

**DRAFT Nottinghamshire Joint Formulary Group Meeting Minutes**

Thursday 18<sup>th</sup> March 2020, 2-5pm

On line Microsoft Teams meeting due to COVID-19

**Present:**

Steve Haigh (SH), Medicines Information Pharmacist, SFHFT (Chair)  
 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  
 Asifa Akhtar (AA), GP Prescribing Lead, NHS Nottingham and Nottinghamshire CCG  
 Tanya Behrendt (TB), Senior Medicines Optimisation Pharmacist NHS Nottingham and Nottinghamshire CCG  
 David Wicks (DW), GP and Local Medical Committee  
 Kuljit Nandhara (KN), Deputy Chief Pharmacist, Head of Pharmacy Mental Health Services, NHCT  
 David Kellock (DK) Consultant, Sexual Health, SFHFT

**In attendance:, NHCT**

Dr Evon Boules; acting NUH Consultant Immunologist and Jonathan Coleman; pharmacist NUH, joined the meeting for items 5a and 5b.  
 Farida Hussain; Consultant Paediatric Nephrologist joined the meeting for item 5c.  
 Dr Gillian Sare, Consultant neurologist, NUH joined the meeting for item 8.

**Apologies:**

Matthew Elswood (ME), Chief Pharmacist, Nottinghamshire Healthcare Trust  
 Hannah Godden (HG), Mental Health Interface Pharmacist, Nottinghamshire Healthcare Trust  
 Steve May (SM), Chief Pharmacist, SFHFT  
 Irina Varlan (IV), Specialist Interface Efficiencies Pharmacist, NHS Nottingham and Nottinghamshire CCG  
 Jill Theobald (JT), Interface efficiencies Pharmacist, NHS Nottingham and Nottinghamshire CCG

| Agenda item                              | Notes   |
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| <b>1. Apologies</b>                      | Noted (see above).  |
| <b>2. Declarations of interest</b>       | Nothing declared from members of the group.<br>Kuljit Nandhara, Deputy Chief Pharmacist, Head of Pharmacy Mental Health Services, NHCT introduced herself to the group as a new member.                                       |
| <b>3. Minutes of previous meeting</b>    | Subject to the correction of a slight typographical error, the minutes were accepted as an accurate record of the meeting.  |
| <b>4. Matters arising and Action Log</b> | <p><b>Matters arising:</b></p> <p><b>Cinacalcet;</b> ePACT usage review has started to show an increase in prescribing. ePACT will be reviewed again in 4 months time.</p> <p><b>ACTION: KR to update the action log.</b></p> |

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|                                   | <p><b>Table of menopausal products;</b> This is now reaching its review date so rather than an interim update for the addition of utrogestan, a full review will be completed.</p> <p><b>ACTION: LK/ KR to review.</b></p> <p><b>Celecoxib (Celebrex®);</b> – No progress yet. LK will bring a formal review of the safety of celecoxib to a future JFG.</p> <p><b>** All other items were either completed or included on the agenda. **</b></p>   |
| <p><b>5. New applications</b></p> | <p><b>a) Ketotifen (Zaditen, Alfasigma) for allergic disorders</b></p> <p>LK presented the ketotifen submission to the group. A formulary submission had been received to add ketotifen 1 mg tablets and ketotifen 1 mg/5ml syrup to the formulary with an Amber 2 classification. The indications covered by the submission were:</p> <ul style="list-style-type: none"> <li>- Chronic spontaneous urticaria resistant to standard treatment and/or not fulfilling eligibility criteria for omalizumab or not responsive to omalizumab</li> <li>- Induced urticaria (including cold or delayed pressure urticaria) resistant to standard treatment</li> <li>- Mast cell activation syndrome (MCAS)</li> <li>- Idiopathic anaphylaxis resistant to standard treatment</li> <li>- Allergic rhino-conjunctivitis: According to the SPC, Ketotifen is licensed to use for symptomatic treatment of allergic rhinitis and conjunctivitis.</li> <li>- Allergic dysmotility and inflammatory responses secondary to food intolerances in children</li> </ul> <p>After initiation, patients will be assessed after 4 to 6 weeks initially then every 6 to 12 months based on clinical need. For some of these conditions, the current alternative would be ciclosporin or prednisolone, so this medication would be preferable from a tolerability perspective.</p> <p>Ketotifen is licensed in adult and paediatric patients for the symptomatic treatment of allergic conditions. The evidence base is extremely limited, but case reports and small historical trials support a benefit. Side effects appear similar to other sedating antihistamines and it is of reasonable cost.</p> <p>It was noted that there is a small amount of prescribing for this medication already in Primary Care and a couple of one-off requests have been received through NUH. Dr Boules joined the meeting, gave an overview and answered question raised. She explained that the NUH service is now seeing increasing numbers of patients with MCAS in whom ketotifen may be indicated and they have recently become aware of its potential benefits for other conditions such as urticaria. Despite it not being included in national guidelines, it is felt that its use could avoid the need for more toxic therapies.</p> <p>It was questioned whether GPs would be able to initiate this medication prior to referral, but it was felt that if patients were not responding to standard options, a specialist review by the allergy clinic is indicated in order to avoid potential misdiagnosis.</p> <p>The group recommended an Amber 2 classification, but requested that patient</p> |

numbers be audited as there have been problems previously with the availability of the licensed product.

**ACTION: LK to take to APC**

**b) Sodium Cromoglicate (Nalcrom, Sanofi) for food allergy, mast cell stabilisation, and systemic mastocytosis**

SW presented the Sodium Cromoglicate submission to the group.

Sodium cromoglicate is licensed as an adjunct to dietary avoidance in patients with food allergy from the age of 2 years old. It is a mast cell stabiliser, which means it reduces the amount of chemicals released by the mast cells.

However, sodium cromoglicate is unlicensed for systemic mastocytosis. It is a recognised treatment for the management of disease-related gastrointestinal symptoms, which is usually used as a 3<sup>rd</sup> line treatment for gastrointestinal symptoms that have failed to respond to H2 blockers and PPIs. As systemic mastocytosis is a rare condition, the availability of evidence is limited to case reports and expert opinion.

Without this option, patients with significant symptoms will need to be considered for immunosuppressive therapy such as prednisolone, interferon, Imatinib and hydroxycarbamide etc. The use of these alternatives is usually undesirable due to the side effect profile.

The group recommended amber 2 for the indications requested.

**ACTION: SW to take to APC**

**c) Solifenacin suspension (Vesicare, Astellas Pharma Ltd) for neurogenic detrusor overactivity in children**

SW presented the submission for Solifenacin suspension for the treatment of Neurogenic detrusor Overactivity (NDO). NDO is a licensed indication of solifenacin suspension for children from 2 to 18 years. It was developed to enable comfortable administration and flexible dosing in the paediatric population.

Farida Hussain (FH) joined the meeting at 3.15pm and explained that the tablet form of solifenacin is currently being used as the third line treatment for NDO. The current practice is to prescribe for 3 to 4 months in the clinic and then request the GP colleagues to continue the on-going prescription thereafter. FH emphasised that there is a small proportion of children in whom swallowing tablets is problematic. FH also informed the committee that their internal guideline is currently being revised to incorporate the solifenacin liquid.

The GPs felt that they rarely prescribe it. However, if liquid is required, this is the most cost-effective and the most appropriate choice. The group recommended Amber 2 with no concerns.

**ACTION: SW to take to APC**

**d) Dapagliflozin (Forxiga, AZ) for heart failure- NICE TA679**

LK presented the dapagliflozin NICE TA679 published on the 24<sup>th</sup> February 2021 requiring implementation by 25<sup>th</sup> May.

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|                                       | <p>Dapagliflozin is recommended as an option for treating symptomatic chronic heart failure with reduced ejection fraction in adults, only if it is used as an add-on to optimised standard care with:</p> <ul style="list-style-type: none"> <li>• angiotensin-converting enzyme (ACE) inhibitors or angiotensin-2 receptor blockers (ARBs), with beta blockers, and, if tolerated, mineralocorticoid receptor antagonists (MRAs), or</li> <li>• sacubitril valsartan, with beta blockers, and, if tolerated, MRAs.</li> </ul> <p>Treatment of symptomatic heart failure with reduced ejection fraction with dapagliflozin should be on the advice of a heart failure specialist. Monitoring should be done by the most appropriate healthcare professional. Dapagliflozin is currently on the formulary for the treatment of diabetes with an Amber 2 classification, but this will be an additional cohort of patients.</p> <p>The JFG discussed this class of medication and felt that usage was likely to continue to increase as more indications are licensed. LK informed the group that the local consensus amongst specialists is that the majority of dapagliflozin use will be as an add-on therapy to sacubitril valsartan. Switching from sacubitril valsartan is unlikely to happen and that sacubitril valsartan will remain first choice therapy for those who are eligible so cost savings are unlikely.</p> <p><b>ACTION: LK to update Nottinghamshire Heart Failure Lights<br/>LK to take to APC</b></p>  |
| <p><b>6. Formulary amendments</b></p> | <p><b>FOR INFORMATION - Log of minor amendments carried out</b></p> <ul style="list-style-type: none"> <li>• Edoxaban (Lixiana<sup>®</sup>) Information added to the joint formulary to reflect SPC guidance that tablets may be crushed and dispersed for patients with swallowing difficulties.</li> </ul> <p><b>FOR DECISION - Suggested amendments</b></p> <ul style="list-style-type: none"> <li>• Dulaglutide (Trulicity<sup>®</sup>) License extension for doses of 3mg and 4.5mg. These are priced equivalent to lower doses already available on the formulary. The JFG agreed to expand the dose range available locally.</li> <li>• Adrenaline 1 in 1000 ampoules. Topical use to reduce surface bleeding in palliative care. Adrenaline topical solution 30ml bottle has recently been classified as Amber 2 for this indication, but this is a special so would not usually be kept in stock. In an emergency the ampoules can be used as an alternative. A request for this to be classified as Amber 2 to allow it to be prescribed in primary care has been received (request attached in the papers). The JFG recommended an Amber 2 classification (highlight that a filter needle is required to draw up for oral surface bleeding).</li> <li>• Canagliflozin, dapagliflozin, empagliflozin,ertugliflozin. A request has been received for the SGLT2 inhibitors to be reclassified from Amber 3 to Green (request attached in the papers).<br/>JFG discussed the appropriateness of a green classification, but felt that an Amber 3 classification was sufficient to allow appropriate usage. It was suggested that education rather than a change in traffic light classification would be required to encourage usage. It was agreed that the traffic light classification of all other 2<sup>nd</sup> line medications eg gliclazide, gliptins and pioglitazones should also be Amber 3 for</li> </ul> |

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|                                   | <p>consistency.</p> <ul style="list-style-type: none"> <li>Galantamine (Galzemic®) 4mg/ml oral solution. New product for the treatment of mild to moderately severe dementia of the Alzheimer type, currently there is no licensed alternative for patients who cannot swallow. Amber 2 classification suggested. KN will discuss at NHCT and establish its potential use/usage.</li> </ul> <p><b>ACTION: KN to update with her findings</b></p> <ul style="list-style-type: none"> <li>Silver nitrate 75% for traffic light reclassification. Currently listed are 95% (green) and 40% (red for umbilical granulomas). Both 75% and 95% are licensed for removing granulation tissue, warts (including verrucae), for cautery and as a caustic. Discussion took place around the requirement for both strengths, but it was highlighted that the 75% is recommended in speciality guidance that stoma nurses follow. LK will review current usage.</li> </ul> <p><b>ACTION: LK to take all to APC</b></p> <p><b>FOR INFORMATION – MHRA</b><br/>Safety alerts were noted.<br/>Due to now having Medicines Safety Officers (MSO) within the CCG who review these alerts, in future these with not be included unless the APC team feel that discussions are required.</p>   |
| <p><b>7. Horizon scanning</b></p> | <p><b>New publications for review</b></p> <ul style="list-style-type: none"> <li>Salmeterol xinafoate/fluticasone propionate inhaler, Fixkoh Airmaster®<br/>New medication, Grey- new initiations of fluticasone/salmeterol not recommended.</li> <li>Magnesium citrate Magnesium, Kora Healthcare® Magnesium Kora Healthcare® is indicated for the treatment and prevention of magnesium deficiency in adults, adolescents and children aged from 12 years. Currently an unlicensed special is used. Price not yet available, consider once a price is released.<br/><b>KR to add to the action log</b></li> <li>Formoterol fumarate dehydrate, budesonide, glycopyrronium (Triexo Aerosphere®). New product<br/><b>Recommend Grey no formal assessment</b></li> <li>Glycopyrronium, formoterol fumarate dehydrate, (Bevespi Aerosphere®)<br/>New product<br/><b>Recommend Grey no formal assessment</b></li> <li><b>Bimatoprost &amp; timolol, Eyzetan®</b> a preservative free eye drop available in a multi dose dropper bottle. Consider preferential use vs UDVs.<br/><b>LK to discuss with ophthalmology</b></li> <li><b>Dexamethasone sodium phosphate, Glensoludex® 2 mg, 4mg and 8mg soluble tablets.</b> New licensed indication added to its SPC: the treatment of coronavirus disease 2019 (COVID-19) in adult and adolescent patients (aged 12 years and older with body weight at least 40 kg) who require supplemental oxygen therapy.<br/><b>No further action- brands not stated on the formulary for dexamethasone</b></li> </ul> |

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|   | <p><b>NICE Guidelines, TAs and Evidence summaries</b></p> <ul style="list-style-type: none"> <li>• Dapagliflozin for treating chronic heart failure with reduced ejection fraction – guidance (TA679) on the agenda</li> <li>• Secondary bacterial infection of eczema and other common skin conditions: antimicrobial prescribing guidance (NG190). Review against local antimicrobial guidelines, obtain opinion from Dr Weston</li> </ul> <p><b>All Noted</b></p>   |
| <p><b>8. Opicapone place in therapy</b></p> | <p>It had been requested that the current restriction on opicapone to second line use after entacapone is removed and this was discussed at the December JFG.</p> <p>LK had attempted to ascertain whether increased use of opicapone could reduce use of adjunctive medications, but as it was not possible to quantify potential reductions, this had not been pursued. The NUH Parkinson’s team had been invited to join the meeting to answer further questions. Feedback from the SFH specialists was awaited.</p> <p>Dr Gillian Sare (GS) joined at 16:15hrs. She explained that from clinical experience with opicapone, there was a desire to be able to use it in some patients without first trialling entacapone. Use of entacapone is limited by diarrhoea and a slow titration period is required before effectiveness can be assessed. In clinical practise, opicapone has been found to be more effective, but opicapone would be avoided in patients with cognitive impairment or frailty.</p> <p>The group had concerns about the lack of published evidence showing benefit of opicapone compared to entacapone and the significantly greater cost. GS suggested that there is a cohort of patients where the benefits of opicapone justify the cost and defined these to be those with significant and/or disabling motor fluctuations, especially younger patients that may still be working. The group requested that the clinicians put together some restriction criteria ahead of the next APC.</p> <p><b>ACTION: LK to work with clinicians and take to APC</b></p> |
| <p><b>12. Dates of next meeting</b></p>     | <p>20th May 2021 (Via Microsoft Teams) Tanya Behrendt to chair</p> <p><b>Chair rota:</b> It was requested that the Chair rota is made into a web link so that members can view the most recent version. It was highlighted that this should be hosted on the N3 server so that names of chairs are not in the public domain prior to the meetings.</p> <p><b>ACTION: KR/LK to update and upload</b></p>  |
| <p><b>13. AOB</b></p>                       | <p>Zonisamide liquid- this has been added to the formulary following a request from paediatrics and was discussed at the last APC meeting. It had since been questioned whether it should also be available for adult patients. The group were in agreement with this but asked for potential patient numbers to be obtained ahead of APC.</p>   |

Hydroxychloroquine- The recommended monitoring requirements have been updated by The Royal College of Ophthalmologists and are no longer in line with our SCPs. It was questioned whether an interim update is required as the ophthalmological monitoring is the responsibility of specialists. TB had been in some previous discussions about this which will be picked back up.

**ACTION: LK/TB to discuss and bring to APC if needed**

COPD Guideline- TB gave an update on the COPD guideline which had been delayed due to the Covid-19 response. It is due for discussion at the next APC, but she highlighted that specialist engagement had been lacking and requested contacts for the next update.

Azithromycin monitoring- LC informed the group that the need for ECG monitoring of respiratory patients on long term azithromycin had been questioned. It was suggested that this may be required because of potential QTc prolongation.

**ACTION: LC to gather further information and bring to APC.**

The meeting finished at 16:36pm

DRAFT