biosimilar etanercept (Benepali®▼) now formulary and added to the Dermatology specialist formulary list. Addition of statement on use of biosimilars added.

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Tayside Area Formulary (TAF) Updates - Apr-Jun 2016 (cont.)

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
13.06	Acne and rosacea	Azelaic acid 20% cream and 15% gel added to formulary (Green traffic light) as treatment option in rosacea [20% cream off-label in rosacea] and treatment option in acne if topical benzoyl peroxide and topical retinoid not tolerated. Combination preparations for acne (topical antibiotic with benzoyl peroxide or retinoid) added as full formulary entries (Green traffic light) include: Adapalene 0.1%, benzoyl peroxide 2.5% (Epiduo®); isotretinoin 0.05%, erythromycin 2% (Isotrexin®); tretinoin 0.025%, erythromycin 4% (Aknemycin Plus®); tretinoin 0.025%, clindamycin 1% (Treclin®); benzoyl peroxide 3%, clindamycin 1% (Duac® Once Daily); and benzoyl peroxide 5%, clindamycin 1% (Duac® Once Daily). Erythromycin 2% and 4% with zinc acetate topical solution and clindamycin 1% topical solution and 1% lotion now non-formulary. Topical metronidazole 0.75% cream and 0.75% gel added to formulary (Green traffic light) as a first line option for papulopustular rosacea and as an option for erthmatotelangiectatic rosacea. Topical ivermectin 10mg/g cream (Soolantra®) added to formulary (Green traffic light) for patients with moderate to severe inflammatory lesions of rosacea as a second line option. Link to new local guidance on rosacea added. Links added to updated local guidance on Management of acne and updated Management of acne - first line treatments algorithm. Link to SMC/SAPG guidance (November 2015) on long term antibiotic use for acne, rosacea and other dermatology conditions added.

SMC Monthly Briefing Notes 2016

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.

Please direct any queries to either:

David Gill
Lead Clinician - Pharmacoeconomics
email: david.gill@nhs.net

or

Claire James
Senior Pharmacist - Clinical Effectiveness
email: clairejames@nhs.net