Nottinghamshire Area Prescribing Committee

Nottinghamshire Joint Formulary Group Meeting Minutes
Thursday 17th December 2020, 2-5pm
On line Microsoft Teams meeting due to COVID-19

Present:
Debbie Storer (DS), Medicines Information Pharmacist, NUH (Chair)
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
Steve Haigh (SH), Medicines Information Pharmacist, SFHFT
David Wicks (DW), GP and Local Medical Committee.
Jill Theobald (JT), Interface efficiencies Pharmacist, NHS Nottingham and Nottinghamshire CCG (left after item 5)

In attendance:
Dr Rahul Mohan, GP and Bev Green, Diabetic Nurse Specialist for item 6
Dr RS Ayyalaraju, Consultant Dermatologist NUH for item 6

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
David Kellock (DK) Consultant, Sexual Health, SFHFT (Chair)

The meeting was not quorate due to having no NHCT representative, however as the group are advisory only it was decided that the meeting could commence with NHCT reviewing the minutes ahead of publication

Agenda item	Notes
1. Apologies	Noted (see above). Currently there was no NHCT representative for JFG. NHCT were currently in the process of recruiting a Deputy Chief Pharmacist and it is understood that they will also become the JFG representative.
2. Declarations of interest	Nothing declared from members of the group. The submitter for item 6a had presented an educational talk at the National PCDS Conference.
3. Minutes of previous meeting	Subject to the correction of a slight typographical error, the minutes were accepted as an accurate record of the meeting.
4. Matters arising and Action Log	**Matters arising:** **Sotagliflozin** (SGLT2/1) TA622, Feb 2020 - not yet available in the UK. **Action: KR to check launch date and price prior to APC, Jan 21.** **Utrogestan**- Green classification was approved at APC. Update to the table of menopausal products is in progress.

	Action: LK to finalise update of the HRT choices table and share via e mail **Action Log:** **Celecoxib** (Celebrex®) - LK will bring a formal review of the safety of celecoxib to a future JFG. **Action: LK to review** **Betesil® (Betamethasone) Plaster,** 6 month ePACT prescribing data shows that there has been significantly less prescribed than the original submission had estimated. **Cinacalcet,** ePACT usage data to be reviewed Feb 21. ***** All other items were either completed or included on the agenda. *****
5. Choice of Vitamin D preparation	Nottingham and Nottinghamshire CCG have issued an updated vitamin D position statement that includes stronger wording about the need for people to purchase their own vitamin D supplements for maintenance and prevention of deficiency. It also states that repeat prescriptions will be reviewed with the aim of changing to self-care and that if prescribing needs to continue then it should be prescribed as the food supplement, ValuPak. The APC guidance currently states that only licensed products may be prescribed and the preferred brand is Stexerol. JT suggested that the guidelines be updated with the following changes: • Removal of preferred brand (Stexerol) from flow chart. No change to recommended dose. • Appendix 3 - Updated price for purchasing OTC vitamin D from less than £3 for 3 months' supply to less that £5. • Appendix 4: Removed statements about only prescribing licensed products, • Table 3 – Maintenance dose table. Updated prices and removal of preferred brand information. Addition of information about gelatin content of ValuPak, and note that it is a food supplement. Removal of information about peanut/soya allergy and added link to SPS document that covers this instead. JFG were supportive of these changes. In addition, all references to micrograms should be written in full and it must be clear that ValuPak is a food supplement rather than being an unlicensed medicine. DS asked if reference could be made to the recent NICE rapid evidence review of the role of vitamin D in COVID, JT suggested that this could be added to the Nottinghamshire COVID FAQs rather than the vitamin D guidance. **Actions: JT to update the adult and children's vitamin D guidelines and take to APC in January.** **JT/LC to add link to NICE rapid evidence review for vitamin D in COVID to the COVID FAQs.**
6. New applications	**A) Semaglutide (Nybelsus, Novo Nordisk Ltd)**. Dr Rahul Mohan, GP & Bev Green, Diabetic Nurse Specialist joined the meeting at 2.45pm SW presented the submission for oral semaglutide for the treatment of Type 2 Diabetes Mellitus (T2DM). The submission requested an amber 2 classification for use in line with the NICE recommendations only, similar to the indications of the subcutaneous GLP-1 inhibitors available in the Nottinghamshire formulary. It was highlighted that oral semaglutide has a low bioavailability and therefore, it should be taken with a sip of water 30 minutes before eating, drinking or taking other oral

	medications, and should not be split, crushed, or chewed. The submitters clarified that the patient cohort will be patients where GLP-1 therapy is anticipated to be beneficial in line with NICE recommendations, but subcutaneous administration is a barrier. Moreover, switching from subcutaneous to oral semaglutide was discouraged particularly when the patient is already settled, effectively managed, and happy with their current therapy. Conversely, if switching is necessary, then the dosage should be done in a stepwise manner. The evidence of cardiovascular benefit was discussed. There is a trial currently on-going investigating the cardiovascular benefit of oral semaglutide, results will be available in 2021-2022. However, a previous trial has shown non-inferiority against placebo. Oral semaglutide 14mg daily was found to be as effective as 1mg once-weekly subcutaneously in terms of reducing body weight and HbA1c in an indirect comparison, but the manufacturer states that 14mg oral semaglutide is comparable to 0.5mg subcutaneous semaglutide. It was discussed that thorough consideration should be given to using the injection first line and the oral preparation chosen only when the subcutaneous route is not suitable. Patient education is essential. The JFG recommended that the oral preparation of semaglutide is added to the formulary with an Amber 2 classification, but there should be strict criteria for use and it should be reserved as a second line option for patients unable to receive the medication via the subcutaneous route. **Action: SW to work with submitter to develop criteria for use and take to APC** **B) Liraglutide (Saxenda, Novo Nordisk Ltd)** for managing overweight and obesity (NICE TA) A brief summary of the NICE TA was presented by SW. Liraglutide has been used as an add-on for T2DM for a while but this NICE TA recommendation is for a different dose and a different indication. NICE recommended Saxenda® as an option for managing overweight and obesity alongside a reduced calorie diet and increased physical activity in adults. There were restrictions within the criteria and discussions were focused on the criteria: *"Saxenda should be prescribed in secondary care by a specialist multi-disciplinary tier 3 weight management service and provided according to the commercial arrangement by the company"*. There is no Tier 3 Weight Management service in Nottinghamshire, and therefore it is unclear how to classify for this indication in the formulary. However, Derbyshire provides a Tier 3 weight management service and contact has been made to seek clarity on referrals. **Action: Await feedback from Derby and SW to take to APC** **C) Topical Sirolimus for facial Angiokeratomas.** Dr RS Ayyalaraju, Consultant Dermatologist, NUH joined the meeting at 3.25pm LK presented the formulary application received from dermatologists for topical

	sirolimus for the treatment of angiokeratomas in patients with Tuberous Sclerosis; an Amber 2 classification had been requested. Topical sirolimus is an unlicensed special that is currently prepared by the NUH non-sterile unit. It is not listed in the Specials tariff so prices paid in primary care may be variable. This is a rare condition and there is currently no published guidance, however, it is listed in Specials Recommended by the British Association of Dermatologists for Skin Disease. If the treatment is successful and the effectiveness is established, long term maintenance may be needed. The product has a short shelf life and needs re-issuing monthly. No monitoring is required. There are only a small number of patients in Nottinghamshire and some have successfully gained treatment via individual funding reviews (IFR). Currently there is limited substantive trial data, with some small trials supporting a benefit and the product is generally well tolerated with adverse effects being mainly application site related. Due to the specialist nature, lack of supportive guidance and rarity of the condition, it was felt that the prescribing should be kept within secondary care and a Red classification was suggested. If a licensed product becomes available and once local experience is gained then this could be reconsidered. It was suggested that the service records audit data such as success and discontinuation rates to aid any future reclassification request. **Action: LK to take to APC** **DS to take to DTC** **LK to contact SFH dermatologists to determine whether there may be need for this product at SFH**
7. Formulary amendments	**a) FOR INFORMATION - Log of minor amendments carried out** Freestyle Libre 2 added to the joint formulary. It is priced the same as Libre 1, specialists will switch patients over to Libre 2 and ask that GPs update the repeat. Libre 2 offers the advantage of having an alarm so there is a reduced need for finger prick testing. Covid-19 vaccine had been added to the formulary as GREEN. Information on all vaccines will be added to a single Covid-19 vaccine entry rather than creating separate entries for each brand of vaccine. **b) FOR DECISION - Suggested amendments** A switch from Clenil to Kelhale MDI as beclometasone MDI of choice for new patients had been suggested as part of the Asthma guideline review. This would rationalise to extra fine beclometasone for adult patients. It is licensed for use with an Aerochamber and could result in a small cost saving. Some concerns were expressed such as confusion over potency, the inhalers are white rather than brown with only a coloured cap indicating strength and in addition Clenil is licensed for use in paediatrics and Kelhale isn't. It was suggested that if a change is being implemented, then a Dry Powdered Inhaler should be considered because of environmental factors. **Action: LK to take feedback to the Asthma Guideline review group.** Theophylline traffic light reclassification to Amber 2 was proposed during the update of local asthma guidelines. Theophylline is not included in local guidelines

	and has a limited place in therapy. Specialists feel that all treatment options at Step 4 of the BTS guidelines should be used on specialist advice only (tiotropium, high strength ICS/LABA) **Recommend: Reclassification from Green to Amber 2.** Zinc Sulfate for Zinc deficiency is currently not classified, but effervescent tablets and Zincomed capsules (food supplement) are listed on the formulary. Indications are not listed, but Solvazinc is licensed for zinc deficiency, ePACT shows a small amount of prescribing locally, approx 150 items prescribed per year. Anorexia and gastric bypass were discussed as possible reasons for prescribing although the clinicians present felt it was not something they would commonly initiate. Amber 2 was pragmatically deemed appropriate. **Recommend: Classify as Amber 2.** Risperidone- a 0.25mg strength had been launched and an addition to the formulary had been requested as an alternative to halving tablets or using small volumes of liquid. **Recommend: Add to the formulary with a GREEN classification for the small cohort of patients that are unable to halve tablets or use liquid.** **c) FOR INFORMATION: MHRA or other safety bulletins** MHRA Drug Safety Update November 2020: Bupropion (Zyban): risk of serotonin syndrome with use with other serotonergic drugs **Recommend: Add hyperlink to the formulary** Modafinil (Provigil): Increased risk of congenital malformations if used during pregnancy. This information is already in the draft Amber 2 Narcolepsy information sheet but a link to the MHRA alert will be added. During MSO discussions, it had been noted that there are a small number of paediatric patients prescribed this via the tertiary service and currently on the formulary no distinction is made for paediatrics within the Amber 2 classification. Modafanil is not licensed for children and no dosing information is given in the BNFc. The JFG felt that paediatric use should be classified RED, but the impact of this should be assessed by a review of ePACT. It was also highlighted that there is illicit use of modafanil, for example amongst student populations and a health education message about potential congenital malformations will be needed. This will be passed onto MSOs. **Recommend: Add a hyperlink to the MHRA warning to the formulary and the Amber 2 Narcolepsy information sheet.** **LK to review epact and take a red classification for paediatric patients to APC.** **LK to highlight health education need amongst illicit users to MSOs.** MHRA Drug Safety Update December 2020: Confirmation of guidance to vaccination centres on managing allergic reactions following COVID-19 vaccination with the Pfizer/BioNTech vaccine. This has been added to the vaccine SOP and screening questions for patients no further action required. **Action: LK to take to APC**
8. Horizon	**a) New publications for review**

scanning	Enerzair Breezhaler® (Indacaterol, glycopyrronium, mometasone furoate), Combination triple DPI licensed for maintenance treatment of asthma. **Recommend: Grey no formal assessment, LK to seek opinion from Asthma Specialists regarding interest in this product.** Atectura Breezhaler® (Indacaterol, mometasone) for maintenance treatment of asthma. **Recommend: Grey no formal assessment, LK to seek opinion from Asthma Specialists regarding interest in this product.** Symbicort®, 100 micrograms/3 micrograms/actuation, MDI. Licence extended to include the treatment of asthma in adults and adolescents (12 years and older). Currently the joint formulary states for COPD only. **Action: LK to seek opinion from Asthma Specialists. Remove reference on the formulary to license being only for COPD.** Rebrikel® is a new brand of buprenorphine transdermal patch available in 5micrograms/hour, 10micrograms/hour and 20micrograms/hour strengths only. This brand does offer cost saving efficiencies compared to the formulary brand choice, however safety concerns around the switching of opioid medications have been raised. **Action: The efficiencies pharmacists (JT/IV) will gain opinion from the Nottingham and Nottinghamshire Medicines Optimisation Teams and bring back to APC/JFG for further discussion. Until feedback has been gained Grey was recommended.** Otigo® (Phenazone and lidocaine) 40 mg/10 mg/g ear drops, for middle ear pain relief. **Recommend: Grey no formal assessment.** Zeposia® (Ozanimod hydrochloride) 0.23mg, 0.46mg, 0.92mg hard capsules, indicated for the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS). **Recommend: Grey no formal assessment, likely to fall under the secondary care high cost drug remit.** Fycompa® (Perampanel), has had a license extension which has reduced the age limits of treatment in paediatrics. **Recommend: Updating the age related comment on the Joint Formulary, ensure specialists pharmacist and paediatricians are aware.** Dyzantil® MR (Sodium valproate/ valproic acid) MR 200mg, 300mg, 500mg. **Recommend: Grey no formal assessment** **b) NICE Evidence summaries** Human and animal bites - NG184 update: Recommendations currently under review by microbiology at NUH. Acute coronary syndromes - NG185 update: IV currently reviewing the update with cardiology specialists. **All noted**
9. NICE NG186:	LK highlighted this guidance from NICE for VTE management in patients with

Reducing the risk of venous thromboembolism (VTE) in over 16s with COVID-19 pneumonia	Covid-19 pneumonia. It states that patients in community settings should be risk assessed and treated with enoxaparin. However, the guidance refers to settings in which a hospital clinician is responsible for patient care, so enoxaparin use would be in line with the current Amber 2 formulary classification.
10. Opicapone place in therapy	Opicapone was added to the formulary in May 2017. At that time a restriction to second line use after entacapone was assigned. It has now been requested that the restriction is removed so that it is not necessary to have tried entacapone prior to commencing opicapone. The request follows the publication of the Optapark study and there were supply problems with entacapone in the summer, but these are now resolved. Optapark was a non-comparative open label trial that investigated 3 months of treatment with opicapone 50mg on the Clinicians Global impression of change score. 43% were very much or much improved (an additonal 28.3% were minimally improved). There were statistically significant improvements in non-motor symptoms as assessed by the Non-Motor Symptoms Scale. It was suggested that although opicapone is more costly than entacapone, benefits on non-motor symptoms could reduce costs of other medications currently used to control these symptoms, therefore consideration needs to be given to this. Clinicians should be asked to clarify the benefits that they have seen in practise now some experience has been gained with this medication and confirm whether there would be an intention to switch current patients. **Action: LK to establish if this request is supported by both SFH and NUH and clarify points raised with requestor. LK to assess cost impact of reducing adjunctive medications such as midodrine and glycopyrronium.**
11. Haloperidol choice of formulation	LC on behalf of HG raised a request for haloperidol 0.5mg tablets following the discontinuation of the more cost effective 0.5mg capsules. NHCT are going to be using haloperidol 0.5mg tablets, however these are expensive compared to other formulations and strengths particularly in primary care. Dosing via liquids had raised concerns about the suitability of withdrawing such small volumes (0.25ml) of liquid. SH suggested that a 0.5mg or 1mg dose could be rationalised to 0.75mg and the 1.5mg tablet could be halved, the 0.5mg tablet could be reserved for use in patients who cannot halve tablets or manage to accurately measure the liquid. **Action: HG to gather ePACT data for APC to estimate patient numbers**
12.	**Dates of future meetings Next meeting:** 25th February 2021 2-5pm, via Microsoft teams **Chair rota:** Noted, Steve Haigh to chair meeting on 25th February 2021. **AOB** Nothing raised

The meeting finished at 4.50pm