TAYSIDE PRESCRIBER

NHS Tayside

Tayside ADTC Supplement No 161 – June 2017

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

Special Points of Interest for Primary Care

SMC Advice - Published 10 April:

- Daclizumab (Zinbryta®)
- Emtricitabine/tenofovir disoproxil (Truvada®)
- Ibrutinib (Imbruvica®)
- Insulin aspart (Fiasp®)(Penfill®) (FlexTouch®)
- Ixekizumab (Taltz®)
- Nepafenac (Nevanac®)
- Ofatumumab (Arzerra®)
- Tenofovir alafenamide (Vemlidy®)
- Ticagrelor (Brilique®)
- Trastuzumab emtansine (Kadcyla ®)

Inside this Issue:

Drug Safety Updates

Please follow link: Drug Safety Updates - **May 2017**

Valproate and Neurodevelopment Disorders

April's Drug Safety Update provides information about the new Patient Safety Alert asking for patient review and further considerations for ensuring health care providers use the available resources to support the safe use of valproate in females of child bearing age.

See Tayside Prescriber, June 2016 on available resources to support appropriate use of valproate in women of childbearing age and important key points for healthcare professionals.

Prescribing Changes

Pregabalin

The product patent on pregabalin expired in 2015 but Pfizer retained a second medical use patent that has created a barrier to using generic pregabalin for the treatment of neuropathic pain; the second-indication patent expires on the 16 July 2017. Secondary care discounts on generics are considerable and the Scottish Drug Tariff price for pregabalin is anticipated to reduce markedly from 1st August 2017.

There is a significant savings opportunity for NHS Tayside that is dependent on changing all remaining prescribing from Lyrica® to generic.

It is worth noting that currently Tayside spends in excess of £4million per year on pregabalin, so every effort must be made to ensure the savings opportunities from the change are maximised. Generic prescribing rates for pregabalin will be monitored over the next few months.

Lidocaine Medicated Plaster - Change to Ralvo®

A branded generic lidocaine 700mg (5% w/w) medicated plaster, Ralvo® is now available. It is manufactured by the same company as the Versatis® 5% medicated plaster. Ralvo® is exactly the same size, strength, and formulation as Versatis® with the same licensed indication and directions for use. Ralvo® is 15% less expensive than Versatis®. In order to release potential cost savings prescribing by brand name is required.

Ralvo® will soon be the brand of lidocaine medicated plaster supplied from hospital pharmacies after stocks of the Versatis® brand are used up. Please refer to the SPC for Ralvo® for prescribing information.

Protelos® (strontium ranelate): Cessation of Supply

Servier will cease production and distribution of strontium ranelate at the end of August 2017. Click here for information from the manufacturer. Further details can be found from UKMi memo on strontium shortage. Strontium is non formulary in NHS Tayside.

Prescribing Changes

New Buprenorphine Patch Prescribing Guidance

In January 2017, The Scottish Medicines Consortium approved buprenophine 5, 10, 15 and 20microgram/hour transdermal patches (Butec®) for the treatment of chronic non-malignant pain of moderate intensity when an opioid is necessary for obtaining adequate analgesia in patients who are > 65 years of age. Following advice issued, NHS Tayside have agreed that Butec® patches will be included on the formulary and can be prescribed for patients who are >65 years of age for the treatment of chronic non-malignant pain of moderate intensity.

PLEASE NOTE: the patch remains non-formulary for patients out with these criteria.

Points to note when prescribing:

1. Patient must be over 65 years of age.
2. Pain must be non-malignant in nature.
3. The brand Butec® must be prescribed and supplied.
4. **Restricted to patients who cannot take (e.g. problems with oral administration) or tolerate less expensive step 2 analgesics for example codeine or tramadol.**
5. May be used for patients where step 3 opioid analgesics such as fentanyl patches are too strong.
6. Apply a new patch every 7 days.
7. Considerably more expensive than codeine or tramadol.

Higher strengths of buprenorphine patch are SMC not recommended and should only be prescribed via the IPTR process.

Management of Nasal Polyps Guidance

Department of ENT guidance on Nasal polyps management has been published within the formulary. The guidance is in an algorithm format, and provides a summary of background information, information on diagnosis, and advice on prescription of a long-term nasal steroid. It also includes the place in management of Flixonase® Nasule® drops and oral steroids, and guidance on referral to ENT.

Flixonase® Nasule® 400microgram/unit dose nasal drops have also been added to the formulary and ENT Specialist Formulary list as an Amber traffic light (may be prescribed by GPs under the direction of a specialist), restricted to use in accordance with the Nasal polyps management algorithm.

Specialist List Updates

Urology Specialist Formulary List

The Urology specialist formulary list and relevant formulary sections have been reviewed and rationalised on the basis of cost-effectiveness and reflect the most up to date evidence.

Updates include:

- Tamsulosin to enhance expulsion of ureteral stones (Medical expulsive therapy (MET)) [off-label] has changed from an Amber to Red traffic light, so is now only for prescribing by hospital specialists (Hospital only).
- Pentosan polysulphate sodium capsules (Elmiron®) [unlicensed] (Hospital Only) for chronic interstitial cystitis after other treatments have been ineffective, is now non-formulary. As this is an unlicensed medicine, a non-formulary request for prescription of a new unlicensed medicine (Category 1) would need to be processed prior to this being initiated for a patient as per the Policy on Prescribing of Non-Formulary Medicines (including Individual Patient Treatment Requests).

Work is ongoing to review the Urology Pathway for Erectile Dysfunction.

For further information on the changes, see the TAF Update table on pages 4 and 5.

Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
Daclizumab 150mg/mL solution for injection in prefilled syringe/pen (Zinbryta®) SMC No. (1216/17) Full submission Accepted restricted	For use in patients with rapidly evolving severe (RES) relapsing remitting multiple sclerosis (RRMS) or in patients with RRMS with an inadequate response to disease modifying therapy. SMC Restriction: for use in patients with rapidly evolving severe (RES) relapsing remitting multiple sclerosis (RRMS) or in patients with RRMS with an inadequate response to disease modifying therapy	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts - decision expected by September 2017	SMC Link SPC Link
Emtricitabine/tenofovir disoproxil 200mg/245mg film-coated tablets (Truvada®) SMC No. (1225/17) Full submission Accepted	In combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in adults at high risk.	Available in line with national guidance	*All prescribing will be via the specialist Sexual Health Service once national implementation arrangements are in place.*
Ibrutinib 140mg hard capsules (Imbruvica®) SMC No. (1151/16) Resubmission assessed under the end of life and orphan medicine process Accepted restricted	Treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy. SMC Restriction: patients with relapsed/refractory CLL and for whom fludarabine-based regimens are inappropriate.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts - decision expected by September 2017	SMC Link SPC Link
Insulin aspart 100 units/mL solution for injection in vial (Fiasp®); solution for injection in cartridge (Penfill®); solution for injection in pre-filled pen (FlexTouch®) SMC No. (1227/17) Abbreviated submission Accepted	Treatment of diabetes mellitus in adults	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts - decision expected by September 2017	SMC Link SPC Link
Ixekizumab 80mg solution for injection (Taltz®) SMC No. (1223/17) Full submission Accepted restricted	Moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. SMC Restriction: patients who have failed to respond to standard systemic therapies, are intolerant to, or have a contra-indication to these treatments and including patients who have failed on one or more tumour necrosis factor (TNF) antagonists.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts - decision expected by October 2017	SMC Link SPC Link
Nepafenac 3mg/mL eye drops, suspension (Nevanac®) SMC No. (1228/17) Abbreviated submission Accepted	Reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.	Available in line with national guidance Hospital Use Only	SMC Link SPC Link
Ofatumumab 100mg & 1000mg concentrate for solution for infusion (Arzerra®) SMC No: (1237/17) Absence of a submission from the holder of the marketing authorisation Not recommended	Treatment of adult patients with relapsed CLL in combination with fludarabine and cyclosphosphamide.	Not available as not recommended for use in NHS Scotland	SMC Link
Tenofovir alafenamide 25mg film-coated tablets (Vemlidy®) SMC No: (1238/17) Absence of a submission from the holder of the marketing authorisation Not recommended	Treatment of chronic hepatitis B in adults and adolescents (aged 12 years and older with body weight at least 35 kg).	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

Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
Ticagrelor 60mg film-coated tablets (Brilique®) SMC No. (1224/17) Full submission Not recommended	Co-administered with acetylsalicylic acid for the prevention of atherothrombotic events in adult patients with a history of myocardial infarction and a high risk of developing an atherothrombotic event.	Not available as not recommended for use in NHS Scotland	SMC Link
Trastuzumab emtansine, 100mg and 160mg, powder for concentrate for solution for infusion (Kadcyla ®) SMC No. (990/14) Resubmission under the orphan and end of life process Accepted	As a single agent, for the treatment of adult patients with human epidermal growth factor type 2 (HER2)-positive, unresectable locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either: received prior therapy for locally advanced or metastatic disease, or developed disease recurrence during or within six months of completing adjuvant therapy.	Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts– decision expected by September 2017	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 Prescribing of Medicines that are Non-formulary (including Individual Patient Treatment Requests).

Updates from previous SMC Advice

Buprenorphine 5, 10, 15 and 20 microgram/hour transdermal patch (Butec®) SMC No. (1213/17) Following a full submission Accepted restricted	In adults, for the treatment of chronic non-malignant pain of moderate intensity when an opioid is necessary for obtaining adequate analgesia. SMC Restriction: for use in patients over 65 years	Available in line with local guidance for prescribing	SMC Link SPC Links: 15 5, 10 & 20

Tayside Area Formulary (TAF) Updates - May 2017

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	Bismuth subsalicylate 17.5mg/mL oral suspension, 262.5mg chewable tablets added to formulary for use in *H.pylori* eradication therapy where indicated in accordance with local guidance on *H.pylori* testing and eradication for adults.
04.01.01	Zaleplon, Zolpidem and Zopiclone	Zaleplon now non-formulary as discontinued.
04.07.01	Moderate pain (step 2)	Buprenorphine 5, 10, 15, 20 microgram/hr transdermal patches (Butec®) added to formulary restricted to those who cannot take (e.g. swallowing difficulties), or cannot tolerate, a less expensive step 2 analgesic (codeine or tramadol) and only for patients >65 years of age for the treatment of chronic non-malignant pain of moderate intensity. See also SMC advice on page 4.
04.07.04.01	5HT1 agonists	Rizatriptan Melt Wafers formulation removed as discontinued. Replaced with orodispersible tablet formulation.
05.03.01	Nucleoside reverse transcriptase inhibitors	Emtricitabine/tenofovir disoproxil 200mg/245mg film-coated tablets (Truvada®) in combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in adults at high risk added to formulary (Hospital Only) as per SMC recommendations for prescribing via the specialist Sexual Health Service once national implementation arrangements are in place. See also SMC advice on page 3.
05.03.03.02	Chronic hepatitis C	Boceprevir (Victrelis®) capsules and Telaprevir (Incivo®) tablets now non-formulary in accordance with Healthcare Improvement Scotland National Clinical Guidelines for the treatment of HCV in adults.

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Tayside Area Formulary (TAF) Updates - May 2017

TAF Section	Drug(s)/Topic	Changes
06.01.02.06	Sodium-glucose co-transporter 2 inhibitors	Links to MHRA Drug Safety Update: SGLT2 inhibitors: updated advice on increased risk of lower-limb amputation (mainly toes), March 2017 added throughout section.
06.05.02	Selective vasopressin V2-receptor antagonists	Tolvaptan (Jinarc®▼) added to formulary (Hospital Only - Renal Clinic) and Renal Specialist Formulary list. See also SMC advice.
Specialist Formulary Lists	Urology	Urology Specialist Formulary List updated to remove Pentosan polysulphate sodium (Elmiron®) (unlicensed). Antibiotics (temocillin, fosfomycin (unlicensed), ciprofloxacin) have also been removed as these are covered by Antimicrobial guidance.
07.04	Drugs for genito-urinary disorders	Links to Urology referral guidance and protocols replaced with a link to the NHS Tayside Urology website (Staffnet site).
07.04.01	Alpha-blockers	Tamsulosin for off-label indication to enhance expulsion of ureteral stones changed from Amber traffic light to Red traffic light (Hospital Only) in formulary and on Urology Specialist Formulary list. Link to European Association of Urology Guidelines on Urolithiasis updated to latest version. Cost of alfuzosin modified-release tablets in comparison to standard tablets highlighted.
07.04.01	5 alpha-reductase inhibitors	New section added to include finasteride 5mg tablets which was previously in section 06.04.02. Link to MHRA Drug Safety Update: Finasteride: rare reports of depression and suicidal thoughts, May 2017 added.
07.04.02	Botulinum toxin (urinary incontinence)	Link to NICE CG148 Urinary incontinence in neurological disease: assessment and management, August 2012 added.
07.04.03	Drugs used in urological pain	Link to European Association of Urology Guidelines on Urolithiasis updated to latest version.
07.04.04	Bladder instillations and urological surgery	Uro-Tainer® Twin Suby G bladder instillation added to formulary (Green traffic light). Bacillus Calmette-Guerin bladder instillation changed to a generic entry in formulary and on Urology Specialist Formulary list. Out of date links removed. Links to NICE NG2 Bladder cancer: diagnosis and management, Feb 2015 added. Bladder instillations for interstitial cystitis used only by Urology specialists removed from main formulary and listed only on Urology Specialist formulary list as Hospital Only: Sodium Hyaluronate 40mg/50mL (Cystistat®), Sodium hyaluronate 800mg/50mL and Sodium chondroitin sulphate 1g/50mL (2%) (iAluRil®), and Sodium chondroitin sulfate 2% (Uracyst®). Pentosan polysulphate sodium (Elmiron®) (unlicensed) for chronic interstitial cystitis if other treatments such as bladder instillations have been ineffective; now non-formulary.
08.03.04.02	Prostate cancer and gonadorelin analogues	Links to Urology referral guidance replaced with a link to the NHS Tayside Urology website (Staffnet site).
10.01.01	Non-steroidal anti-inflammatory drugs	Link to European Association of Urology Guidelines on Urolithiasis in diclofenac entry updated to latest version.
11.08.02	Ocular peri-operative drugs	Nepafenac 3mg/mL eye drops added to formulary and Ophthalmology Specialist formulary list as Hospital Only (Red traffic light). Nepafenac 1mg/mL eye drops already on formulary.
12.01.01	Corticosteroids	Fluticasone propionate nasal drops (Flixonase® Nasule®) added to formulary and ENT Specialist formulary list – GPs may prescribe under specialist direction (Amber traffic light) for nasal polyps in accordance with the Nasal polyps management algorithm.

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.

CLICK HERE 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. Please direct any queries to either:

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