Nottinghamshire Area Prescribing Committee

Nottinghamshire Joint Formulary Group Meeting Minutes
Thursday 21st April 2022, 2-5 pm
Online Microsoft Teams meeting, due to COVID-19

Present:
Laura Catt (LC), Prescribing Interface Advisor, NHS Nottingham and Nottinghamshire CCG (Chair)
Asifa Akhtar (AA), GP Prescribing Lead, NHS Nottingham and Nottinghamshire CCG (left at 4:38pm)
Esther Gladman (EG), GP Prescribing Lead, NHS Nottingham and Nottinghamshire CCG
Hannah Godden (HG), Mental Health Interface Pharmacist, NHS Nottingham and Nottinghamshire CCG/NHCT
Steve Haigh (SH), Medicines Information Pharmacist, SFHFT
Lynne Kennell (LK), Interface/Formulary Pharmacist, SFHFT
Steve May (SM), Chief Pharmacist, SFHFT (left at 4:30pm)
Karen Robinson (KR), APC/Interface/Formulary Support Technician, NHS Nottingham and Nottinghamshire CCG
Debbie Storer (DS), Medicines Information Pharmacist, NUH
Shary Walker (SW), Interface/Formulary Pharmacist, NUH
Ann Whitfield (AW), Patient Representative
David Wicks (DW), GP Prescribing Lead, NHS Nottingham and Nottinghamshire CCG *(joined at 3pm)*

In attendance:
Mariella De Rosa, Obstetrics and Gynaecology Pharmacist, NUH for item 5a
Miss Anita Juliana, Lead for Menopause Service, NUH for item 5b
Simone Stokley, Consultant Paediatric Haematologist, NUH for item 5c
Jackie Dziewanowska, Nurse consultant, NottsHC for item 5d
Helena Nicholson Cardiology specialist pharmacist, NUH for item 6

Rachel Bird, Mandy Lee, Gursimran Singh, Ryan To, Jessica Hall, Grace Murefu, SFHFT Pre-registration Pharmacists, joined the meeting as observers.

Apologies:
David Kellock (DK) Consultant, Sexual Health, SFHFT
Tanya Behrendt (TB), Senior Medicines Optimisation Pharmacist, NHS Nottingham & Nottinghamshire CCG
Kuljit Nandhara (KN), Deputy Chief Pharmacist, Head of Pharmacy Mental Health Services, NHCT

- Due to a lack of NHCT representation, the meeting was not quorate. NHCT will be asked to approve the actions and recommendations ahead of APC.

Agenda item	Notes
1. Apologies	Noted (see above).
2. Declarations of interest	One member had personal experience of taking rivaroxaban for a different indication, but this was not considered to be a conflict for item 5c. No further declarations of interest were declared.
3. Minutes of previous meeting	The minutes of the last meeting were agreed as an accurate record.

4. Matters arising and Action Log	**Matters arising:** **Low Carbon Inhalers** KR explained that the updated adult asthma guideline will be brought to the May APC meeting. The guideline reflects the changes that were previously made to the formulary regarding the choices of low carbon salbutamol inhalers. **Pridinol (Myopridin®) submission** A submission for pridinol had been discussed at the previous JFG meeting. LK updated the group with the further information that had been requested. Surrey APC had recently approved pridinol for short-term use and had been contacted to establish the evidence used in their decision-making. They had acknowledged a lack of good quality evidence in their decision- making and had not considered any evidence additional to that considered at the February JFG meeting. Details of planned publications had been obtained, but these were not RCTs and therefore would not provide any newer evidence than that already obtained. It was highlighted in the update that pridinol is included in German pain treatment guidelines and that imminent NICE guidance on prescribing medications associated with dependence or withdrawal symptoms will limit the situations where diazepam could be prescribed and where pridinol would provide an alternative. The original request was for a GREEN classification, but the submitters had since revised this to an AMBER 2 classification. However, JFG felt that, due to the acute nature of the condition, an AMBER 2 classification would not be appropriate. Evidence of efficacy was discussed and members felt that, although it could potentially be beneficial for this patient group if effective, there was insufficient evidence currently available to support its use locally, and a GREY classification was agreed. **ACTION: LK to take to APC.** **Palforzia update** SW informed the committee that Derbyshire and Leicestershire have classified Palforzia® as RED on their formularies. Leicestershire allergy clinic will be providing this service, but the timeline is still unclear, due to capacity issues. The allergy clinic in Leicester does not yet have a clinical pathway in place so it is unlikely it will be accepting any referrals from the Nottingham allergy service. DS also updated the meeting that the NUH allergy service is waiting for further national guidance and many areas have similar issues. The DTC was reluctant to classify Palforzia® as RED in the formulary if it will not be available for patients. JFG agreed that Palforzia® should remain unclassified, conscious that NICE compliance will not be achieved as there is neither the capacity nor the resources for this service to be provided. **ACTION: SW/ DS to provide a further update at June JFG.** **Chloral Hydrate- Clarification of traffic light classification and indication** APC had agreed with JFG's recommended traffic light classifications. Work is underway with the MSO group to identify current patients in primary care and ensure appropriate review following the MHRA drug safety alert in October 2021 and subsequent NPPG guidance.

	Appropriate repatriation should take place for any patients identified for review as careful withdrawal of the medication will be required. **Action log:** **Desizon (zonisamide) oral suspension 20mg/ml** APC requested an ePACT audit on patient numbers 12 months after the submission approval. In the last 12 months only one prescription has been issued, so numbers are below the submission request. This will now be removed from the action log. **Mesalazine 1G (Octasa® 1G Suppositories)** SFHT have moved to generic prescribing, NUH have decided to remain with Pentasa® suppositories, in line with the NHS contract line. This has been highlighted to the CCG, to demonstrate that not all medication savings identified are possible across the health community. ***** All other items were either completed or included on the agenda. *****
5. New applications	**a) Progesterone micronised vaginal capsules for recurrent miscarriage (Utrogestan®, Besins Healthcare UK) – Mariella De Rosa (MDR), Obstetrics and Gynaecology Pharmacist in attendance.** SW presented a submission for micronised progesterone vaginal capsules. In November 2021, NICE updated their guidance on the management of miscarriage, to offer vaginal micronised progesterone 400mg twice daily to those women with intrauterine pregnancy confirmed by a scan who have vaginal bleeding and have previously had miscarriage/s. NICE also recommends that if there is a confirmed foetal heartbeat, micronised vaginal progesterone treatment should continue until 16 completed weeks of pregnancy. SW highlighted that this is an off-label indication. NICE recommendations were based on the evidence from the multi-centre PRISM trial which concluded that there was "good evidence" that twice daily 400mg of micronised vaginal progesterone increases the number of live births in women with early pregnancy bleeding and a previous miscarriage, with no difference in adverse events likely when compared to placebo. There was no evidence of harm to women or babies following the use of vaginal micronised progesterone (no increased risk of stillbirth, ectopic pregnancy, congenital abnormalities or adverse drug reactions). However, the new guideline also stated that there was "evidence of no benefit" in women with early pregnancy bleeding but no previous miscarriage, nor in women with a previous miscarriage but no early pregnancy bleeding in the current pregnancy. Additionally, the new guideline acknowledged the lack of evidence of benefit for any other forms of progesterone (e.g., dihydrogesterone or 17-hydroxyprogesterone) or for other forms of preparations administered orally or intramuscularly. MDR confirmed and discussed the evidence in the PRISM trial. She explained that patients can refer themselves with bleeding, but it is generally GPs who refer the patients to the clinic and they are seen without delay, the same day. It was highlighted that Cyclogest® pessary is currently being used at SFH; this is a cheaper progesterone alternative. Although it is included in the formulary, indications are not specified and it has never been specifically assessed for this indication. MDR confirmed that Cyclogest® pessary is not being widely used at NUH

	as there are some doubts among clinicians regarding the effectiveness of the intervention. The request to make micronised progesterone available is largely driven by patient demand following its inclusion in NICE guidance. It was suggested that the use of Cyclogest rather than micronised progesterone be explored The predicted patient numbers at SFH are 50, compared to 1,800 at NUH. This will result in a considerable cost impact above the threshold of the APC's mandate and therefore a business case would be required. Some clinical questions were raised, such as the extent of bleeding needed to meet the eligibility criteria and the circumstances of early pregnancy loss that would constitute a miscarriage; MDR felt that it would be more appropriate for a clinician to answer these. **ACTION: SW to take to APC and invite Dr Judith Moore, consultant in Obstetrics and Gynaecology, to answer questions, particularly the clinical queries. SW to seek local specialist opinion on evidence of using Cyclogest® as an alternative.** **b) Testosterone gel for women (Testogel®, Besins Healthcare UK)/ Tostran® (Kyowa Kirin Ltd) – Miss Anita Juliana (AJ), Lead for Menopause Service in attendance.** LK presented the formulary submission for testosterone gel for women. Following several reports of requests for primary care to prescribe testosterone supplementation for post-menopausal women, a formulary application from secondary care clinicians was requested and received. Testosterone therapy for loss of libido in post-menopausal women is supported by NICE in NG23 for women in whom HRT is inadequate. Currently there is no licensed product for this indication available in the UK and the products suggested for formulary inclusion are Tostran® pump and Testogel® sachets, in line with guidance from the British Menopause Society. Due to the low doses required by women, Testogel® requires some estimation by the patient and counselling on administration is required. AJ explained that hair growth is possible, and care is needed to apply the gel to a non-hairy area. Testosterone should be given as a trial for 3 months to determine whether symptomatic benefit is obtained, and women should have been taking HRT for at least 6 months before testosterone is trialled. Evidence supports a value in improving quality of life and it appears to be well tolerated. Miss Juliana confirmed that there are no age restrictions on testosterone therapy and explained that the cardiovascular risk associated with HRT is when it is initiated at older ages; continuing HRT after the age of 60 if indicated is not associated with excess risk. The predicted patient numbers given in the submission were questioned and it was agreed this was probably an underestimate. The British Menopause Society website has guidance that prescribers can follow; however, the recommendations on regular monitoring are vague. AJ did not feel regular monitoring was necessary, but JFG requested that the opinions of other clinicians be sought, including those of an endocrinologist.

	After discussion, JFG felt that an AMBER 2 classification might be appropriate, subject to clarification of potential monitoring requirements and patient numbers. Members felt an information sheet should be provided if the submission was approved. **ACTION: LK to attempt to obtain more definitive potential patient numbers and seek further opinions regarding monitoring.** **LK to take to APC.** **c) Rivaroxaban for paediatric VTE (Xarelto®, Bayer)– Simone Stokley (SS), Consultant Paediatric Haematologist in attendance.** SW presented a formulary submission for rivaroxaban for paediatric VTE. The British Society for Haematology (BSH) have updated their guideline on the investigation, management and prevention of venous thrombosis in children, to now offer rivaroxaban for the treatment of venous thrombosis in people of less than 18 years of age, following at least 5 days of parenteral anticoagulation. Rivaroxaban is licensed for this indication and the suspension is the most cost-effective preparation. It has the advantage of being an oral agent that does not require frequent monitoring. It is more attractive to parents, especially of young children, because it improves quality of life due to there being no requirement for blood test monitoring, unlike the alternatives of warfarin and low molecular weight heparin (LMWH). SS confirmed that, unlike for adults taking rivaroxaban, there are no monitoring requirements for children (e.g., CrCl, dose reduction after 6 months etc.). The dose of rivaroxaban is determined based on body weight. SS explained that the treatment duration will be decided straightaway, and the dosage will remain the same when taken for short durations as there will be no major change to the patient's weight. Ideally, GPs would continue prescribing rivaroxaban for the duration required. She highlighted that there will be oversight by secondary care and this will be coordinated by the child's team, e.g. neuro or paeds, rather than haematology. Dabigatran is also recommended in the BSH guideline but is not yet available in a formulation suitable for paediatric administration, so had not been requested. Some concerns were raised about the presentation of the suspension since two different products are in existence, with different size syringes depending on body weight. Attention will therefore need to be paid to this if approved. The appropriateness of prescribing in primary care was discussed. Generally, treatment of VTE is initially for 3 months but can be extended to 12 months in some circumstances. It was suggested that short courses (e.g., 3 months) should be provided by secondary care, but primary care prescribing would be appropriate for children requiring much longer-term therapy. **ACTION: SW to take to APC.** **d) Guanfacine for adult ADHD (Intuniv®, Takeda)– Jackie Dziewanowska (JD), Nurse consultant in attendance.** LK presented a formulary submission to extend the use of guanfacine to adult patients. Guanfacine is currently on the formulary for use in paediatrics and adolescents for those requiring a non-stimulant as a second line to atomoxetine or

	as an alternative if atomoxetine is clinically inappropriate. This use is currently classified RED, but a reclassification request to AMBER 1 was an item for discussion later in the meeting. An AMBER 1 classification was also requested for adults, subject to it being incorporated into the SCP LES. Guanfacine for adults is included in the RMOC proposals for shared care. The RMOC SCP for guanfacine in ADHD in adults is awaiting sign-off from NHS England. Use of guanfacine in adults is off-label but NICE supports its use if initiated by tertiary care. JD informed the group that guanfacine is considered a last-line medication and that current patient numbers were approximately 50. It was highlighted that the cost was likely to be close to the threshold of APC's mandate. Concern was expressed about prescribing for adults in the primary care setting as actual patient contact might be limited, whereas paediatric care is usually overseen by a parent/ carer. HG explained that as it was a shared care request, care would also remain with Notts HC Trust, with annual reviews and support available from the specialist if needed. JD suggested that these potential issues apply to all ADHD medications and are not specific to guanfacine. Advice was requested on the management of non-attenders, given the need to avoid sudden treatment cessation with guanfacine. It was also highlighted that, in addition to patients newly diagnosed in adulthood, there was a need to consider those individuals who may be transitioning from paediatric to adult services. If shared care is agreed for paediatrics, the need to access a psychiatric hospital for their medication after previously obtaining this via their GP may have a detrimental effect on patients' health. SM questioned the validity of the evidence reviewed, due to the utilisation of Likert scales. LK agreed to investigate this further. As a Local Enhanced Service (LES) agreement would need to be in place prior to any prescribing in primary care and as the RMOC are due to publish their guanfacine in Adults SCP soon, JFG suggested waiting for the RMOC shared care protocol and considering an AMBER 1 classification once it is published. **ACTION: LK to look at supporting evidence in more detail and feed back at June JFG.** **LK/ HG to take to APC once the RMOC SCP has been published by NHS England.** **e) NICE TA773 – Empagliflozin for heart failure (Jardiance®, Boehringer Ingelheim Ltd.)** NICE TA773: Empagliflozin for treating chronic heart failure with reduced ejection fraction was published on10th March 2022, with implementation being required by June 2022. Empagliflozin is recommended as an option for treating symptomatic chronic heart failure with reduced ejection fractions in adults only if it is used as an add-on to optimised standard care with: • angiotensin-converting enzyme (ACE) inhibitors or angiotensin-2 receptor blockers (ARBs), with beta-blockers, and, if tolerated, mineralocorticoid receptor antagonists (MRAs), or • sacubitril valsartan, with beta-blockers and, if tolerated, MRAs

	Treatment of symptomatic heart failure with reduced ejection fraction with empagliflozin should be on the advice of a heart failure specialist. Monitoring should be done by the most appropriate healthcare professional. Dapagliflozin is an alternative already in use for this indication, following a positive NICE TA in 2021. No differences between dapagliflozin and empagliflozin that will impact on current prescribing practice are anticipated, so patient numbers are expected to be in line with current use of dapagliflozin. JFG agreed that an AMBER 2 classification should be recommended. It was highlighted that there had been some interest at NUH in the use of empagliflozin for patients with preserved ejection fraction and it was agreed that it should be made clear that approved use is only in line with the current licence and NICE TA. **ACTION: SW to take to APC.** **KR to amend formulary entries for dapagliflozin and empagliflozin to highlight that SGLT2 usage for heart failure with preserved ejection fraction is GREY: no formal assessment.** **f) NICE TA775 – Dapaglifozin (Forxiga®, AZ) for CKD** NICE TA775 was published in March 2022, requiring implementation by June 2022. Dapagliflozin is recommended as an option for treating chronic kidney disease (CKD) in adults. It is recommended only if: - it is an add-on to optimised standard care including the highest tolerated licensed dose of angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs), unless these are contraindicated, and - people have an estimated glomerular filtration rate (eGFR) of 25 to 75 ml/min/1.73m^2 at the start of treatment and - have type 2 diabetes or have a urine albumin-to-creatinine ratio (uACR) of 22.6 mg/mmol or more. Dapagliflozin is currently classified as AMBER 3 for glycaemic control in type 2 diabetes, as a second- or third-line agent, but a business case for earlier use in patients with cardiovascular disease or heart failure is in development, following the publication of updated NICE NG28 guidance. It is also classified as AMBER 2 for the treatment of heart failure with reduced ejection fraction, in line with NICE TA679. There is expected to be a significant number of patients locally that meet the criteria outlined in NICE TA775 and discussions are ongoing at a regional level regarding implementation and guidance. The potential cost impact has been highlighted to the CCG. Some concerns were raised regarding the likelihood of identification of patients and the implementation of this intervention in primary care. Further clarity was requested on the information that should be given to patients regarding adverse effects and sick day rules. An AMBER 3 classification was felt to be most appropriate and it was agreed that the NICE guidance would be considered appropriate as supporting guidance, in the absence of local or regional guidance.

	ACTION: LK to seek further clarity on the sick day rules advice and take to APC in May.
6 Formulary amendment	**FOR INFORMATION**: The log of formulary amendments already completed was noted by members. **FOR DECISION – suggested amendments:** **Guanfacine –** a request from community paediatrics at NUH to reclassify guanfacine for ADHD in children and young people from RED to AMBER 1 (shared care) had been received. Specialists from SFH and NHCT have been consulted. This is a licensed indication, although the commissioning decision regarding adding this to the shared care LES is still pending. There will be a cost pressure to the primary care prescribing budget, very close to the APC's mandate. **ACTION: HG to chase up LES progress and, if guanfacine is added to the LES, take an updated SCP and guanfacine prescribing information sheet to APC.** **Sharps bins** – A request had been made to add these to the formulary with a GREEN classification, together with information about prescribing and collection. JFG agreed. **Ethyl Chloride Cryogesic Spray –**This is currently classified as GREEN but is no longer prescribable on FP10. A request had been made to consider classifying it as GREY non-formulary. It was felt that this would be inappropriate as there is significant use and it can be obtained through alternative routes. **ACTION: To remain GREEN but add a note that it is not to be prescribed on FP10.** **ONS products –** Completed submission forms received were included. These ONS products requested are the most cost-effective of their types. They were all requested on an AMBER 2 classsification, on a dietitian recommendation - only basis. JFG agreed with their inclusion. **ACTION: SW to take to APC.** **Lokelma® (sodium zirconium cyclosilicate) traffic light reclassification** Helena Nicholson (HN), Cardiology Specialist Pharmacist,NUH. joined the meeting for the discussion. Lokelma® is used for treating hyperkalaemia in adults, in line with NICE TA 599, and is currently classified as RED as it was previously available only in secondary care. A recent update to NICE TA guidance recommends Lokelma® as an option for treating confirmed persistent hyperkalaemia in adults, when started in specialist care for people who are not taking an optimised dose of renin-angiotensin-aldosterone system (RAAS) inhibitors because of hyperkalaemia. Eligibility criteria include: • having a confirmed serum potassium level of at least 6mmol/litre, **and** • not taking an optimised dosage of renin-angiotensin-aldosterone system (RAAS) inhibitor (because of hyperkalaemia), **and**

	• not being on dialysis. The recommendation also states that Lokelma® should be stopped if RAAS inhibitors are no longer suitable. The course length is likely to be indefinite, based on potassium levels. If potassium drops below 3.5mmol/litre, Lokelma® should be stopped. The recommended starting dose of Lokelma® is 10g TDS, followed by a maintenance dose when normal serum potassium levels are reached after 3 days. During the maintenance phase, the minimal effective dose to prevent hyperkalaemia recurrence should be established. The recommended initial dose is 5g daily, which can be titrated up to 10g daily or titrated down to 5g once on alternate days, as needed. If normokalaemia is not achieved within 72 hours, Lokelma® should be stopped. HN explained that currently the community heart failure nurses identify patients who need RAAS inhibitors. The MDT meets weekly to discuss the benefit of adding Lokelma®, then passes the patient's details to the cardiologist for a prescription. The community heart failure nurse also does the monitoring. An AMBER 2 traffic light for Lokelma® will allow patients to obtain ongoing prescriptions in primary care. No additional monitoring will be required in primary care other than that being undertaken currently. Heart failure nurses will continue to identify eligible patients and to monitor patients on Lokelma®. The monitoring results will be available to GPs. JFG agreed that an AMBER 2 classification would be appropriate but requested that the classification is added to the Heart Failure Treatment Guidelines. Lokelma is associated with a significant cost of £1,898 per patient per year for a 5g daily dose. Therefore, potential patient numbers should be clarified, to determine whether the cost implication is within APC's financial mandate. **ACTION: SW to take to APC and include a suggested amendment to the Heart Failure Guidelines.** **SW to clarify potential patient numbers and cost implication.**
7. Horizon scanning	**New publications for review:** All horizon scanning suggestions were agreed. **NICE Guidelines, TAs and Evidence summaries:** Noted – no further action required.
8.	**Dates of future meetings:** • **Next meeting: 16th June 2022** (Via Microsoft Teams). Chair: Debbie Storer • **Chair rota**
9.	**Any other business** **Future meeting change of date:** The October JFG meeting date will move a week earlier to avoid half term. The updated date of 13th October 2022 was agreed. **ACTION: KR to update the meeting date.**

	Silver Nitrate pencils SH raised the listing of various Silver Nitrate strengths on the formulary, questioning whether all were required. The group thought that the different strengths were used for different indications; this will be looked into further. **ACTION: KR to incorporate in formulary amendments.** **Hypothyroidism in Pregnancy Guideline** EG had had cause to use the Hypothyroidism in Pregnancy Guideline recently presented at APC and wondered when it would be published. It was understood that Nichola Butcher, the author, was awaiting feedback from Jennifer Moss Langfield regarding the standardisation of care arrangements across the county. **Action: LC will discuss progress with the author to determine whether the guideline could be published in the interim.**

The meeting finished at 17:10hrs.