These minutes are in draft form until ratified by the committee at the next meeting on 19th October 2023

Nottinghamshire Area Prescribing Committee Formulary Meeting Minutes

APC Meeting 17th August 2023: The meeting took place as a web conference using 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**
David Kellock (DK)	**Consultant in Sexual Health & SFH Drug and Therapeutics Committee Chair**	**Sherwood Forest Hospitals NHS Foundation Trust**
Tim Hills (TH)	**Assistant Head of Pharmacy**	**Nottingham University Hospitals NHS Trust**
Jennifer Moss Langfield (JML)	**GP**	**LMC Representative**
Ann Whitfield (AW)	**Patient Representative**	**Representative for the local population**
David Wicks	**GP**	**Mid-Notts PBP, NHS Nottingham & Nottinghamshire ICB**
Khalid Butt	**GP**	**Mid-Notts PBP, NHS Nottingham & Nottinghamshire ICB**
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 ICB**
Adam Stocks (AS)	**Area Pharmacist – Offender Health (Nottinghamshire Cluster)**	**Nottinghamshire Healthcare NHS Foundation Trust.**

In Attendance:

Rebecca Dickenson, Community Pharmacy Clinical and Assurance Lead, attended for agenda item 6) Community Pharmacist Independent Prescribing Update.

Interface Support (NHS Nottingham & Nottinghamshire ICB):

Lynne Kennell (LK), Specialist Interface & Formulary Pharmacist for SFH
Shary Walker (SW), Specialist Interface & Formulary Pharmacist

1. Welcome and apologies.

Apologies received from:
Asifa Akhtar (AA), GP South Notts PBP, Nottingham and Nottinghamshire ICB.
Katie Sanderson (KS), Patient Representative for the local population.
Deborah Storer (DS), Medicines Information Manager and D&T Pharmacist, NUHT.

2. Declarations of interest

APC members and the APC support team made no declarations of interest.

3. Minutes of the last meeting

The minutes from the previous meeting were reviewed and accepted as an accurate record.

4. Matters arising and action log

- **Thealoz Duo® for severe dry eye syndrome**

No further correspondence had been received from the clinicians regarding its potential place in therapy. The committee agreed to remove this item from the action log.

- **NICE TA875 – Semaglutide**

LK informed the members that semaglutide (Wegovy®) remains unavailable in the UK. Surveillance suggested that the product is unlikely to become available until mid-2024.

ACTION: No action is required. To remain classified as GREY.

- **Vaginal lubricants** for post-feminising surgery for transgender patients.

Following a feminising procedure, there is a long-term need for a vaginal lubricant or moisturiser. These products are classified Grey with a direction to self-care. They were previously included in the local Low priority list and PrescQIPP recommends OTC use of vaginal moisturisers and lubricants for vaginal dryness in its menopause briefing.

LK provided an update on the actions suggested at the previous meeting. No correspondence from Notts HC transgender lead had been received. Similarly, the ICB Equality Impact Assessment (EQIA) did not aid the decision-making for this specific query. It was questioned whether other areas had guidance on this issue, but no active decisions appear to have been made elsewhere specifically for this cohort. Derbyshire's formulary recommends self-care for these products.

The committee considered the equity concerns and felt that the recommendation in the formulary, "*Patients should be advised to purchase over the counter, product not recommended for prescribing on the NHS in Nottinghamshire*", should remain for all cohorts.

AW had raised this topic with Healthwatch who had expressed interest in investigating. Therefore it was suggested that these communications could continue and any outcomes could be brought back to the APC.

ACTION: No change in the formulary classification. LK and AW will liaise with the Health Watch team to gain their thoughts.

- **HRT guidelines.**

The committee agreed that the review and development of the HRT guideline will progress following the imminent publication of the NICE HRT guidelines.

- **Shingles vaccination.**

The Green Book has now updated its recommendation; from the 1st of September 2023, Shingrix® will be offered to immunocompetent individuals routinely at 60 years of age and to immunocompromised individuals aged 50 years and over. The formulary has been updated. It was requested that communication on this topic be included in the APC bulletin and Hints and Tips to support practices implementing the update.

ACTION: LK to add this topic to the Hints and Tips and APC bulletin.

- **COVID-19 Treatments**

NICE guidance recommends nirmatrelvir plus ritonavir or sotrovimab as treatment options for patients with COVID-19 who do not need supplemental oxygen and have an increased risk for progression to severe COVID-19. However, appeals were submitted against NICE's draft recommendations for remdesivir and molnupiravir not being cost-effective options.

NHS England published a policy statement that aims to clarify the access to remdesivir and molnupiravir for the period during which the appeal process is conducted. However, local consensus based on clinical experience and expert opinion stated that:

a) remdesivir will not be recommended locally for non-hospitalised patients due to negative NICE appraisal on cost-effectiveness grounds, and there are current supply issues with remdesivir.

b) since molnupiravir is free of charge nationally, this is a cost-effective option and will remain on the formulary until the stock is exhausted.

The APC is asked to endorse this position on behalf of the Nottingham and Nottinghamshire ICS as it extends to the position of these medicines via the CMDU service, which is an ICS service.

The APC agreed to endorse the statement.

ACTION: LC to update the formulary.

5. New applications

- **Intranasal naloxone for substance misuse**

LK presented the formulary submission for naloxone (Nyxoid®) 1.8mg nasal spray. Having nasal naloxone as an additional option to intramuscular naloxone (Prenoxad®) widens access to naloxone and may increase the opportunity to provide potentially life-saving interventions and reduce opioid-related deaths.

Injectable naloxone will remain the first-line option for most service users; however, intranasal naloxone may be a preferred option for a small cohort of patients. These may include:

- Service users who do not inject opioids and prefer a need-free option.
- Service users who no longer inject due to fear of triggers or relapse.
- Service users and staff with dexterity issues may struggle to use the naloxone IM or be at risk of a needle stick injury.
- A family member or carers may feel more comfortable having a non-injectable form of naloxone in emergencies.
- Staff working in other services may be more willing to carry a non-injectable naloxone.
- Nyxoid offers a licensed nasal product for minor service users aged 14 – 17.

Naloxone nasal spray is given as a single 1.8mg dose in one nostril. A second dose may be given if the patient doesn't respond or relapses into respiratory depression. Each pack contains two single-dose sprays. Administration may be compromised if the nasal passages are blocked with blood or mucus or damaged by drug misuse.

There were apprehensions about the requested GREEN traffic light classification. The committee felt it was inappropriate for the GPs to initiate without prior discussion or recommendation by the drug team or take responsibility for training the service user/carer as this is a more specialised area. Therefore, an AMBER 2 classification was suggested as more suitable, with recommendations to initiate remaining within the Substance Misuse Team. There were also some concerns expressed that the ease of access to intranasal naloxone could encourage behavioural risks of the service users, i.e., misuse of higher dosages of illicit drugs due to having a safety net.

The committee was supportive in principle but felt that more information was necessary, such as:

- How to identify the eligible patient? Will the Substance Misuse Service (SMS) identify them?
- How critical is the training, and whose responsibility will that fall?
- Potential patient numbers given that it is desired that this product will increase access to naloxone and estimates given are based on current patient numbers.
- What is the most appropriate classification?

Traffic light suggestion: AMBER 2 classification, following advice and guidance, with a caveat that GPs can initiate within their competence if there is an interest in Substance Misuse.

ACTION: LK to seek further information from submitters and to email members for approval via email.

6. Community Pharmacist independent prescribing update

Rebecca Dickenson (RD), Community Pharmacy Clinical Lead, joined the meeting and updated the committee about the development of the Independent Prescribing in Community Pharmacy Pathfinder model. Initially this will be based on the Community Pharmacy Consultation Service, where a community pharmacist can prescribe a prescription-only medication (POM) on a prescription rather than under a patient group direction (PGD). The second stage will be to develop a Hypertension service.

The aim of the project at this point is about learning from the Pathfinder sites as to how Community Pharmacist prescribers can be used in the NHS.

RD explained that the primary care system platforms, SystmOne, EMIS and OptimiseRx, were not designed for community pharmacy use. However, a bridging computer program is expected at the end of the year. The Community pharmacist will prescribe using a standalone EPS system which may have the function to have a limited formulary added.

Reassurance was provided that there are strict criteria to follow the Joint Formulary and prescribing will be monitored. The need for better IT access connectivity was expressed.

The APC were optimistic about the model, with its potential to ease pressure from General Practise and requested that the APC are kept updated with progress.

7. Formulary amendments

FOR INFORMATION – Log of minor amendments carried out

No traffic light classification change

- Emollients containing urea – the formulary was updated to add "not available on prescription". Emollient formulary to be updated.

- NICE patient decision aid for stopping benzodiazepines or z-drugs– link added to the chapter entry.
- Freestyle Libre 2 sensors – information added about where to obtain a replacement sensor if faulty or damaged.
- COVID-19 vaccine entry updated to reflect vaccines currently offered by the programme.
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GREY

- Sunsense® – discontinued.
- Synalar® C – discontinued.
- Orabase® paste – discontinued with no further stock available.

RED

- Ambrisentan, tadalafil (Adcirca®), macitentan (Opsumit®), riociguat (Adempas®) – classification changed from GREY as these are commissioned via Specialist Centres.

FOR DECISION – Suggested amendments

No traffic light classification change

- Octenilin® Wound Irrigation Solution – restriction lifted to allow practices to prescribe as per SPS recommendation, following discontinuation of Unisept® and Tisept® solutions.

GREY

- Unisept® solution (0.05% solution 100mL and 25mL sachets) – discontinued.
- Tisept® solution (100mL and 25mL sachets) – discontinued.

AMBER 2

- Hydralazine, methyldopa, moxonidine, and minoxidil for hypertension– NICE recommends that specialist advice is sought before prescribing these antihypertensives, and therefore an AMBER 2 classification is more appropriate.

GREEN

- Venlafaxine – the AMBER 2 restriction was lifted for doses ≥ 300mg. This was based on a historical licensing restriction. SNRI blood pressure monitoring advice is available within the formulary. All doses of venlafaxine are now GREEN.

8. Horizon Scanning

- **New Horizon Scanning publications for review**

No traffic light classification

- Metaperex® capsule contains RRR-α-tocopherol 280 mg (equivalent to 400IU of Vitamin E) – add to action log for follow-up review once the price becomes available.
- Empagliflozin (Jardiance®) for CKD– add to action log for review once launched. NICE TA expected Feb 2024.

GREY no formal assessment

- Desmopressin acetate (Demovo® 360 micrograms/mL) oral solution – indicated in the treatment of central diabetes insipidus and the treatment of primary nocturnal enuresis in patients (over 5 years). Several formulations are already available on the formulary and the products are not directly interchangeable.
- Lidocaine and tetracaine 70mg/g + 70mg/g (Pliaglis®) cream.
- Cytisinicline (Belnifrem) 1.5mg tablet (Tabex®) for smoking cessation.
- Drospirenone (Slynd®) 4mg tablet.
- Budesonide and formoterol fumarate dihydrate (GoResp® Digihaler) 160mcg/4.5mcg and 320mcg/9mcg inhalation powder.
- Eszopiclone (Lunivia®) tablets for insomnia.
- Vibegron (Gemtesa®) for overactive bladder.
- Tamsulosin hydrochloride and solifenacin succinate (Vecit®) Modified-release 6mg/0.4mg tablets for LUTS.

AMBER 2

- Fludrocortisone acetate 0.1mg/mL oral solution – licensed for use in primary adrenocortical insufficiency in Addison's disease. Add a note stating, "A licensed liquid is available, but it is expensive compared to standard tablets that can be dispersed in water".

ACTION: Request that the OptimiseRx and SystmOne teams review current messages provided for expensive licensed liquids.

- **New NICE guidelines**

  NICE TA902 – Dapagliflozin for heart failure with preserved or mildly reduced ejection fraction

Dapagliflozin is recommended in NICE TA902 for heart failure with preserved or mildly reduced ejection fraction in adults. Compliance with the TA is required by the 19th of September, 2023.

The current treatment options for heart failure with preserved or mildly reduced ejection fraction in adults are limited to loop diuretics. Dapagliflozin is an additional treatment option for this cohort of patients.

Dapagliflozin is already available locally with an Amber 2 classification for Heart Failure with reduced ejection fraction in line with NICE TA 679. It is also available for treating Type 2 Diabetes (Amber 3) and CKD (Amber 3).

The NICE TA committee concluded that dapagliflozin would be started on the advice of a heart failure specialist who can determine the most appropriate treatment. NICE's guideline on chronic heart failure in adults recommends the measurement of NT-proBNP in people with suspected heart failure, followed by specialist assessment and transthoracic echocardiography.

Financial predictions for local implementation of this TA have been provided to finance. Financial impacts of SGLT2 inhibitors are monitored by the ICB's MO team.The APC approved as AMBER 2 in line with the NICE TA.

ACTION: LK to update formulary.

NICE TA906 – Rimegepant for migraine prevention

The NICE TA906 rimegepant (Vydura®) for preventing migraine was published in July 2023 and required implementation by mid- October 2023.

The NICE TA recommends rimegepant as an option for preventing migraine in adults who have at least 4 migraine attacks but fewer than 15 migraine attacks per month and tried at least 3 preventative treatments that have not worked.

It is an oral treatment in the form of oral lyophilisate. The recommended dose is 75mg every other day, which can be taken with or without meals. The most common adverse reaction

reported was nausea, and the adverse events were mild to moderate in severity. Rimegepant is contraindicated when hypersensitive to the ingredient and also contraindicated if there is end-stage renal or liver impairment. NICE recommends stopping use after 12 weeks if the frequency of migraine attacks does not reduce by at least 50%.

The injectable monoclonal antibodies (erenumab, fremanezumab and galcanezumab) were directly used in the trial as comparators. These injectables are 4th line treatments for migraine and currently RED; NUH consultant neurologist recommendation only locally. Indirect comparisons suggest that rimegepant is likely to be similar to or less effective than these injectables. Having an oral option for fourth-line preventative treatment increases choice and may be preferred by some people.

After including the comparator's confidential commercial discounts, NICE's cost-effectiveness estimates showed that rimegepant is less expensive and less effective than some standard treatments. The Neurology team estimates 30 patients a year. The annual saving estimate when rimegepant is used rather than the injectable monoclonal antibodies for the 30 patients ranges from £80k to £100k.

Derbyshire has changed their formulary for rimegepant to RED (hospital use only). However, the NUH Neurology team suggested it would be appropriate for an AMBER 2 classification. The NICE TA committee acknowledged that rimegepant could eventually be used in primary care but recognised that it would need specialist involvement.

TB highlighted rimegepant being excluded from tariff; therefore, the ICB will bear the cost even if classified as RED. Due to current funding streams, RED was suggested as a suitable traffic light classification as an interim measure until the committee could ascertain further details on the financial implications.

ACTION: TB to link with the HCD team regarding costing and bring it back to the October APC meeting. SW to liaise with NUH for inclusion of rimegepant in the next DTC agenda for an interim RED classification.

9. Biosimilar insulin formulary section review

LC presented the biosimilar insulin formulary review on behalf of the Medicines Optimisation (MO) team.

A local enhanced service is available in primary care, encouraging practices to hold diabetes clinics. The service aimed to upskill the practice staff (nurses) to manage diabetes and are looking into initiating insulin within the practices.

However, some of the insulins were classified as AMBER 2 in the formulary, which requires a specialist to initiate prescribing. This would mean that even if the staff were upskilled, they would not be considered to be specialists so would not be able to initiate. Some of these entries were outdated and required reviewing as they probably were new insulins at the time of the traffic light assignment.

The biosimilar insulins were the first group to be reviewed as part of this work.

Since there is APC guidance available, it was proposed to re-classify all biosimilar insulins as AMBER 3 to allow practices to initiate prescribing of these cost-effective insulins. The

additional wording in the formulary would also help encourage appropriate prescribing.

Issues were raised during this review about Semglee® being recommended as first line insulin glargine in the formulary. Anecdotal feedback had been received from the diabetes team about a lack of support from the manufacturer and inaccuracies in the patient literature. There were also some concerns raised about the product's clinical effectiveness and duration of action in practise. It was suggested that experience of other areas that have large volumes of Semglee prescribing be sought and that potential savings of using Semglee locally be calculated to offer clinicians some perspective on the validity of the anecdotal concerns.

ACTION: All biosimilar insulins were approved as AMBER 3, but highlight that Semglee® is the most cost-effective insulin glargine product. LC to feedback to the MO diabetes team.

10. <u>Continence formulary</u>

The Continence Formulary Group have added four new sections to the continence formulary. These 4 new sections include Dilatation catheters, Non-lubricated intermittent catheters, Pre-lubricated intermittent catheter sets, and Mitroffanoff catheters. Each section of the formulary has a review date set three years from the date of the last review. No changes were made to the rest of the continence formulary which was not included in the papers.

In addition to the new formulary sections, 3 guidance sections were added: Catheterisation gels, Faecal collectors, and Anal plugs.

Secondary care has not been consulted because they use the products available in their contracts. Moreover, the prices also differ between Primary and Secondary Care. However, the Continence Formulary Group are in the process of organising a meeting between the provider's urology teams, Primary Care continence team and ICB meds optimisation team to discuss a way forward.

The APC members approved the new formulary and guidance sections of the Nottingham and Nottinghamshire Continence formulary.

ACTION: JT to update the formulary with the following changes:
• First-line products to the formulary as GREEN after completing a continence assessment.
• Second line products to the formulary as AMBER 2 following recommendation by a continence advisor and for existing patients.

• Non-formulary products will not be made GREY or listed on the formulary, but a note will be added to say that *"Non-formulary continence products may be used in exceptional circumstances where none of the formulary options are suitable. Non-formulary continence products must be recommended and fitted by a continence advisor, and the reason documented in the patient's medical record."*

11. <u>Any Other Business</u>

- SW shared that the high-cost drug pathways have been ratified and uploaded to the APC website.

<u>Date of next APC Formulary meeting</u> – Thurs, 19th October 2023 (2pm – 5pm, MS Teams)

<u>Date of next APC Guideline meeting</u> – Thurs, 21st September 2023 (2pm – 5pm, MS Teams)

The meeting closed at 16:15.