These minutes are in draft form until ratified by the committee at the next meeting on 15th June 2023

Nottinghamshire Area Prescribing Committee Formulary Meeting Minutes

APC Meeting 20th April 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 - Chair	**Prescribing Interface Advisor**	**NHS Nottingham & Nottinghamshire ICB**
David Kellock (DK)	**SFH Drug and Therapeutics Committee**	**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**	
Tanya Behrendt (TB)	**Senior Medicines Optimisation Pharmacist**	**NHS Nottingham & Nottinghamshire ICB**
David Wicks (DW)	**GP Prescribing Lead**	**Mid-Notts PBP, Nottingham & Nottinghamshire ICB**
Asifa Akhtar (AA)	**GP**	**South Notts PBP, Nottingham & Nottinghamshire ICB**
Katie Sanderson (KS)	**Patient Representative**	
Steve Haigh (SH)	**Medicines Information Pharmacist**	**Sherwood Forest Hospitals NHS Foundation Trust**
Hannah Godden (HG)	**Principal Pharmacist – Adult Mental Health Community Teams**	**Nottinghamshire Healthcare NHS Foundation Trust**
Georgie Dyson (GD)	**Advanced Clinical Practitioner**	**Nottingham Urgent Treatment Centre, CityCare**
Ankish Patel (AP)	**PCN Pharmacist lead**	**Nottinghamshire**

In Attendance:

Alex Molyneux (AM), Chief Pharmacy Officer for the South Yorkshire Integrated Care Board (ICB).

Dr. Sowjanya Ayyalaraju, NUH Dermatology Consultant attending for item 5a, Tirbanibulin (Klisyri®) for Actinic Keratosis.

Dr. Pradeep Archana and Dr. Dalia Said, Ophthalmology Consultants NUH attending for item 5b, Thealoz Duo® for Severe Dry Eye Syndrome.

Dr. Robert Lenthall, Consultant Interventional Neuro Radiologist, and Emma Grace, NUH Lead Clinical Pharmacist for Health Care of Older People and Stroke Services, attending for 6b, Prasugrel for Use in Interventional Neuroradiology (INR) Procedures.

Interface support team in attendance (NHS Nottingham & Nottinghamshire ICB):

Lynne Kennell (LK), Specialist Interface & Formulary Pharmacist for SFH.
Shary Walker (SW), Specialist Interface & Formulary Pharmacist for NUH.
Karen Robinson (KR), APC Interface and Formulary Pharmacy Technician.

1. Welcome and apologies

Apology received from Khalid Butt (KB), GP and LMC Representative, Mid Notts PBP, Nottingham & Nottinghamshire ICB

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

The minutes of meetings now include an action statement to inform members of progress.

- **Testosterone information sheet** (February 23)

The testosterone information sheet had been updated and circulated; final ratification was still awaiting members' agreement in line with the ToR for quoracy.
ACTION: LK to recirculate to members

- **Shingles vaccines for Rheumatology patients** (February 23)

LK informed the committee that from September 2023, shingles vaccination of immunosuppressed patients will be incorporated into the National Immunisation schedule.

This had been confirmed in personal communication with NHS England, but the Green Book was yet to be updated. Therefore the issues previously discussed around the vaccination of rheumatology patients with shingles vaccines needed to be resolved.

The most appropriate setting for vaccination of non-immune patients with varicella vaccine prior to commencement of immunosuppressive therapy was discussed. As the potential patient numbers are likely to be small and there is a need for timely administration of a 2-dose schedule prior to biologic commencement, it was felt it would be best administered by the specialist service.

ACTION: LK to discuss Varicella vaccination with specialist services. LK to update the formulary in line with Green Book recommendations once updates about shingles vaccination have been published.

- **Metolazone (Xaqua)** (February 23)

ACTION: LK to raise during Heart Failure guideline update work.

- **Enoxaparin (Clexane®)** (February 23)

Since discussions at the previous APC meeting it had been confirmed that there would be no imminent changes to the brand of enoxaparin used in Secondary Care. Therefore no update to the Enoxaparin guideline had yet been made. It was still intended to make the guidance about the brand of choice in Nottinghamshire less prescriptive, to allow for future changes. JML explained that some changes would be needed to the guideline as a result of discussions about the differences in enoxaparin doses used in maternity at NUH and SFH.

ACTION: LK to provide an update at the next APC formulary meeting.

Action Log

Lyumjev® (insulin lispro)

Epact2 data for Lyumjev had been reviewed and it was confirmed that current prescribing levels remained consistent with initial predictions for patient numbers. Lyumjev® is currently restricted on the formulary to consultant initiation only. It was agreed that this restriction could be changed to specialist initiation to allow the specialist diabetic nurses to initiate prescribing. Remove item from action log.

It was questioned whether the APC has an appropriate definition of a specialist and it was suggested that as the APC framework is under review. LC will review the 'specialist' terminology to ensure it captures the appropriate prescribers.

ACTION: LK to remove the item from the action log. LC to update the framework if required.

Qlaira®
The current prescribing levels were as predicted on the submission. It was agreed that Qlaira® should be removed from the action log.

ACTION: LK to remove the item from the action log.

Actimorph® orodispersible tablets
Epact data showed that the prescribing levels were lower than anticipated. However, it was felt that this item should remain on the action log for a further 6 months to monitor prescribing levels.

5. New applications.

- **Tirbanibulin (Klisyri®▼) for Actinic Keratosis (AK).**

SW presented tirbanibulin to the meeting. Tirbanibulin is a topical therapy licensed for the field treatment of non-hyperkeratotic, non-hypertrophic AK (Olsen grade 1) of the face or scalp in adults. Tirbanibulin ointment is for external use only, available in a single-use sachet. A thin layer of ointment should be applied to cover an area no larger than 25cm^2 once daily for one treatment cycle of 5 consecutive days. Therapeutic effects can be assessed approximately 8 weeks after treatment starts. If the treated area does not show complete clearance, the treatment should be re-evaluated, and management reconsidered. If recurrence occurs or new lesions develop within the treatment area, other treatment options should be considered, as no clinical data for more than 1 treatment course of 5 consecutive days are available.

Consultant dermatologist Dr. Sowjanya Ayyalaraju (SA) attended the meeting and explained that the submission was not to replace the 1st line choice of Efudix®, as this was particularly effective for larger areas. Tirbanibulin's place in therapy was for a small area of up to 25 cm^2. Discussions around efficacy followed, recognising that all the treatments were not curative and all caused inflammation and blistering. The inflammation is a required component for the treatment to be effective. Tirbanibulin is not expected to be used for recurrent disease. SA noted that for recurrent AK disease, it would be better to use Efudix®.
GP members explained that it was difficult for patients to comply with the use of Efudix® due to the longer treatment duration, and hence longer inflammatory side effects. Compared to tirbanibulin, the treatment duration is much shorter. Therefore, it was assumed that patients would request the tirbanibulin treatment rather than Efudix®, resulting in increased spending.

Amber 3 classification was requested, so a guideline is required before inclusion in the formulary.

Predicted patient numbers were unavailable and needed to be included in the decision-making process.

ACTION: SW to work with the consultant to clarify patient numbers and predict the potential cost impact for the next APC formulary meeting in June.

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

SW presented Theoloz duo®, noting that it was a resubmission and no new clinical evidence was available since the last submission in 2019, when it was declined.

Dr. Pradeep Archana and Dr. Dalia Said, NUH Ophthalmology Consultants, attended the meeting and explained that Theoloz duo® offered greater osmoprotectant and was effective for up to 4 hours as opposed to others which only lasted only 40 minutes. In their opinion, this leads to better compliance due to the reduced applications required of only 4 to 6 times daily. Furthermore, Theoloz duo® is suitable for contact lens users and has a 6-month expiry period from being opened, longer than most of the other eye drops in the formulary.
The place intended in therapy was for prescribing for severe dry eye(s) only after measuring the eye's osmolarity. Once the osmolarity had improved, the patients could be switched to an alternative product.
Included in the submission was a table taken from the DRAFT NUH Dry Eye Guideline (Severity of Dry Eye Disease). GP members felt that this was not consistant with current practice. TH noted that the draft guideline had not been submitted to NUH DTC for approval. LK noted that the place in therapy as presented seemed limited to those with hyper-osmolality, which had not been suggested previously. There is currently approximately £30K PA of prescribing in primary care. DW suggested that this may be due to the opening of a new dry eye clinic.

Members felt that further evidence of benefit compared with alternatives was required before it could be considered a formulary addition. In addition, the NUH guideline would require updating.

ACTION: The submission was declined and remained GREY in the formulary due to there being no new evidence since the last submission and its not being cost-effective compared with alternatives. The NUH Severe Dry Eyes Guideline quoted was not an NUH-ratified guideline. SW to feed the outcome back to the submitters.

- **Selenium for deficiency associated with therapeutic low protein diets.**

LK presented a submission for selenium for deficiencies secondary to therapeutic low-protein diets. Children with PKU must adhere to a stringent protein-restricted diet to maintain blood phenylalanine concentrations within European PKU Guidelines therapeutic ranges. This diet requires avoidance/restriction of all foods high in protein which tend to be rich sources of dietary selenium. Therefore, this cohort of patients has a tendency to become selenium-deficient.
It had been requested that selenium supplements (Selenase oral solution and 200 mcg tablets) be added to the formulary with an Amber 2 classification. They will be used for those children with biochemical evidence of selenium deficiency before developing clinical symptoms that may be severe and irreversible if the deficiency is prolonged.

The expected patient numbers are small (currently less than 5 a year) therefore any cost impact on primary care is likely to be minimal as the tablet formulation is a nutritional supplement, and brand prescribing is recommended due to the cost variation between products.

It was suggested that medicines for metabolic diseases should be reviewed as a topic as it had been previously highlighted that there are variations in prescribing responsibility and medicines are often unlicensed and/ or high cost. LK had begun some work on this but the

commissioning arrangements had been difficult to decipher and may be subject to imminent change.

Members agreed on an AMBER 2 classification.

ACTION: LK to feed back to the submitter and update the formulary.

6. Formulary amendments

a. FOR INFORMATION – Log of minor amendments carried out

GREY

- Pholcodine: MHRA alert, all products containing pholcodine recalled.
- Enfamil O-Lac®: Discontinued.
- Digoxin (Lanoxin®) elixir 50 microgram/mL, Discontinued, oral solution remains available
- Chlorhexidine 0.02% catheter maintenance solution: previously unclassified. Community continence advisors confirmed that not used. NUH and SFH confirmed that no recent orders.

b. FOR DECISION

Prasugrel for use in interventional Neuroradiology procedures

A formulary amendment request had been made to consider changing the traffic light classification of prasugrel from RED to AMBER 2 for patients under the care of the Interventional Neuroradiology (INR) team. The request was also to extend the indication to all patients to prevent and treat device-related thrombus formation during and after unruptured brain aneurysm procedures. Prasugrel is currently used as a first-line option at NUH for patients with intracranial stenting and may be considered for other high-risk patients, or those with known clopidogrel resistance, although prasugrel is not licensed for this indication.

The committee was advised of the plan to upskill the NUH INR service by 2024 as a tertiary center, to become a 24-hour, 7-day week service. As an implication of this is that the number of patients will increase to about 30 to 40 in subsequent years, although some of these will be from outside Nottinghamshire.

Prasugrel is more expensive than clopidogrel, but if prasugrel is effective at reducing thromboembolic complications, there are potential savings by reducing the length of hospital stay and readmissions. It was noted that the prasugrel 5mg tablet is 4 times more expensive than the 10mg tablets, but the lower dose is used for patients from 75 years old or patients weighing less than 60 kg. Dr. Lenthall explained that the 5mg tablets may also be used to reduce the risk of bleeding.

Dr. Robert Lenthall, Consultant Interventional Neuro Radiologist, and Emma Grace, NUH Lead Clinical Pharmacist for Health Care of Older People and Stroke Services, attended the meeting.

ACTION: AMBER 2 agreed. SW to feed back to the submitter.

GREY

- Ibuprofen 200mg/5mL, although this addition may offer cost savings compared to the 100mg/5ml strength, concerns were expressed about the availability of two strengths and associated risk issues. To realise any savings, an active switch would be required and this item is also in category M so any savings were likely to be seen as a cost impact elsewhere.

Other

- Sitagliptin: generic versions of sitagliptin are now available. The brand name is to be removed from the formulary entry. Generic prescribing is to be encouraged via Optimise so that savings are realised once the drug tariff price decreases. A suggestion of bulk switching was made but it was highlighted that this decision would need to be made by individual practices.

ACTION: KR to remove the brand name from the formulary entry.

- Assicco®, (glycopyrronium) tablets: Assicco® is a more cost-effective branded generic of glycopyrronium tablets that may offer cost savings compared to current liquid formulations. Brand prescribing is required to realise these savings and failure to prescribe by this brand would result in a cost pressure due to the Drug Tariff price being significantly more than for the Assicco® brand.
  The Parkinson's team has indicated that a tablet formulation would benefit patients who struggle to measure liquid doses. The use of both liquid formulations and Assico in adults is off-label.
  The Paediatric pharmacist at NUH had requested that Sialanar® remain the product of choice for children and had suggested rationalising liquid products as there are currently two strengths available on the formulary. This was agreed as Sialanar is now the more cost-effective product.

ACTION: KR to update the formulary and inform the optimise team. LK to highlight to Parkinson's teams.

ACTION: KR to complete the formulary amendment changes.

7. Horizon Scanning

a) New Horizon Scanning publications for review

GREY no formal assessment

- Ovamex®, ganirelix acetate 0.25 mg/ 0.5 mL solution for injection in a pre-filled syringe to prevent premature luteinising hormone (LH) surges in women undergoing assisted reproduction techniques (ART).
- Vaxchora® ▼, cholera vaccine for active immunisation against disease caused by *vibrio cholerae* serogroup.
- Qdenga®, a dengue vaccine, for the prevention of dengue disease

- Gefapixant, for treatment of refractory or unexplained chronic cough. Currently, there is no marketing authorisation in the UK, although a NICE TA is expected during 2023.
- Zavzpret®, zavegepant, nasal spray for migraine.
- Fezolinetant, a 'nonhormonal treatment for moderate to severe vasomotor symptoms associated with menopause'. A NICE TA is expected during 2024.
- Kinpeygo® budesonide is an orphan medicinal product for the treatment of IgAN, a rare, progressive autoimmune disease of the kidney. The European Commission (EC) granted conditional marketing authorisation for Kinpeygo, which has been approved in the UK.
- Camzyos®, Mavacamten capsules for the treatment of symptomatic obstructive hypertrophic cardiomyopathy. A NICE TA is expected during 2023.
- AVAXIM® Junior, , Hepatitis A vaccine (inactivated, absorbed) for children from 1 year up and including 15 years of age. This is not yet listed in the green book; however, AVAXIM is listed for those over the age of 16 years. To be classified as GREY, no formal assessment until the green book is updated.

Other

- Bimi®, bimatoprost 300 microgram/ml eye drops. Bimatoprost 3% PF is classified as GREY on the formulary.
  Bimi® is being promoted as a multidose bottle helping to reduce plastic consumption of single-dose units, facilitating another step towards the 'net zero' National Health Service target. It may also offer cost savings compared to the product currently recommended on the formulary. Current choices of prostaglandin analogues are to be reviewed.
- Beclu®,100 pMDI contains 100 micrograms of beclometasone dipropionate for the management of mild, moderate, or severe asthma in adults or children.
  Highlight the respiratory group as a cost-effective choice.
- Beclu® 200 pMDI contains 200 micrograms of beclometasone dipropionate for the management of mild, moderate, or severe asthma in adults.
  Highlight the respiratory group as a cost-effective choice.
- COVID-19. Spikevax bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/mL dispersion for injection - multidose vial - Check for local use expected at vaccination centres and traffic light accordingly.
- COVID-19. Spikevax bivalent Original/Omicron BA.4-5 25 micrograms/25 micrograms dispersion for injection - single dose vial - Check for local use expected at vaccination centres and traffic light accordingly.
- COVID-19. VidPrevtyn Beta solution and emulsion for emulsion injection of COVID-19 vaccine (recombinant, adjuvanted) - Check for local use expected at vaccination centres and traffic light accordingly.
- Levorol®, levomepromazine hydrochloride 5 mg/ml oral Solution. Update the prices on the formulary, add liquid as a licensed option for those unable to swallow tablets, but highlight the high cost and option to crush tablets if required.

ACTION: KR to complete the horizon scanning formulary changes.

b) New NICE guidelines.

Barrett's oesophagus and stage 1 oesophageal adenocarcinoma: monitoring and management NG231 – noted, no further action required.

NICE TA875 – Semaglutide for managing overweight and obesity.

LK presented the TA and explained that the licensed brand of semaglutide for weight loss is not yet available in the UK. However, currently there is no local service that is able to prescribe it. The NICE TA positions it for prescribing by Tier 2 and/or Tier 3 Specialist Weight management services. Nottinghamshire Public Health service offers a Tier 2 service, but this does not have prescribing capabilities. Currently, the ICB refer to a Tier 3 service in Derby, but it is unclear whether they would be able to prescribe for our patients and there have been issues highlighted about access to this service. Commissioners are in discussions about the situation and a a Task and Finish group is currently reviewing obesity management services. It was suggested that a holding statement be developed while the medicine is unavailable.

ACTION: LK will feed back as commissioning progress is made.

NICE TA877 – Finerenone for treating chronic Kidney disease in Type 2 Diabetes.

LK presented the NICE TA. Finerenone is recommended as an option for treating stage 3 and 4 chronic kidney disease (with albuminuria) associated with type 2 diabetes in adults. It is recommended only if:

- It is an add-on to optimised standard care; this should include, unless they are unsuitable, the highest tolerated licensed doses of:
    - Angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs) and
    - sodium–glucose cotransporter-2 (SGLT2) inhibitors and
- the person has an estimated glomerular filtration rate (eGFR) of 25 ml/min/1.73 m2 or more.

Renal physicians had suggested an initial Amber 2 classification which members agreed when used in line with the NICE TA. It was highlighted that patients would require monitoring and it was requested that patients are given relevant information such as sick day rule advice.

The requirement for women of childbearing potential to use adequate contraception was noted and it was requested that an Optimise message be created to highlight this at the point of prescribing.

ACTION: LK to update formulary and link sick day rule advice. Optimise message to be requested about use in women of childbearing potential.

8. Buprenorphine patches – brand of choice.

KS declared an interest as a user of patches and removed herself from the decision-making process.

LK informed the group that the Acute trusts were considering buprenorphine patch choices following an NHS Secondary care contract review and requested views about a potential change of brand. It was felt that due to the existence of two types of patches and therefore potential for confusion, continuity of brand across the interface should be maintained wherever possible.

ACTION: LK to provide an update at the next APC formulary meeting

9. Any Other Business.

Declaration of Interest (DOI). KR had recently updated the DOI process following discussions with the ICB Corporate Governance Team. All NHS organisations and their employees are mandated to follow the NHSE guidance. As such, members employed by organisations outside of the ICB can submit their corresponding organisation's form as their DOI record. All members whom the ICB already employs will complete the ICB form as requested by the governance team. Patient representatives must complete the Nottingham and Nottinghamshire ICB Declaration of Interest Form.
The APC website had been updated accordingly.

A request had been made by a GP for clarity about monitoring requirements for warfarin, Haematologist's advice was that it would not be unreasonable to monitor U &Es, FBC and LFTs annually. Members questioned the purpose of this because INR levels were regularly monitored.
ACTION: LK to feedback at the June meeting

Praise was given to AW, who had won an award for the development of a pharma café. The pharma café allows student pharmacists to chat with older people about their medications.

The meeting closed at 17:06

Date of next APC Formulary meeting – Thursday, 15th June 2023 (2 pm – 5 pm, MS Teams)
Date of next APC Guideline meeting – Thursday, 18th May 2023 (2 pm – 5 pm, MS Teams)