Nottinghamshire Area Prescribing Committee

Nottinghamshire Joint Formulary Group Meeting Minutes
Thursday 20th May 2021, 2-5 pm
On line Microsoft Teams meeting due to COVID-19

Present:
Tanya Behrendt (TB), Senior Medicines Optimisation Pharmacist NHS Nottingham and Nottinghamshire CCG (Chair)
Steve Haigh (SH), Medicines Information Pharmacist, SFHFT
Debbie Storer (DS), Medicines Information Pharmacist, NUH
Esther Gladman (EG), GP Prescribing Lead, NHS Nottingham and Nottinghamshire CCG
Lynne Kennell (LK), Interface/Formulary Pharmacist, SFHFT
Shary Walker (SW), Interface/Formulary Pharmacist, NUH
Karen Robinson (KR), APC/Interface/Formulary Support Technician, NHS Nottingham and Nottinghamshire CCG
Laura Catt (LC), Prescribing Interface Advisor, NHS Nottingham and Nottinghamshire CCG
Kuljit Nandhara (KN), Deputy Chief Pharmacist, Head of Pharmacy Mental Health Services, NHCT
David Kellock (DK) Consultant, Sexual Health, SFHFT
Hannah Godden (HG), Mental Health Interface Pharmacist, Nottinghamshire Healthcare Trust

In attendance:
Dr Neil Nixon joined the meeting at 14:22hrs for the Agomelatine submission
Dr Ravikanth Gouni, Consultant Diabetologist, joined the meeting at 15:26hrs for the SGLT2 inhibitors traffic light reclassification discussion

SFHT pre-registration Pharmacists observing :
Harry Moore
Charmayne Yen
Aala Ali
Laura Simpson
Denna Jacob
Amaka Okpalugo

Apologies:
David Wicks (DW), GP and Local Medical Committee
Irina Varlan (IV), Specialist Interface Efficiencies Pharmacist, NHS Nottingham and Nottinghamshire CCG
Matthew Elswood (ME), Chief Pharmacist, Nottinghamshire Healthcare Trust
Steve May (SM), Chief Pharmacist, SFHFT
Asifa Akhtar (AA), GP Prescribing Lead, NHS Nottingham and Nottinghamshire CCG
Jill Theobald (JT), Interface efficiencies Pharmacist, NHS Nottingham and Nottinghamshire CCG.
*Post-meeting note JT is currently on secondment to the vaccination programme

Agenda item	Notes
1. Apologies	Noted (see above).
2. Declarations of interest	Nothing declared from members of the group or submitters.
3. Minutes of previous meeting	The minutes were accepted as an accurate record of the meeting.

4. Matters arising and Action Log	**Matters arising:** **Dapagliflozin (Forxiga, AZ) for heart failure- NICE TA679** Nottinghamshire Heart Failure Lights guideline have been updated and emailed out for comment to reflect the traffic light change **ACTION: LK to update and upload** The following 2 items are from the formulary amendments and horizon scanning: **Galantamine (Galzemic®) 4mg/ml oral solution**. . Amber 2 classification had been agreed at APC. KN fed back that this was discussed within NottsHC and it was felt that there was little usage of galantamine liquid so it was not expected to have significant cost implications. **ACTION: KR to make Amber 2** **Bimatoprost & timolol, Eyzeetan®** a preservative-free eye drop available in a multi-dose dropper bottle. LK had attempted to obtain ophthalmological views on preferential use vs UDVs, but nothing had yet been received. **ACTION: LK to pursue discussions with ophthalmology** **Hydroxychloroquine** The recommended monitoring requirements have been updated by The Royal College of Ophthalmologists and were no longer in line with our SCPs. LK has updated the SCPs as per the update and was awaiting agreement from the specialists. As the amendments were minor they will be emailed out to APC members for formal agreement prior to uploading. **ACTION: LK to email APC members** **Chair rota** The chair rota had been updated and linked to the SFHT website. KR to email DW to inform him he is the next chair and provide the link for future meeting dates. **ACTION: KR to contact DW** **Action Log** The action log had been updated with recommendations and prices where applicable; all were noted and agreed by JFG. Rosacea is to be removed from the action log, Dermatology (NUH) does not currently have an antimicrobial champion to take this forward. Efracea® (doxycycline 40mg) indicated for facial rosacea is classed as non-formulary and would therefore require a submission. Once received a rosacea guideline would be recommended. **ACTION: Update log KR** ***** All other items were either completed or included on the agenda. *****
5. New applications	**a) Agomelatine (generic). Dr Neil Nixon joined the meeting at 2.22 pm** SW presented the agomelatine submission to the group. A formulary reclassification for agomelatine had been submitted by Nottinghamshire Healthcare NHS Trust, requesting an Amber 2 classification as a fourth-line option for the treatment of major depression in adults where other antidepressants have proven ineffective or poorly tolerated. Agomelatine is a melatonin receptor agonist and a serotonin receptor antagonist. It is licensed for major depressive episodes in adults.

	Place in therapy of agomelatine was discussed. The NICE depression guideline update is still pending but the draft indicates that first-line antidepressant will still be SSRIs. Agomelatine would serve as a third or fourth line alternative to the current strategies used offering a more favourable side effect profile. Dr Nixon explained that it is particularly useful when sleep is a problem and people want to avoid sedating antidepressants (such as mirtazapine) and antihistamines which can cause next-day hangover effects and increased appetite/weight gain. Agomelatine avoids these side effects due to the different mechanism of action. These benefits of agomelatine are particularly helpful when trauma (PTSD) is an aspect of depression. Poor sleep is common amongst people with complex PTSD so it is helpful to treat both depression and poor sleep with agomelatine. Dr Nixon explained that agomelatine is well tolerated, as shown in the results of the 2018 network meta-analysis by Cipriani *et al* and isn't associated with discontinuation symptoms. Dr Nixon explained that agomelatine is relatively safe compared to other antidepressants but notes the reports of hepatitis and the need for the liver function monitoring protocol. In summary, place in therapy of agomelatine would be further down the line of antidepressants and dependent on the co-existing problems people presented with. TB asked if agomelatine is mentioned in the NICE draft antidepressant update guidance. Dr Nixon confirmed that it isn't mentioned but neither are many other antidepressants as NICE provides more general guidance rather than specific antidepressants. Dr Nixon confirmed that agomelatine isn't included as a 'do not recommend' in the draft NICE guidance. TB asked about liver function monitoring and who would be responsible for this. Dr Nixon explained that secondary care should be agreeable to doing this monitoring in the initiation period. HG clarified that LFTs are required at baseline, 3, 6, 12 and 24 weeks as per the manufacturer's information. It was discussed that the baseline, 3,6 and 12-week monitoring would probably have to be done in secondary care but the 24 week LFT monitoring could be carried out in primary care. DS asked whether any prescribing would be appropriate/ expected outside of NHCT. Dr Nixon confirmed that, with the currently licensed indication, it is expected that current initiation would be by a psychiatrist in NHCT and then to discharge back to primary care once people are settled and well in their mental state. Currently, due to the red traffic light classification patients need to stay within secondary care mental health services for prescriptions despite clinical improvements and stability in a mental state which would support discharge. TB asked about the clinical experience of symptom response times to agomelatine. Dr Nixon explained that the advice is the same as for other antidepressants. Look for an effect within 4-6 weeks and consider increasing the dose to 50mg daily or discontinue treatment if no effect. The effect on sleep may be much quicker, sometimes an improvement is seen within days. EG highlighted that agomelatine has been around for a while so queried why the submission now. There was an initial NICE TA which the manufacturer didn't submit all of the evidence for. Dr Nixon highlighted more recent studies including the 2014 meta-analysis and 2018 network meta-analysis. Also, agomelatine has come off patent so it's cheaper than previously. Clinical experience has shown a good safety profile and acceptability to patients.

	EG asked about the safety of agomelatine in overdose. Dr Nixon explained there is no data to suggest that it is problematic in overdose, it doesn't cause brain effects or QTc prolongation and is, therefore, unlikely to cause cardiac death in overdose. Dr Nixon explains that he feels comfortable using agomelatine in this group and doesn't particularly worry about the risk of overdose. Dr Nixon is not aware of any studies indicating that agomelatine is risky in overdose. TB asked if changing the traffic light classification of agomelatine could result in potential cost implications as usage may increase. Dr Nixon acknowledged this may be the case but highlighted the importance of reviewing therapy and discontinuing if the required effect is not seen. Dr Nixon would be happy for primary care to discontinue agomelatine and doesn't feel that patients would need a referral back to NHCT for cessation of treatment. EG asked about the duration of treatment for agomelatine. Dr Nixon explained that the advice on the duration of therapy is the same as for other antidepressants. People with multiple episodes of depression, high vulnerability and suicidality may need to remain on an antidepressant longer term. A review of ePACT2 data showed that there are approximately 15 patients who have currently prescribed agomelatine in Primary care. Locally only Leicester has it on the formulary as shared care. Agomelatine is on the do not prescribe list in Derbyshire and is Red traffic light classification in Lincolnshire. KN highlighted that the traffic light status of agomelatine seems to vary across the country from being either Red (hospital only) or 3rd/4th line option. Many regions classified it before the newer meta-analyses were published. Some mental health trusts are waiting for the updated NICE depression guidelines. EG was the only GP present and felt that GP colleagues opinions were required before making a decision. **ACTION: SW to take to APC with a recommendation of Amber 2 with a caveat for needing a wider Primary Care opinion. A prescribing information sheet may be required if it becomes amber 2. HG to clarify the proposed place in therapy.** **b) Bempedoic acid with ezetimibe (Nustendi®/ Nilemdo®, Daiichi Sankyo) NICE TA 694** LK presented the Bempedoic acid with ezetimibe TA to the group. NICE published this on the 28th April 2021 requiring implementation by 27th July 2021. Bempedoic acid with ezetimibe is recommended as an option for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults. It is recommended only if: • statins are contraindicated or not tolerated, • ezetimibe alone does not control low-density lipoprotein cholesterol well enough, and • the company provides bempedoic acid and bempedoic acid with ezetimibe according to the commercial arrangement. Bempedoic acid with ezetimibe can be used as separate tablets or a fixed-dose combination.

	Bempedoic acid is available alone and in a combination preparation (Nustendi®) that also contains ezetimibe, but it is more cost-effective to prescribe the combination preparation. A Patient Access Scheme exists, but any saving is likely to be made direct to NHS England. The group recommended an Amber 2 classification for both products in line with the NICE TA, but with encouragement to prescribe the more cost-effective combination product. The hyperlipidaemia guideline will need a slight amendment to include Nustendi®/ Nilemdo®. **ACTION: LK to take to APC** **c) Nutrizym 22® (Pancreatin, Zentiva)** SW presented the submission for Nutrizym 22®. A formulary reclassification for Nutrizym®22 (Pancreatin) was submitted by NUH hepato-pancreato-biliary (HPB) surgical consultants and HPB Dieticians. An Amber 2 classification was requested for the indication of pancreatic exocrine insufficiency in patients experiencing an allergic reaction or intolerance symptoms with Creon®. Nutrizym®22 is currently non-formulary but it is the cheapest and closest alternative to Creon® 25,000. SFHT gastro consultants had been consulted and they were in agreement with the formulary addition. The group agreed on an Amber 2 classification, for second-line use after Creon®. **ACTION: SW to take to APC**
6. Formulary amendments	**FOR INFORMATION - Log of minor amendments carried out** • UCS debridement cloth - Added to Joint formulary as listed in CityCare formulary. • Lisdexamfetamine (Elvanse® Adult) - Brand added to the formulary as licensed in adults whereas Elvanse capsules aren't. Elvanse adult is already widely prescribed Clarification for prescribers to prescribe by brand where possible so it's clear whether to supply Elvanse or Elvanse adult. • Theophylline - Amber 2 classification agreed previously for asthma. Amber 2 classification applied for all conditions. (Theophylline not included in updated COPD guidance.) • Lecicarbon C - Removed temporary green classification for children which applied during bisacodyl shortages as supply problems are now rectified. **FOR DECISION - Suggested amendments** • Hypromellose 0.5% (Isopto Plain®) - Discontinued due to manufacturer of hypromellose withdrawing certificate of suitability, **Recommend** reclassification as grey. Investigate whether all hypromellose products are likely to be affected. • Tiotropium, aclidinium, umeclidinium - Updated COPD guidance now published and LAMAs alone no longer recommended. Existing patients may continue until it is deemed appropriate to change. Tiotropium

	currently green and aclidinium/ umeclidinium currently A3. **Recommend** reclassification as Amber 3 for existing patients, grey for new patients. • Salmeterol, olodaterol, formoterol - Updated COPD guidance now published and LABAs alone no longer recommended. Existing patients may continue until it is deemed appropriate to change. Salmeterol and formoterol currently green and olodoterol currently A3. **Recommend** reclassification as Amber 3 for existing patients, grey for new patients. • **SGLT2 inhibitors traffic light reclassification- Dr Ravi Gouni, Consultant Diabetologist, NUH in attendance** Currently, the SGLT2 inhibitors are classified as Amber 3. The diabetes team put forward a request to reclassify these to green in order to increase their usage. Currently, Nottinghamshire has a lower than average prescribing volume for SGLT2 inhibitors, but a higher than average sulphonylurea usage. Secondary care is getting many unnecessary referrals and it is felt that the current classification is preventing GPs from initiating SGLT2 inhibitors, despite the guideline allowing this. The amber classification could be a barrier for some and many other areas classify these medications as green. It was explained that the Nottinghamshire Amber 3 classification is designed to encourage prescribers to use local guidelines and this applies to many other therapeutic areas also. The JFG felt that more education around the traffic light classification was required within Primary Care rather than the re-classification of medications and were minded to keep the Amber 3 classification for SGLT2 inhibitors. Reclassification of gliclazide and pioglitazone as Amber 3 in line with other 2nd line medications for T2DM was also discussed and agreed upon. Metformin reclassification was considered but it was felt that green was appropriate for first-line use. Dr Ravi Gouni agreed to share his slides so that they can be presented at the next APC. **ACTION: LK to liaise with Dr Gouni and take to the APC**
7. Horizon scanning	**New publications for review** • Beclometasone dipropionate/ formoterol fumarate dihydrate/glycopyrronium bromide inhaler (Trimbow®) license extension to include asthma. **Recommend** grey classification no formal assessment for asthma indication. • Mesalazine 1G (Octasa® 1G Suppositories) – Provides a more cost-effective option to Pentasa suppositories. **Recommend** seek gastroenterology opinion as a more cost-effective alternative and refer to efficiencies team if agreed. **NICE Guidelines, TAs and Evidence summaries**

	All Noted
8. **Dates of next meeting**	15th July 2021 (Via Microsoft Teams)- David Wicks to chair
9. AOB	• Blood glucose testing meters- an issue has been raised by the paediatric diabetes team at NUH. The formulary currently has three preferred meters listed for Type 1 diabetics. Due to some issues with the Glucomen Areo meter that was being used, the NUH team wish to use the Freestyle Optium® testing strips which are compatible with the Freestyle Libre reader and don't require a separate meter to be carried by patients. These are considerably more expensive in Primary Care than the formulary products listed. LK is currently in discussions with the team and plans to bring this issue to the next APC. **ACTION: LK to gather more information and bring it to the APC**

The meeting finished at 15:47