Nottinghamshire Joint Formulary Group Meeting Minutes
Thursday 18th June 2020, 2-5pm
On line Microsoft teams meeting due to Covid 19

Present:
Tanya Behrendt (TB), Senior Medicines Optimisation Pharmacist NHS Nottingham and Nottinghamshire CCG (Chair)
David Kellock (DK) Consultant, Sexual Health, SFHFT
Debbie Storer (DS), Medicines Information Pharmacist, NUH
Steve Haigh (SH), Medicines Information Pharmacist, SFHFT
Laura Catt (LC), Prescribing Interface Advisor, NHS Nottingham and Nottinghamshire CCG
Esther Gladman (EG), GP Prescribing Lead, NHS Nottingham and Nottinghamshire CCG
Hannah Godden (HG), Mental Health Interface Pharmacist, Nottinghamshire Healthcare Trust
Lynne Kennell (LK), Interface/Formulary Pharmacist, SFHFT
Jill Theobald (JT), Interface Efficiencies Pharmacist, NHS Nottingham and Nottinghamshire CCG
Karen Robinson (KR), APC and Formulary Support Technician, NHS Nottingham and Nottinghamshire CCG
Steve May (SM), Chief Pharmacist, SFHFT
Naveen Dosanjh (ND), Deputy Chief Pharmacist, Nottinghamshire Healthcare Trust
David Wicks (DW), GP and Local Medical Committee.

In attendance:
Sharymar Walker, Interface/Formulary Pharmacist, NUH from July 1st 2020
Dr Sarah Khan, Consultant Oncologist, NUH - for ibandronic acid submission
Miss Anita Juliana, Lead for Menopause and Gynaecology, NUH - for utrogestan submission
Dr Sumeet Singhal, Consultant neurologist, NUH - for methylphenidate/dexamfetamine submission
Geri Gray, Community diabetes specialist nurse – for Humalog 200 submission

Apologies:
None received

Agenda item	Notes
1. Apologies	Noted (see above).
2. Declarations of interest	Nothing declared. A reminder for completion of DOI forms for 2020/2021 was given.
3. Minutes of previous meeting	Accepted as accurate.
4. Matters arising and Action Log	**Celecoxib** (Celebrex®) - SH will bring a formal review of the safety of celecoxib to a future JFG. No update Sodium chloride 3% and 7% solution for nebulisation – DS confirmed that NUH guidelines were now available. **Action: JT to link NUH guideline to Joint Formulary** Semglee (Biosimilar insulin glargine) - Prescribing data shows little usage of Semglee; 146 items in past 12 months representing 0.8% of total glargine pen usage. Semglee is 20% cheaper and Abasaglar 7% cheaper than Lantus. **Action: Interface team to discuss with diabetes nurse specialists and the**

	prescribing data will be promoted to the Medicines Optimisation Teams (MOT). ***** All other items were either completed or included on the agenda. *****
5. New applications	**A) Ibandronic acid (generic) for adjuvant treatment of breast cancer** - LK presented Dr Sarah Khan, Consultant oncologist joined the meeting at 2.15pm A formulary application had been received from oncology at NUH for ibandronic acid to be used as an adjuvant therapy for women with node-positive invasive breast cancer or node-negative invasive breast cancer and a high risk of recurrence. An AMBER 2 classification was requested. Ibandronic acid is not licensed for this indication but the use of bisphosphonates in this way is supported by NICE guidance (NG101, Early and locally advanced breast cancer: diagnosis and management) and is in line with current practice at other local and national breast cancer centres. This intervention is supported by evidence from a large meta-analysis that demonstrated decreased incidence of breast cancer recurrence and decreased mortality at 10 years. The proposal was to give one IV dose of zoledronic acid (if receiving chemotherapy) then a prescription for 3 months of ibandronic acid from the acute trust. The patient would then be invited for a follow up prior to being discharged into the community. A total of 3 years treatment is required. It was confirmed that the responsibility to stop ibandronic acid treatment after 3 years would be that of GPs and the Primary Care Teams, although the duration of treatment will be provided in the discharge letter. Renal function monitoring will be required annually. A potentially more cost effective proposal of giving 6 monthly IV zoledronic acid in the community had been put forward and Dr Khan was asked her opinion on the feasibility of scoping this further. The oncology team had considered IV zoledronic acid but it was felt better for the patient to receive oral medication in the community rather than return to secondary care for treatment. In order to deliver IV zoledronic acid in the community, a specifically commissioned service would be required. The committee felt that this would be the preferred option due to concerns about patient compliance with oral bisphosphonates. The potential use of alendronate and risedronate for this indication was discussed. These medicines are used widely in Nottinghamshire for the treatment of osteoporosis, but Dr. Khan confirmed that there was no evidence to support their use in this indication. The JFG recommended that this request should be approved clinically, but due to the significant cost associated with the intervention, further commissioning approval will need to be sought as this request exceeds the threshold for the APC's financial mandate. **ACTION:** **LK to take to APC with an update on progress of financial business case.** **LK to feedback to submitters about the request to scope a community based IV zoledronic service as a future development.**

	B) Utrogestan (Micronised progesterone, Besins Healthcare (UK) Ltd) - LK presented. Miss Anita Juliana, Lead for Menopause and Gynaecology 2WW service, NUH joined meeting at 3.15pm along with Bella Shah, senior pharmacist NUH. A submission for Utrogestan® 100mg capsules was received from NUH, an AMBER 2 classification was suggested. Progestogens are added to HRT regimens to reduce the increased risk of endometrial hyperplasia and cancer with unopposed oestrogen in women with an intact uterus. Utrogestan® is the only available oral progesterone licensed for use in HRT when separate oestrogen and progesterone products are needed. The Mirena IUS (levonorgestrel 20mcg/24hrs) is an alternative, but it would not suit all women and needs to be fitted. In the current situation of shortage in supply of HRT patches and many other types of HRT, alternatives to standard combination products may also be required. It had been suggested that micronised progesterone has fewer side effects and is considered safer than synthetic progestogens and that it may be associated with a reduced risk of breast cancer and thrombotic risk. However the evidence surrounding these statements was contradictory. Miss Juliana explained that the Utrogestan® submission was for women whom the combined preparations were not suitable due them being considered high-risk patients. The high-risk patient groups included women with increased BMI or a history of thromboembolism or migraines. For these patients the oral route for oestrogen is not recommended leaving just patches and gels as an option. Women who still have a uterus are limited to Evorel Conti® which has no flexibility in the oestrogen dose and not all women tolerate norethisterone. Mirena® coil is an option as separate progesterone, but not all women would chose to have a coil fitted. Other progesterones; medroxyprogesterone and norethisterone, are on the formulary but they are not licensed for HRT and they carry more risk for thrombosis and prostogenic side effects. If the separate oestrogen and progesterone are given the oestrogen dose can be better tailored for patients. Miss Juliana felt that as most patients would prefer one preparation, this wouldn't be prescribed first line, but should be an option for patients unsuitable for standard options. An AMBER 2 classification was requested, but the committee felt that a GREEN classification would be more appropriate and this was agreed for patients in whom standard combination products are unsuitable, such as those at high risk of VTE requiring transdermal oestrogen or variable oestrogen doses. **ACTION:** **LK to develop a definition of the eligible patient cohort with submitter and take to APC.** **If agreed by APC, KR to add Utrogestan to the formulary choices flow chart and table.** **LK to review and add British Menopausal Society guidance link to the formulary.** **C) Methylphenidate (generic) and dexamfetamine (generic) for narcolepsy** - LK presented. Dr. Sumeet Singhal, Consultant Neurologist at NUH, joined the meeting at 3.45pm.

	A submission was received from NUH for the inclusion of methylphenidate hydrochloride and dexamphetamine sulphate on the formulary for narcolepsy, with an AMBER 2 status. They would be second-line options where modafinil was contraindicated or not tolerated. Locally about 10-20% of patients do not tolerate or respond to modafinil. Any decision to use either of these drugs will be a joint decision made in the Neurorespiratory Sleep Clinic, jointly run between Neurology and Respiratory and a proposed treatment pathway was included with the submission. Modafinil is classified as AMBER 2 on the formulary. Methylphenidate is currently not listed on the formulary for this indication. Dexamphetamine is currently listed as GREY (awaiting submission and local guidance). However both agents have historically been prescribed by specialists and some patients receive prescriptions in primary care. There is no currently accepted guidance on the treatment of narcolepsy in the UK. Methylphenidate and dexamfetamine are among the treatments for narcolepsy acknowledged by NICE in its guidance on pitolisant. The RMOC guidance on sodium oxybate requires patients to have tried or have contraindications to more than one stimulant for narcolepsy, and more than one anticataplectic agent before being eligible for sodium oxybate. These medications have been in use for a significant number of years, but have a limited published evidence base. Dr Singhal gave an account of his experience of using them in practice for Narcolepsy. These are well tolerated and effective and patients do not appear to development tolerance. This is also reflected by experience of other colleagues. It was confirmed that methylphenidate is used in preference to dexamfetamine due to cost and slightly improved evidence base. As methylphenidate and dexamfetamine are prescribed on a shared care basis for ADHD in paediatrics, the potential for shared care of these patients was questioned. Dr Singhal explained the monitoring was similar to modafinil but a shared care protocol would not be an issue. Some GPs were already prescribing these medications as it was more convenient for patients. Currently patients who are stable on modafinil are not routinely followed up but they are able to make contact with the narcolepsy clinic when needed, even from other parts of the country should they move. EG and DW thought prescribing was taking place but questioned whether appropriate monitoring is being carried out. The JFG felt that modafinil should be re-classified as shared care along with methylphenidate and dexamfetamine and the monitoring requirements should be highlighted. In order to ensure that these patients are managed appropriately it was felt that this needs to be a properly resourced service. The NUH clinic provides sleep services across the region, and it was highlighted that the APC's decision would only apply to Nottinghamshire patients. Other areas would need to be made aware of any change in traffic light status. **ACTION:** **LK to work with submitter to develop a shared care protocol for modafinil, methylphenidate and dexamfetamine and bring to APC. Flowchart to be updated to reflect treatment options and diagnostic criteria.** **LC/TB to raise with commissioners.**

D) Humalog® 200 (insulin lispro 200 units/ml, Eli Lilly) – LK presented. Geri Gray, Diabetic specialist nurse joined the meeting at 4.30pm.

A formulary application was received from diabetologists at NUH to add the 200 units/ml strength of Humalog® (insulin lispro) to the formulary for patients who require higher doses of insulin due to insulin resistance. It is felt that there are a small group of patients that would benefit from increased blood glucose control using higher concentration rapid acting insulin. Although it is claimed bio-equivalent, in small trials about a 20% decrease of insulin was found.

Humalog® (Insulin lispro) 100unit/mL is available on the formulary; GG explained that the addition of a 200unit/mL option was desired as it offers a smaller injection volume and causes less pain and less chance of creating a lipoma. As the absorption is more efficient, glycaemic control is improved.

To decrease the risk of dosing error, the pens and packaging of the different strengths are different colours and the dose is measured in number of units, although a risk of overdose exists if insulin is withdrawn from the pen using a needle and syringe. Fewer pens are required therefore less fridge storage space is required and there will be less environmental impact from disposable pens. Both strengths of Humalog® are the same price.

As this was a new insulin product, LK had completed an RMOC risk assessment. Points for local implementation were highlighted such as storage and prescribing.

A discussion took place around Humulin R® 500, this is classified Red for use in secondary care, suggestions had been made that the addition of Humalog 200unit/mL could reduce the number of patients on Humulin R 500 but this hadn't been quantified.

The JFG recommended an Amber 2 classification.

ACTION:
LK to take to APC

E) Isocarboxazid - HG presented
Not formally assessed previously.

A submission was received for Isocarboxazid 10mg tablets to be used for Major Depressive Disorder – persistent and treatment resistant without bipolarity. In practice, this often means years of treatment within secondary care before MAOIs are considered, frequently including inpatient admissions and ECT.

The current irreversible MAOI of choice for these patients is phenelzine (AMBER 2). There are on-going supply problems with phenelzine and there has been no UK licensed product available since July 2019 with supply issues likely to continue long term. Patients are currently supported with imported US-licensed product but this is currently unavailable due to a global shortage. Isocarboxazid may therefore be the only effective and tolerable option for people currently on phenelzine, who are now faced with rapid discontinuation. Isocarboxazid is in the same class of antidepressant (irreversible MAOI) as phenelzine and is chemically and pharmacologically similar.

The global supply issue of phenelzine is now critical so action has been taken to

	centralise all patients prescribed phenelzine back to NHCT for slow discontinuation in order to avoid abrupt withdrawal and the associated discontinuation symptoms (risk of hypertensive crisis). There are approximately 25-30 patients across Nottinghamshire in this cohort. 8 of these patients are under the specialist depression service where isocarboxazid is most likely to be initiated. Other patients under local mental health teams will be reviewed on an individual basis to consider a broader range of alternatives (e.g. complete withdrawal of antidepressant treatment or alternative antidepressants) alongside the option of isocarboxazid. The monitoring requirements for withdrawal of phenelzine are weekly blood pressure monitoring due to possible rebound hypertension, then during the two week wash out period between stopping phenelzine and starting isocarboxazid and through the titration period. The initial review of patients has shown that a number of patients have home BP monitoring devices, however a small number may need to be seen in GP practices. Only stabilised patients would be transferred back to GPs, stabilisation will take around two months. The formulary will be linked to flag up MAOI safety warnings regarding interactions and an optimise Rx message will be created. JFG recommended an AMBER 2 classification **ACTION:** **HG to take to APC and feed back to the submitter.**
6. Formulary amendments	**a) FOR INFORMATION - Log of minor amendments carried out** **Retinyl palminate and soft paraffin eye ointment,** VitA-POS® for dry eye the brand name has changed to HYLO-NIGHT® - Formulary amended **Oral rehydration salts -** Electrolade® removed as it has been discontinued. Dioralyte® only prescribable option, but patients should be advised to purchase OTC where possible - Formulary amended **Insulin aspart 100 units per ml** - Fiasp® FlexTouch pre-filled pen - added the name FlexTouch to the formulary entry for clarity between products. **b) FOR DECISION - Suggested amendments** **Zonisamide** - Currently AMBER 2 for adults and children once stabilised on treatment by a specialist. A request had been received from neurologists to remove the requirement for **adult** patients to have been stabilised on treatment by neurologist before transfer to primary care. DW commented that he felt GPs would be uncomfortable initiating antiepileptics in primary care and would prefer patients to be stabilised first. EG and SH felt that it could be acceptable if the titration regimen was clearly stated and there was the option of referring back to neurologists if there was a problem. The committee asked that further GP opinion was sought. **ACTION:** **LK to seek further GP opinion, including that of Khalid Butt as LMC representative.** **Aymes® Shake Compact** (powdered food supplement) - Request to add to formulary with AMBER 3 classification. The committee were minded to recommend approval of AMBER 3 status and addition to the Oral Nutritional

	Supplement (sip feeds) guideline which Matt Lawson, Senior CCG Medicines Management Dietician is currently in the process of reviewing **Evolve HA** - SH has updated the eye lubricant product list to include this – the committee recommended that it should be added to the formulary with a GREEN classification. **Systane® Ultra and Optive® Plus** – Request to change classification from AMBER 2 to GREY for new patients because there were more cost effective options on the eye lubricant formulary, switching current patients to an alternative is not expected. SH had discussed this with SFH ophthalmologists and had their agreement. JFG recommended GREY classification and TB asked that a note be added to the formulary to confirm that there was no expectation to switch existing patients. **ACTION:** **JT to get NUH opinion** **HydraMed® or Xailin Night® -** Request to replace Hylo Night® (was VitA-POS®) with HydraMed and/or Xailin Night® as they are more cost effective. **ACTION:** **LK to discuss with SH post meeting.** **JT to get NUH opinion** **Danazol** - Discontinued and remaining supplies are now exhausted. DHSC guidance recommends that patients taking this for licensed indications are switched to an alternative and those taking for an unlicensed indication are prescribed unlicensed product. **ACTION:** **JT to request that the CCG Medicines Optimisation Team complete an audit in order to establish indications that danazol is being prescribed for prior to APC.** **Levetiracetam –** Request to remove restriction for neurology / paediatrician initiation and advice re contacting medicines management team for advice if patient unable to swallow tablets. JFG agreed with this recommendation. **c) FOR INFORMATION – MHRA** **Valproate Pregnancy Prevention Programme:** temporary advice for management during coronavirus (COVID-19) a link to the alert has been added to the formulary. **Yellow Card reporting during Coronavirus (COVID-19):** New website to report suspected side effects to medicines or medical device and diagnostic adverse incidents used in coronavirus treatment. No further action required. **ACTION:** **LK to take recommendations to APC**
7. Horizon scanning	**a) New publications for review** **Methylphenidate Hydrochloride,** Ritalin XL® is a new product, highlighted to Hannah Goddan **Lenzetto® (estradiol) 1.53 mg/spray, transdermal spray** - JFG recommended GREY no formal submission

	Myloxifin® (naloxone / oxycodone) 5 mg/2.5 mg, 10mg/5mg, 20mg/10mg, 40mg/20mg prolonged-release tablets. Similar to Targinact® which is GREY non-formulary. JFG recommended GREY non-formulary. **Epiduo® (adapalene, benzoyl peroxide) 0.3% / 2.5% gel, JFG recommended** suggested GREEN, but felt that dermatology opinion would be helpful. **ACTION:** **JT to contact Dermatologists for their opinion.** **Buscomint® peppermint oil 0.2ml gastro-resistant capsule** - Mintec is the current formulary choice. **ACTION:** **KR to get pricing information prior to APC** **Amoxicillin 1000 mg Dispersible Tablets-** as an additional formulation **ACTION:** **KR to get pricing information prior to APC** **Otezla® (apremilast) 10mg, 20mg, 30mg tablets** - for the treatment of adult patients with oral ulcers associated with Behcet's disease. Defer to DTCs to consider RED classification. **Staladex® 10.72mg implant pre-filled syringe (leuprorelin acetate**) – JFG recommended investigating cost efficiency further to determine if this would be a suitable option. **ACTION:** **KR to get pricing information prior to APC.** **Jorveza® (Budesonide) 500mcg orodispersible tablets -** defer to DTCs to consider RED classification. **Rybelsus® (Semaglutide) oral -** currently no UK launch date, JFG recommended adding as GREY no formal assessment. **Aklief® 0.005% cream (trifarotene)** - JFG recommended adding as GREY no formal assessment. **b) NICE Evidence summaries** **Sotagliflozin** (SGLT2/1) TA622, Feb 2020 - not yet available in the UK, **ACTION:** **KR to check launch date and price prior to APC**
8. Psoriasis guideline	Dermatologists at NUH had written guidance for managing psoriasis in primary care which was welcomed by JFG. However this contained several products which were not currently listed on the formulary. JFG recommended adding the following products to the formulary: • **Clobavate®** (clobetasone) – recommended adding as GREEN as an alternative to Eumovate® • **Betacap®** (betamethasone valerate 0.1%) – Recommended adding as GREEN to replace Dermovate® scalp application as is more cost effective. • **Psoriderm®** shampoo (coal tar 2.5%) – recommended adding as GREEN as alternative to Capasal® (coal tar 1%) and Alphosyl® (coal tar 5%). • **Polytar®** shampoo (coal tar 4%) – currently GREY with a note that it is

	discontinued, but now available again so recommended adding as GREEN. • **Cocois®** (coconut oil compound containing coal tar 12%, salicylic acid 2% and sulphur 4%) - recommended adding as GREEN as an less expensive alternative to Sebco® (same active ingredients). **Tacrolimus (Protopic®)** – currently Amber 2 (specialist initiation). Dermatologists requested Amber 3 for initiation in primary care in line with this guidance. NICE (CG153) recommends specialist initiation and GPs agreed that would prefer it stay Amber 2, but that initiation could be via "advice and guidance" rather than a referral. **ACTION:** **JT to discuss tacrolimus with specialists** **Trimovate® (clobetasone / oxytetracycline / nystatin)** – suggested as a first line option for flexural psoriasis. EG and DW commented that GPs are discouraged from prescribing Trimovate®, due to risk of antimicrobial resistance, and would prefer that it was removed from the guidance. **ACTION:** **JT to discuss Trimovate® with dermatologists prior to APC.** EG asked why only ointments were recommended and patients often prefer cream as a less greasy option, especially on the face. **ACTION:** **JT to ask dermatologists if creams could be added as an option.** DS requested a patient information leaflet as an appendix or a link to a patient information leaflet. **ACTION:** **JT to add link to patient information leaflet and links to further information for patients.** EG and DW asked that the interface team raise the issue of non-compliance with the emollient formulary in secondary care outpatient prescribing. **ACTION:** **JT to discuss adherence to the emollient formulary with dermatologists.**
9. Interface team update	Irina Varlan returns from maternity leave on 1st July as Interface Efficiencies Pharmacist. Sharymar Walker recruited to the NUH interface formulary pharmacist role and also starts on 1st July.
10. **Dates of future meetings**	**Next meeting:** 20th August 2020 2-5pm, via Microsoft teams
11. Any other business	Nil