These minutes are in draft form until ratified by the committee at the next meeting on 28th February 2024.

Nottinghamshire Area Prescribing Committee Formulary Meeting Minutes

APC Meeting 14th December 2023: Room GF02, Home Brewery Building, Sir John Robinson Way, Arnold, NG5 6DA. The meeting was conducted as a hybrid meeting, with some attendees joining remotely via Microsoft Teams.

All attendees should be aware that public authorities are legally required to comply with the Freedom of Information Act 2000. The minutes and papers from this meeting could be published on the Publication Scheme or internet with all names included unless notified to the Chair before the meeting commences or included in a pre-agreed confidential section due to the sensitive nature of the topic.

Present: -

Laura Catt (LC) (Chair)	**Prescribing Interface Advisor**	**NHS Nottingham & Nottinghamshire ICB**
Tanya Behrendt (TB)	**Senior Medicines Optimisation Pharmacist**	**NHS Nottingham & Nottinghamshire ICB**
Jennifer Moss Langfield (JML)	**GP**	**LMC Representative**
Ann Whitfield (AW)	**Patient Representative**	**Representative for the local population**
Asifa Akhtar (AA) joined remotely.	**GP**	**South Notts PBP, Nottingham & Nottinghamshire ICB**
Dr Khalid Butt (KB) joined remotely.	**GP**	**South Notts PBP, Nottingham & Nottinghamshire ICB**
Dr David Wicks (DW) joined remotely.	**GP**	**Mid Notts PBP, Nottingham & Nottinghamshire ICB**
Deborah Storer (DS)	**Medicines Information Manager and D&T Pharmacist**	**Nottingham University Hospitals NHS Trust**
Steve Haigh (SH)	**Medicines Information and Formulary Pharmacist**	**Sherwood Forest Hospitals NHS Foundation Trust**
Hannah Godden (HG)	**Principal Pharmacist, Adult Mental Health Community Teams**	**Nottinghamshire Healthcare NHS Trust**
Georgina Dyson (GD)	**Advanced Nurse Practitioner**	**CityCare**
Ankish Patel (AP)	**Head of PCN Workforce**	**GP Alliance**

	Nottingham City GP Alliance	
Beth Rushton (BR) joined remotely.	**Senior Clinical Pharmacist**	**Nottingham West PCN**

In Attendance:

Dr Julie Wong, Consultant and Mariella De Rosa, Specialist Pharmacist at NUH, joined for item 5a.
Dr Jane Ravenscroft, Consultant Dermatologist at NUH, joined for item 5b.
Emma Grace, Specialist Pharmacist at NUH, joined for item 5c.

Interface Support (NHS Nottingham & Nottinghamshire ICB):

Lynne Kennell (LK), Specialist Interface & Formulary Pharmacist for SFH, Nottingham & Nottinghamshire ICB
Shary Walker (SW), Specialist Interface & Formulary Pharmacist, Nottingham & Nottinghamshire ICB
Lidia Borak (LB), Interface Pharmacist Nottingham & Nottinghamshire ICB

1. Welcome and apologies.

Noted.

2. Declarations of interest

None declared.

3. Minutes of the last meeting

Accepted as an accurate record of the meeting, subject to minor amendments.

4. Matters arising and action log.

- **NICE TA875 – Semaglutide for weight loss (LK)**

LK informed the committee that the ICS was now non-compliant with this TA, due to a lack of commissioned service to prescribe it. This had been escalated within the ICB.

ACTION: LK to feedback on progress.

- **Intranasal naloxone for substance misuse (LK)**

This had been approved at the previous meeting as AMBER 2, but a Prescribing Guideline had been requested to support a potential AMBER 3 classification. Content suggestions for the guideline were requested from Primary Care but none had been received. It was suggested that Dr Stephen Willott be contacted.

ACTION: LK/HG to feed back to John Lawton.

- **Cyclogest pessaries for preventing pre-term birth (LC)**

A formulary application had been discussed and approved at the previous meeting. Feedback from the submitter was noted about their perception of the meeting experience. Members were reminded of the need for discussions to be relevant to the item presented.

5. New applications

a) Micronised Vaginal Progesterone (Cyclogest®) for threatened miscarriage (SW)

A formulary submission had been received for micronised vaginal progesterone for use in line with NICE NG126. This guidance recommends that these are offered to women with an intrauterine pregnancy confirmed by a scan, if they have vaginal bleeding, and have previously had a miscarriage. A similar submission had been discussed in May 2022, but at that time the Utrogestan® brand had been requested. This is an off-label indication for both brands, but Cyclogest® is the more cost-effective brand, and it has since been clarified within the SPC that Cyclogest® is a micronised progesterone. It also offers environmental advantages due to the plastic applicators provided with Utrogestan®.

APC members agreed with the clinical appropriateness of the medication, but questions were raised about the most appropriate mechanism for prescribing. GP members felt that this would be better suited to be prescribed by the specialist, but as this medication is continued until 16 weeks of pregnancy and women are not routinely retained under specialist care, this was not felt to be a practical option. It was suggested that this should be taken to the Women's and Children's forum via JML and brought back to a future meeting for a decision about traffic light classification.

Due to the potential for large patient numbers, this intervention is associated with a significant cost impact exceeding the APC's threshold for a financial referral, so this will require consideration, depending on the place of prescribing discussions.

ACTION: JML to discuss via the ICS Women's and Children's forum and Interface team to bring back to a future APC meeting for traffic light decision and to escalate for financial sign-off.
SW to update the submitters.

b) Spironolactone for acne (SW)

A submission had been received from Dermatologists for spironolactone for the treatment of acne in female patients older than 18 years. It is not suitable for use in male patients because of adverse effects associated with decreased testosterone levels seen with spironolactone. This is an off-label indication, but it is anticipated that its availability will reduce the reliance on antibiotics by some patients and potentially reduce referrals for isotretinoin.

Trial evidence supported a dose of spironolactone of up to 150mg daily, but it was suggested that 100mg may be the effective dose required, and this may reduce concerns about hyperkalaemia. It was questioned whether this medication would be used long-term, and it was suggested that regular

6-monthly reviews would be required as acne may improve with time, or that the medication should be stopped if there is no significant benefit. Trials without treatment should be encouraged.

The APC agreed with spironolactone being available with an AMBER 3 classification and requested that it be incorporated into the local acne antimicrobial guidelines. Pregnancy concerns should be highlighted in the guidance due to the risk of feminisation of the male foetus.

During discussions it was highlighted that there had been a recent change to the isotretinoin referral process, in response to MHRA requirements for two prescribers to be involved in the decision to commence treatment in patients under 18 years of age. A referral form had been developed that offered the opportunity for the referring clinician to act as the second prescriber, but there is no obligation for them to do this and the form allowed for an option to decline the responsibility.

ACTION: SW to incorporate spironolactone into local acne guidance and take it to the January APC for ratification of AMBER 3 classification.

c) Ticagrelor for stroke prevention (LK)

A formulary application had been received from stroke physicians for the use of ticagrelor following Transient Ischaemic Attack (TIA) or minor stroke, as an alternative to clopidogrel in those with suspected CYP2C19 loss of function ("clopidogrel resistance") or clopidogrel allergy. This is an off-label indication but in line with National Clinical guidelines for stroke.

Short-term use of dual antiplatelet therapy (DAPT) using aspirin and a P2Y12 inhibitor (such as clopidogrel) has been shown to significantly reduce the risk of recurrent ischaemic stroke and major cardiovascular events following TIA and minor stroke. However, clopidogrel is a prodrug requiring conversion into its active metabolite by CYP2C19. It is, therefore, expected that clopidogrel may be less effective for the secondary prevention of stroke in carriers of CYP2C19 loss-of-function alleles. Currently, there is no available test for CYP2C19 loss of function, so patient selection will be based on clinical suspicion. Although the widespread availability of such genomic testing has the potential to significantly change clinical practise, this is thought to be some way off in the future.

Trial evidence supports the increased effectiveness of ticagrelor when compared to clopidogrel for decreasing the incidence of stroke in a population with CYP2C19 loss of function. It was noted that trial evidence for this indication is limited to 90 days, and when used for cardiology indications it is used for a maximum duration of 3 years, with a dose reduction occurring after 1 year.

The APC supported the use of ticagrelor in this population, with an AMBER 2 classification. However, based on the predicted patient numbers provided, the cost impact was in excess of the APC's threshold for a financial referral, so further financial sign-off was required.

It was requested that clinician communication to Primary Care was clear regarding treatment durations.

ACTION: LK to escalate within the ICB for financial sign-off. If approved, the formulary is to be updated with AMBER 2 classification.
LK to feed back to submitters regarding need for clear communication at discharge.

LK to check existing OptimiseRx messages about duration of therapy for ticagrelor to ensure that not contradictory to this indication.

6. Formulary amendments

FOR INFORMATION – Log of minor amendments completed.

Lecicarbon C suppositories- reclassified as GREEN temporarily due to supply problems, for use in children where bisacodyl suppositories would otherwise be indicated. This will be reviewed once the availability of bisacodyl suppositories improves.

Meflynate®, methylphenidate XL capsules – additional and more cost-effective brand of methylphenidate added, with an AMBER 1 classification.

FOR DECISION – Suggested amendments

Riluzole orodispersible film (Emylif) - a request had been received to add this formulation to the formulary for those unable to swallow crushed tablets. It was noted that this product was significantly more expensive than the tablet formulation. APC members questioned why a patient would be unable to swallow a dispersed tablet.

ACTION: LK to obtain further information from the submitter.

7. Horizon Scanning

- **New Horizon Scanning publications for review**

- Sertraline concentrate for oral solution- Requires dilution prior to administration, and concerns raised that this may get overlooked. It contains ethanol, which makes it unsuitable for some patients. It was questioned whether this might be useful for some patients who are discontinuing therapy. However, liquid is not thought to offer significant advantages over tablet formulations; therefore, it is classified as GREY.
- Calcifediol, Domnisol® 266 microgram capsules- GREY no formal assessment.
- Dabigatran and Pradaxa® granules in sachets- significantly more expensive than tablet formulations and alternative DOACs are licensed for manipulation for patients with swallowing difficulties and therefore classified as GREY.
- Estriol 0.5 mg pessary- GREY no formal assessment.
- Levonorgestrel and ethinylestradiol 100/20 microgram tablets, Violite®- GREY no formal assessment.

ACTION: KR/LK to update the joint formulary.

- **New NICE guidelines**

NICE TA919: Rimegepant for treating migraine.

Rimegepant had been approved at the previous meeting with an AMBER 2 classification for the prevention of migraine in line with NICE TA 906. NICE TA919 recommends that rimegepant is an

option for the acute treatment of migraines with or without aura in adults, but only if for previous migraines:
• at least 2 triptans were tried, and they did not work well enough, or
• triptans were contraindicated or not tolerated, and non-steroidal anti-inflammatory drugs (NSAIDs) and paracetamol were tried but did not work well enough.

Neurologists had requested that it be available for Primary Care initiation for the treatment of migraine, because of concerns about service implications due to the potential patient numbers who may be eligible. However, APC members felt that a neurology opinion prior to it being commenced was desirable and did not feel that this would increase referrals to Secondary Care. It was, therefore, approved with an AMBER 2 (specialist advice or recommendation) classification, but it was highlighted that a review of this could be considered once experience had been gained.

ACTION: SW to feed back to Neurology.
SW to update the Headache pathway to include rimegepant.

NICE TA924: Tirzepatide for type 2 Diabetes

Due to time constraints, this item was deferred. Tirzepatide was awaiting launch in the UK.

NICE TA922: Daridorexant for treating long-term insomnia.

Daridorexant is a recently launched hypnotic, recommended by NICE for treating insomnia in adults with symptoms lasting for 3 nights or more per week for at least 3 months, and whose daytime functioning is considerably affected, but only if:
• cognitive behavioural therapy for insomnia (CBTi) has been tried but has not worked, or
• CBTi is not available or is unsuitable.

Currently, there is no service commissioned locally that offers CBTi unless there are other co-existing mental health conditions. Concerns were raised about implementing this guidance without the first-line treatment being available, particularly as it has been predicted that there will be a significant cost pressure associated with the availability of daridorexant. This will be flagged up through Mental Health commissioners.

As it was likely that daridorexant initiation would need to be in the Primary Care setting, it was felt that there needed to be supporting guidance for Primary Care prescribers. It was highlighted that there is no Summary of Product Characteristics available and easily accessible via the EMC website. NICE implementation deadlines were noted, and it was agreed to classify daridorexant as AMBER 3, subject to the ratification of prescribing guidance.

ACTION: LK/LC to raise issues of access to CBTi with ICB Mental Health Commissioners.
LK to contact Primary Care Mental Health leads for opinion on daridorexant.
LK to produce interim Prescribing guidance for daridorexant and take to January APC for ratification.

8. Prescribing of RED medications in Primary Care by specialists (LK/LC)

LK reported that queries had been received about the appropriateness of prescribing RED medicines in Primary Care if a specialist does this, for example GPwSI by the Community Dermatology service. The current definition of a RED medicine implies it being Hospital only. It was agreed to circulate the revised wording via email.

ACTION: LK to email APC members with revised wording for the definition of a RED medicine.

9. Any Other Business

- Apixaban- this is now available generically and represents the most cost-effective DOAC. Prescribing guidance is being updated, but currently, the formulary recommends edoxaban preferentially, and it was requested that this be amended. It is not envisaged that existing patients will be switched, but the APC agreed that apixaban should now be the first- line DOAC for new patients. It was agreed that the edoxaban position statement should be retired, but that the availability situation of apixaban be confirmed before it is recommended.

  Post-meeting note- the supply situation of generic apixaban had been confirmed via Prescqipp and it was understood to be in sufficient supply to support new patients being initiated. If existing patients were to be switched, supplies could not be guaranteed; NHS England is advising not to do so, and this will be highlighted regionally.

ACTION: Interface team to update formulary regarding apixaban being first-line DOAC. Edoxaban position statement is to be retired.

- Face-to-face meetings- it was planned to host the March 24 APC meeting as a hybrid meeting. It was suggested that as the hybrid meeting model had worked well, the same venue was recommended.

- Vitamin D dosing- communications had been circulated about patients purchasing vitamin D supplies, and questions had been raised about appropriate vitamin D doses. It was agreed that APC guidance on doses should be followed.

- Pharmacy First- It was highlighted that this is being relaunched, and it was suggested that it might be useful for Rebecca Dickenson, Community Pharmacy lead at the ICB, to provide the APC with an update at the next meeting.

Action: LC to invite Rebecca Dickenson to a future APC meeting.

- The APC was informed that Sharymar Walker would be leaving the ICB in January. The committee thanked Sharymar for the work she had done for the APC and wished her well in her new role.

Date of next APC Formulary meeting - Thursday, 28th February 2024 (2 pm – 5 pm, MS Teams)
Date of next APC Guideline meeting – Thursday, 18th January 2024 (2 pm – 5 pm, MS Teams)