DRAFT Nottinghamshire Area Prescribing Committee
Formulary Meeting Minutes
Thursday 16th June 2022, 2-5 pm
Online Microsoft Teams meeting, due to COVID-19

Present:
Steve May (SM), Chief Pharmacist, SFHFT (Chair)
Laura Catt (LC), Prescribing Interface Advisor, NHS Nottingham and Nottinghamshire CCG
Asifa Akhtar (AA), GP Prescribing Lead, NHS Nottingham and Nottinghamshire CCG
Debbie Storer (DS), Medicines Information Pharmacist, NUH
Ann Whitfield (AW), Patient Representative
Katie Sanderson (KS), Patient Representative
David Wicks (DW), GP Prescribing Lead, NHS Nottingham and Nottinghamshire CCG
David Kellock (DK) Consultant, Sexual Health, SFHFT
Kuljit Nandhara (KN), Deputy Chief Pharmacist, Head of Pharmacy Mental Health Services, NHCT
Esther Gladman (EG), GP Prescribing Lead, NHS Nottingham and Nottinghamshire CCG
Jill Theobald (JT), Senior Medicines Optimisation Pharmacist, NHS Nottingham and Nottinghamshire CCG
Jenny Moss Langfield (JML), GP, LMC representative, Nottingham and Nottinghamshire CCG
Sarah Northeast (SN), Advanced non-medical prescriber, Nottingham CityCare

In Attendance
Lynne Kennell (LK), Interface/Formulary Pharmacist, SFHFT
Karen Robinson (KR), APC/Interface/Formulary Support Technician, NHS Nottingham and Nottinghamshire CCG
Shary Walker (SW), Interface/Formulary Pharmacist, NUH
Hannah Godden (HG), Mental Health Interface Pharmacist, NHS Nottingham and Nottinghamshire CCG/NHCT

Apologies:
Steve Haigh (SH), Medicines Information Pharmacist, SFHFT
Tanya Behrendt (TB), Senior Medicines Optimisation Pharmacist, NHS Nottingham & Nottinghamshire CCG

Agenda item	Notes
1. Apologies	Noted (see above).
2. Declarations of interest	None declared
3. Terms of reference (TOR)	LC presented the revised TOR, explaining that these have been updated to reflect the new APC and JFG combined meeting structure. The new structure will give both meetings decision-making authority and it is intended that one month will focus on formulary content, with the next month focusing on guideline content. The bulletin will be produced and circulated bi-monthly to reflect the decisions made at both APC formulary and guideline meetings. Some concerns were raised by members of the group, one being the skill set mix divided across both meetings as it was felt this could lead to a delay in the decision-making process. To prevent this from occurring, it was proposed that both meetings needed at least two doctors in attendance, one of which a GP.

	The members also agreed that another secondary care medic should be in attendance; SFHT already had member representation so, ideally, a second medic should represent NUH. This has been raised in the past and it will be raised again at DTC. It was also highlighted that there is currently no Local Pharmaceutical Committee (LPC) representative, and this will be requested again via the LPC. The patient representatives asked for guidance to be included about the expectations of them in their role as members. **ACTION: LC to update the TOR to reflect the quoracy need for 2 doctors, with at least one being a GP. LC to send out invitations for additional membership and provide guidance for the patient representatives.**
4. Minutes of previous meeting	The minutes of the last meeting were agreed as an accurate record, subject to minor amendments.
5. Matters arising and Action Log	**Matters arising:** **Guanfacine for adult ADHD** LK had previously presented a formulary submission that requested extending the use of guanfacine to adult patients. SM had questioned the validity of the evidence reviewed, due to the utilisation of Likert scales in the clinical trials. LK had investigated this further and had determined that the rating scales used in the trials were standard assessments for ADHD. SM requested statistician input. The Local Enhanced Service (LES) for shared care medicines is currently being reviewed with regard to the addition of guanfacine. Also, publication of the RMOC shared care protocol (SCP) for guanfacine has been delayed. Once these matters have progressed, the local SCP will be brought to APC for ratification. **ACTION: SM to look into concerns about utilising Likert scales further. HG/LK to update on progress with commissioning developments.** **Palforzia update** SW and DS gave an update on Palforzia®. Previously it had been agreed that Palforzia® should remain unclassified while an appropriate service was established, despite NICE compliance not being achieved. This decision was made due to the Nottingham allergy service not having the capacity or the resources for the provision of an appropriate allergy service clinic locally. Members raised concerns about out-of-area patients or private patients having an expectation that GPs will prescribe on-going maintenance treatment. DS explained that this was unlikely to happen imminently due to the 5-month titration window. It was suggested that Palforzia® be raised at the next RMOC meeting, where SM and LC would be in attendance. In the interim, it will remain unclassified. **ACTION: SM and LC to provide an RMOC update at the next APC formulary meeting in August.** **Action Log:** **Trimbow® MDI** – Available data does not distinguish between asthma and COPD indications. Therefore, a more detailed audit is required to determine patient numbers following the approval of the Trimbow® MDI inhaler for asthma. This is currently in progress. **ACTION: SW to feedback audit data at the August APC meeting.**

	Safinamide – epact2 data will be monitored and feedback provided at the August APC meeting. **ACTION: SW/LK to feedback data at the August APC meeting.** ***** All other items were either completed or included on the agenda. *****
6. New applications	**a) Lenzetto® (estradiol transdermal spray, Gedeon Richter)** LK presented a formulary submission for Lenzetto®, estradiol transdermal spray. This is an alternative transdermal oestrogen HRT formulation requested as an addition to the current formulary options of Oestrogel® and oestrogen patches. A green classification has been requested, which is in line with the existing alternative preparations. British Menopausal Society (BMS) suggest that 2 sprays of Lenzetto® daily is approximately equal to 1 pump of Oestrogel® or an estradiol 25 microgram patch, but the maximum licensed dose is 3 sprays daily. There is no direct comparative evidence, but a meta-analysis found it to have an equivalent response to an estradiol patch. The spray offers an alternative formulation of transdermal oestrogen to Oestrogel® and patches. This may be of benefit to women who have experienced sensitivity reactions with other formulations and the quicker drying time compared to a gel formulation may be preferred by some, but it is more costly than alternatives. Recently there have been numerous supply issues around HRT products and Lenzetto® would provide an alternative option. The clinicians present agreed that supply problems have created issues for patients and an alternative formulation would allow for more prescribing options, but longer-term this product should be restricted to use after more cost-effective products have been found to be unsuitable. Oral products should be emphasised as 1st line unless there are contraindications. The APC currently provides an HRT formulary choices document to be used in line with the NICE Menopause Guideline (NG23) and NICE CKS for Menopause. APC formulary members agreed a Green classification with the addition to the HRT formulary choices document to include the number of sprays recommended. It was suggested that longer-term, once supplies of HRT products have settled, HRT prescribing should be audited to ensure that it is in line with formulary recommendations. **ACTION: LK to add to the formulary with a GREEN classification and feedback to clinicians** **KR to add Lenzetto to the HRT formulary choices document.** **LK to add to the action log to review ePACT data for HRT in 6 months.** **b) Venlafaxine and clomipramine for narcolepsy** LK presented a request for venlafaxine and clomipramine to be added to the formulary for narcolepsy with cataplexy. Venlafaxine and clomipramine are established treatments for this indication but have never been considered formally for formulary inclusion. Both medications are on the formulary with a Green classification for mental health indications (venlafaxine is classified Amber 2 when used at doses >300mg daily). A request had been received to add these

	medications to the formulary with an Amber 2 classification for the treatment of narcolepsy with cataplexy. Currently, there is no national guidance on the optimal treatment pathway for narcolepsy (with or without cataplexy) in the UK. These medications are however, listed as treatment options that should be trialled in the NHS England Commissioning policy for sodium oxybate. They are also included in European treatment guidelines. Only a small number of patients are expected to require this treatment and NUH has indicated this to be approximately 10 per year for venlafaxine and 5 per year for clomipramine. APC formulary members agreed an AMBER 2 classification was appropriate but requested clarity from the submitter about monitoring requirements as currently monitoring would only be conducted routinely for higher doses of venlafaxine. **ACTION: LK to clarify monitoring expectations with Neurologists.** **LK to add this indication to the formulary with an AMBER 2 classification.** **c) Rufinamide for adults** Currently, rufinamide is RED and restricted to paediatric neurology for use as an adjunctive treatment for Lennox-Gastaut syndrome. LK presented a formulary request to expand the indication of rufinamide to include its use in adult patients along with a reclassification to Amber 2 for both adults and paediatrics. A classification of AMBER 2 would allow specialist initiation, with a view to the GP taking over after approximately 6 months, once the patient is established on the medication. Rufinamide is licensed in patients aged 1 year of age and older and the current restriction to paediatrics is understood to be because of the origins of the original submission and the usual presentation of this form of epilepsy in childhood. The NUH and SFH epilepsy clinics have approximately 40+ adult patients on this medication and acquire 2-5 patients each year in the transition from paediatrics. All patients and GPs will have direct phone and email access to the epilepsy team. Patients are encouraged to discuss any issues over rufinamide directly with their Neurology team, and not the GP. Paediatric teams are also supportive of reclassification to AMBER 2. The SPC for rufinamide contains warnings about the need for women of childbearing potential to use adequate contraception; concerns were raised about the governance arrangements surrounding use in females of childbearing potential. It was noted that there are national recommendations for valproate to be used on a shared care basis in females of childbearing potential, but this medication has a formal Pregnancy Prevention Programme. It was requested that LK look further into the risks of pregnancy exposure to rufinamide and scope the guidance available for other anti-epileptics. LK highlighted that the transfer of prescribing for the current cohort could result in a cost impact in excess of the current financial mandate. Further discussion will take place outside the APC meeting by the Interface team to determine the appropriate route for financial approval.

	LK informed the APC that since the papers had been distributed, the neurology team had expanded the indication requested to include use outside LGS, which is off-label but in line with NICE guidance. It was agreed that LK would look into this indication further and bring it to the August meeting. The APC agreed a reclassification to AMBER 2 for use in Lennox Gastaut Syndrome, subject to clarification of guidance about use in women of childbearing potential and appropriate financial approval. **ACTION: LK to clarify guidance about use in females of childbearing potential and ascertain financial approval required.** **LK to update the formulary once the above caveats have been satisfied.** **LK to bring revised formulary submission for use outside LGS to August meeting.** **d) Qlaira® (estradiol & dienogest, Bayer plc)** SW presented the formulary request from the NUH Genitourinary Medicine (GUM) team for Qlaira as AMBER 2, as a 5th line oral contraception option, when other combination hormonal contraception (CHC), other progestin-only, copper IUD have been tried, are not tolerated, or are unsuitable (e.g. a patient has uterine structural abnormality).The request for AMBER 2, specialist initiation only, was to ensure that Qlaira is only to be used when other methods are precluded Qlaira® is combined oral contraception (COC), licensed for oral contraception and as a treatment for heavy menstrual bleeding in women without organic pathology who desire oral contraception. It has 17β-estradiol (E2V) as the oestrogen component, which is chemically identical to human oestradiol, and dienogest (DNG), a synthetic progestogen component with a strong progestogenic effect. It has four phases covering 26 days of the active tablets and 2 days of placebo tablets making up the 28-day preparation. The regimen appears complex, but it allows for a stable level of E2V throughout the cycle, preventing "hormonal withdrawal" symptoms and menstrual complaints. According to the journal published by the Faculty of Sexual and Reproductive Healthcare (FSRH), reducing the hormone-free interval has been shown to decrease mood changes, headaches, menstrual loss, and pelvic pain. Studies showed that Qlaira® was equally effective in those over and under 35. The intracyclic bleeding was described as "comparable" between the Qlaira® and Miranova® groups. However, it also showed that Qlaira® users had significantly fewer bleeding/spotting days, with shorter and lighter withdrawal bleeds. More of the women on Qlaira® did not have withdrawal bleeding. All COCs have similar adverse effects and safety precautions, in that all COCs carry an increased risk of venous and arterial thromboembolism with increasing age, a family history of thromboembolism, and obesity. This is consistent with the recommendation from the FSRH. Qlaira® has different missed-pill rules and has five different types and colours of pills. This is potentially a confusing regimen, particularly complicated for dealing with missed pills. In addition, it is considerably more expensive than any of the COCs currently available in the UK and costs about £109 per patient per year. The submitter predicted a small number of patients, around 5-10 outpatients per year. SFH stated that this COC is not currently needed but they are happy to support the submission. EPACT data for the last 12 months showed a total quantity of 4,410 items issued in primary care, which means that there are about 13 patients using Qlaira®.

	The submitter stated that there is a need for Qlaira® in a small number of women, who experienced multiple hormonal side-effects, breakthrough bleeding, and UKMEC3 (UK medical eligibility criteria) where the alternative progestin or the oestradiol can be better tolerated. It was emphasized that Qlaira® is comparatively cheaper than maternity care or an abortion, and is the only licensed COC in the UK for the treatment of heavy menstrual bleeding. Finally, in terms of monitoring, the NUH ISHS complex contraception service stated that they will be responsible for monitoring the patients 3 to 6 monthly, and once stable and settled, the patient will be discharged to primary care, where the GP will continue the BP and BMI monitoring yearly, as a minimum. **ACTION: SW to add to the formulary as AMBER 2 and to add to the action log to review patient numbers via ePACT in 6 months.** **e) Zoely® (estradiol & nomegestrol, Theramex UK Ltd)** SW presented the formulary request from NUH GUM for Zoely® as AMBER 2, 5th line option for oral contraception when other CHCs, other progestin-only, copper IUD have been tried, not tolerated or are unsuitable. Zoely® is a monophasic combined oral contraceptive pill, licensed for contraceptive use. It contains 17β-estradiol, an oestrogen component chemically identical to human oestradiol, and nomegestrol acetate (NOMAC), a progestogen component, with a strong affinity with the human progesterone receptor, strong anti-gonadotrophic, and mild anti-androgenic activity. 1 tablet is to be taken orally daily for 28 days. Each pack starts with 24 white active tablets, followed by 4 yellow placebo tablets, a 24/4 regimen with no pill-free interval. Zoely® was previously submitted in 2014 and was classified as GREY. The minutes stated that the lack of withdrawal bleeding may be disliked by some patients. However, according to the submitter, a lack of withdrawal bleeding may also be considered a benefit by other users. Another point raised at the last meeting was concern that the missed dose advice for Zoely® was confusing, which may lead to a higher risk of contraceptive failure. The submitter therefore requested an AMBER 2 classification, with specialist initiation only, to allow the specialist team to advise on missed pill rules. These rules are also printed on the box for the user to refer to. There has been no new published evidence since the NICE evidence summary review in 2013, but the post-authorisation safety study was published in 2021. The primary objective was to characterise and compare the risk of Zoely® use with the use of levonorgestrel-containing COCs (COC_{LNG}). The study design is a multinational, non-randomised, controlled, prospective, active surveillance study. The baseline characteristics and cardiovascular risk factors at study entry were similar between the user cohorts. There were 101,498 women included in the study. There were no substantial differences between Zoely® users and COC_{LNG} users regarding their risk of thromboembolism. Overall, the study demonstrated a favourable benefit/risk ratio for Zoely®. Zoely® costs about £85.80 per patient per year; it is considerably more expensive than any other COCs currently available in the UK but is cheaper than Qlaira®. The predicted number of patients is small, around 5-10 outpatients per year. ePACT data showed 2,289 items issued in primary care during the last 12 months, with about 6 patients using this item. Zoely® has the same proposed place of therapy, patient cohort, and monitoring requirements as Qlaira®. The APC formulary committee agreed that there are some benefits for some women but felt that there is no advantage in having both expensive COCs containing the almost human-like oestrogen. The committee agreed to accept Qlaira®, due to its being licensed as combined oral contraception and as a treatment for women with

	heavy menstrual bleeding, compared to Zoely®, which is only licensed as an oral contraceptive. **ACTION: SW to add to the formulary as GREY non-formulary**
7. Formulary amendment	**FOR INFORMATION**: The log of formulary amendments already completed was noted by members. GREY no formal assessment: Dressing retention systems e.g., HidraWear®; Olmetec Plus®, hydrochlorothiazide/olmesartan various strengths. RED: OncoTICE®, BCG bladder instillation. Other: Denosumab MHRA safety alert link added to the joint formulary. Itzenal® (Alimemazine liquid), 7.5mg/5ml and 30mg/5ml notify the optimise team to produce a message once the product is available on First Databank. HRT supply:-the British Menopause Society link has been added to the joint formulary. Further clarification was requested for the following two items: Riboflavin: JT highlighted that the formulary amendment request was to link the riboflavin entries together to provide clarity for the Medicines Optimisation (MO) team. **ACTION: SW to investigate the request further.** Stemetil® Syrup (prochlorperazine mesylate): JT commented that the liquid was a syrup with a high sugar content and questioned its suitability in children. **ACTION: KR/SW to investigate further.** Lixisenatide 10micrograms/ 20micrograms treatment initiation packs and lixisenatide 10micrograms/0.2ml solution for injection are being discontinued; LK highlighted that new patients could therefore no longer be commenced on lixisenatide. She had also received further information that lixisenatide 20micrograms is also likely to be discontinued. **ACTION: KR to reclassify lixisenatide as GREY** **FOR DECISION – suggested amendments:** Nustendi®▼ (Bempedoic acid 180mg/Ezetimibe 10 mg) Bempedoic acid:- Request for traffic light reclassification from AMBER 2 to AMBER 3 by Dr Hrushikesh Divyateja, Consultant Lipidologist Nottingham University Hospitals. APC formulary members felt AMBER 3 was appropriate **ACTION: Change to AMBER 3.** Tiotropium inhaler (Tiogiva®):- The NHS secondary care contract for Tiotropium 18 mcg has been awarded to Tiogiva®; SFH is considering switching from Spiriva to Tiogiva® if supplies are required while a patient is in hospital. The products are very similar and Tiogiva® is also the more cost-effective product in primary care.

	ACTION: Add Tiogiva® brand to the formulary to allow use as a cost-effective choice if desired. Cavilon®: :- Historically this product has been GREEN despite not being included in the Barrier preparations formulary last reviewed in June 2021. There is significant usage in primary care and the formulary suggests that it may be used on Tissue Viability advice in secondary care. A review of the traffic light classification and formulary status had been requested. **ACTION: LK/SW to establish usage in secondary care and obtain an opinion from secondary care TVNs.** Ciclosporin (eye section):- A formulary tidy-up had been completed. However, JT suggested further action was needed as the tidy-up did not answer the MO query. **ACTION: SW to determine what changes are required.** Levetiracetam:- Request to remove administration advice for IV preparation from the formulary as the volume stated is inappropriate for children. LK highlighted that this information was readily available elsewhere and not usually detailed on the formulary. **ACTION: KR to remove the IV administration information.** Hydrofilm® plus:- Addition following Mid-Notts wound care formulary update. Post-meeting comment: Hydrofilm® plus is also a product choice for City Care. **ACTION: Add a line to the formulary stating as per County and City Care formularies.** Wound Care formularies:- To be discussed further outside the meeting as there were differences between the County and City Care formularies and these needed further clarification. **ACTION: KR to discuss with SW/LK.**
. Horizon scanning	**New publications for review:** All horizon scanning suggestions were agreed, as follows. VLA2001® ▼ COVID-19 vaccine. 10 dose vial 40 antigen units/0.5ml dose: Confirm if plans for this vaccine to be used locally; no further action at present. Fidaxomicin. Dificlir® 40 mg/ml granules for oral suspension: price equivalent to tablets. **ACTION: KR to add to the formulary as an alternative formulation to tablets.** Leuprorelin mesilate 42mg prolonged-release suspension for injection formulation. Camcevi® :- Price not yet available. Add to action log to review pricing compared to 3-monthly formulations, once a price becomes available. **ACTION: KR to add to the action log and review once a price becomes available.** Melatonin. Adaflex® 1, 2,3,4,5 mg tablets:- Melatonin usage is being reviewed by an ICS-wide steering group. Consideration is being given to switching to

	licensed products in secondary care, but individual products will be considered by DTCs as classified Red. **ACTION: KR to add to the formulary with a GREY no formal assessment classification.** Chloral hydrate 500mg/5ml oral Solution:- licensed solution now available: JT questioned the suitability of the excipients in the solution. LK confirmed this had been discussed with Andrew Wignell, Specialist Paediatric Pharmacist, and the solution was considered suitable. **ACTION: KR to remove reference to solution being unlicensed on the formulary.** NovoPen® 6 and NovoPen® Echo Plus:- Update formulary to reflect pens in use, NovoPen 5s are being phased out and will be discontinued. **ACTION: KR to add NovoPen® 6 and NovoPen® Echo Plus to the formulary as GREEN and make the NovoPen® 5 GREY product discontinued.** Accord® sitagliptin/metformin hydrochloride (bioequivalent generic of Janumet):- **ACTION: KR to genericise the current Janumet® entry on the formulary.** Kinpeygo®, budesonide 4 mg modified-release hard capsule:- **ACTION: KR to make GREY no formal assessment.** **NICE Guidelines, TAs and Evidence summaries:** Noted – no further action required.
9.	**Dosing for oral iron supplements** LK informed members of updated guidance from the BSG for once-daily treatment with oral iron supplements rather than the traditional thrice-daily regimens for iron deficiency anaemia. SFHT gastro teams are switching patients to once-daily regimens. GP members confirmed that this practice is also occurring to some extent in primary care and is supported by NUH gastro teams. It was felt that there may be a lack of awareness in other specialities eg obstetrics and that the recommendations should be published further because of the potential benefits to patients. As this dose is not yet detailed in the BNF, it was requested that some information and a link to the guidance be added to the formulary. It was also highlighted that the SystmOne formulary dosing template should be updated. **ACTION: LK/ SW to publicise in secondary care.** **LK to suggest inclusion in future Hints and Tips newsletter.** **LK to request amendment of SystemOne formulary dosing template.**
10.	**Hormonal treatments for transgender adults** Guidance around hormonal treatments for transgender adults is in development and it had been highlighted that testosterone products did not have this indication listed on the formulary and also that some oestrogen products had been requested which were currently non-formulary. There are a number of supply

	problems with HRT products and Sandrena® gel and Progynova® had been requested as alternative options for use in case of supply problems. The view was expressed that product availability should be equitable across indications. If these products were made available in local guidance and on the formulary for transgender adults, they should also be available to prescribe for HRT. However, specialists felt that there was a need for alternative products to be detailed in guidance because of different dosing for this indication. Without such guidance, clinicians may lack the confidence to prescribe for this indication, whereas guidance for HRT prescribing is more readily available. These specific products were also those listed in the service Specification for transgender adults. It was suggested that if these products are to be included in the guidance, it should be emphasised that they were 2nd line options. Explanatory text will be added to the formulary chapter page when the guidance is ratified and linked, rather than changing the formulary status of individual HRT products. **ACTION: LK/HG to update formulary as above once guidance has been ratified.**
11.	**Dates of future meetings:** • **21st July APC guidelines meeting** (Via Microsoft Teams). • **18th August 2022 APC formulary meeting,** (Via Microsoft Teams). Apologies received from JT and LC.
12.	**Any other business** EG enquired as to when the updated Asthma guideline would be available. KR explained that she had fed back the comments noted at the last APC meeting to the author Peter Richards and was awaiting an update of the document. This item is on the agenda for July's APC guidelines meeting. An update on progress in updating the Diabetes Guidelines was requested. LC explained that a business case had been submitted but the mechanisms for approval within the CCG were unclear. In the meantime, work on updating the guidelines is underway. As an interim measure, LK was working on producing an SGLT2 information document that can then be incorporated into the final diabetes guideline.

The meeting finished at 16:54hrs.