These minutes are in draft form until ratified by the committee at the next meeting on 13th Oct 2022.

Nottinghamshire Area Prescribing Committee Formulary Meeting Minutes

APC meeting 18th August 2022: 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:

Steve May (SM) (Chair)	**Pharmacist**	**Sherwood Forest Hospitals NHS Foundation Trust**
David Kellock (DK)	**SFH Drug and Therapeutics Committee**	**Sherwood Forest Hospitals NHS Foundation Trust**
David Wicks (DW)	**GP**	**NHS Nottingham and Nottinghamshire**
Esther Gladman (EG)	**GP**	**City PBP, NHS Nottingham & Nottinghamshire**
Debbie Storer (DS)	**Medicines Information Pharmacist**	**Nottingham University Hospitals NHS Trust**
Ann Whitfield (AW)	**Patient representative**	
Asifa Akhtar (AA)	**GP**	**NHS Nottingham and Nottinghamshire**
Khalid Butt (KB)	**GP**	**NHS Nottingham and Nottinghamshire**
Kuljit Nandhara (KN), from 2:15pm	**Deputy Chief Pharmacist, Head of Pharmacy Mental Health Services**	**Nottinghamshire Healthcare NHS Foundation Trust**
Deepa Baxi (DB) (Deputising for JT)	**Senior Medicines Optimisation Pharmacist**	**NHS Nottingham and Nottinghamshire**

In attendance:

Professor Stephen Ryder, Consultant Hepatologist and Clinical Director and Mr Edward Nicholson, Specialist Hepatology Pharmacist, joined the meeting at 16:10 for item 9d.

Interface support (NHS Nottingham & Nottinghamshire ICB):

Nichola Butcher (NB), Medicines Optimisation and Interface Pharmacist
Hannah Godden (HG), Specialist Mental Health Interface Pharmacist
Lynne Kennell (LK), Specialist Interface & Formulary Pharmacist for SFH
Michalina Ogejo (MO), Medicines Optimisation and Pain Clinic Pharmacist
Shary Walker (SW), Specialist Interface & Formulary Pharmacist for NUH

Karen Robinson (KR), APC/Interface/Formulary Support Technician, NHS Nottingham and Nottinghamshire

1. Welcome and apologies

Apologies

Tanya Behrendt (TB), Senior Medicines Optimisation Pharmacist, NHS Nottingham & Nottinghamshire
Laura Catt (LC) Prescribing Interface Advisor, NHS Nottingham & Nottinghamshire
Jennifer Moss Langfield (JML), GP, LMC representative
Steve Haigh (SH) Medicines Information Pharmacist, SFHT
Sarah Northeast (SN), Advanced Podiatrist, Nottingham City Care
Jill Theobald (JT), Senior Medicines Optimisation Pharmacist, NHS Nottingham & Nottinghamshire

2. Declarations of interest

MO (interface support) gave a brief overview of her role within the Pain Clinic and how it related to item 9b. No further declarations were made.

3. Minutes of the last meeting

The minutes from the previous meeting were reviewed and accepted as an accurate record, subject to minor amendments.

4. Matters arising and action log

Trimbow® MDI –SW explained that the information had been added to the action log, and the patient numbers were not significant. No further action is required.

Safinamide – ePACT2 data will be monitored, and feedback will be provided at the October APC formulary meeting.

ACTION: LK/SW to feedback data at the October APC formulary meeting.

Guanfacine (HG)
HG explained to the group that LC had attended a meeting with the commissioners to review the Local Enhanced Service (LES); and no progress had been made to incorporate guanfacine. LC flagged up the risk that the Regional Medicines Optimisation Committee (RMOC) had published the SCP for adults, and a follow-up meeting was planned, then later cancelled. LC suggested delaying publishing the SCPs for guanfacine until the LES was resolved, members agreed with this.

ACTION: LC to provide an update at the October APC formulary meeting.

5. FOR RATIFICATION – Information and Guidance on Prescribing in Transgender Health (stated as Transgender position statement on the agenda)

HG presented the updated position statement. The update includes information on NHS England's new regional model of transgender care for children and adolescents and a ruling from the Court of Appeal in September 2021 relating to consent to the use of hormone blockers in patients under the age of 16. There has also been a clarification that any recommendation made by a gender clinic for a GP to prescribe must be directly from a suitably qualified medical or non-medical prescriber. DS highlighted a reference to CCG

that needs to be changed to ICB. APC agreed to ratify the update with minor clarification in wording to acknowledge the difference between recommendations to prescribe and prescribing advice.

ACTION: HG to update and upload to the APC website.

6. **FOR RATIFICATION – Transgender collaborative care protocol and prescribing information sheets (HG)**

HG presented a new collaborative care protocol and information sheets for prescribing feminising and masculinising hormones to transgender adults. The ICB executive champion for LGBTQ+ had requested that the APC scope and develop prescribing guidance for primary care, to improve medicines management for adult transgender patients. HG explained that the guidance was developed in conjunction with specialists at the Nottingham Centre for Transgender Health (NCTH). It was acknowledged that the primary care commissioning arrangements for this activity are still being worked through locally. DW/KB highlighted that there are workload and training implications for primary care undertaking this work. It was agreed that primary care access to timely specialist advice on prescribing and monitoring of hormone treatment is critical while the patient is with the transgender service, as well as post discharge. Concerns were raised about patients accessing treatment via a private gender clinic and then going on to request collaborative care with their GP. There are not the same assurances about timely and ongoing access to a specialist when a patient seeks private treatment. DS highlighted that some medicines included in the guidance are not included on the local formulary or are included, but a gender dysphoria indication is not listed. EG highlighted that monitoring requirements for testosterone do not align with other APC testosterone prescribing information. APC members discussed whether the titles of the information sheets used the correct language. A 3-year review date was agreed, while it was acknowledged that this is a rapidly changing area of practice. The APC agreed to ratify the documents, with minor clarifications to language.

ACTIONS:
HG to liaise with specialists to seek advice on language.
Interface team to review formulary entries for feminising/masculinising hormone treatments.
Record any updates on formulary amendments.
LC to feedback to ICB LGBTQ+ executive champion about concerns raised regarding patients accessing private gender clinics.
HG to update and upload to the APC website.

Post meeting note: EG requested additional information on reference ranges for LH, FSH and SHBG.

7. **FOR RATIFICATION – Shared Care Patient information leaflets (HG)**

HG presented a suite of patient information leaflets that have been identified for shared care medicines. This work was an APC action following a local serious incident relating to the monitoring of a shared care medicine. HG explained that the patient information leaflets had been approved by local specialists. APC approved the patient information leaflets.

ACTION: HG to link the patient information leaflets to the APC website, relevant shared care protocols and joint formulary.

8. **FOR RATIFICATION – Continence sheaths formulary**

SW presented the updated continence sheaths formulary, which has been reviewed and produced by the continence formulary group. The group comprises of CityCare continence advisors, Notts Healthcare Trust continence advisors, and ICB Medicines Optimisation team members. The group actively reviewed the new and existing products and considered the cost, style and size range available, as well as the packaging and ease of application, including environmentally sustainable packaging. In addition, they will review each section of the formulary and will set a review date 3 years from the date of the latest review.

It is anticipated that the total spend on sheaths will decrease as more patients are started on first-line cost-effective options. Patients may, however continue to use their existing sheaths, including the non-formulary sheaths.

The SpiritCare® sheath is the same price as Clinisure®, but the continence formulary group needed more experience in using it before recommending it as the first option.

Particularly in the North of the County and Bassetlaw, anyone that knows how to measure for a sheath and who has completed a continence assessment can commence someone on a sheath system, using the first-line products highlighted in GREEN. In City and South Nottinghamshire, however, this would always go through the continence service due to differing service arrangements.

Members agreed the following:
First line sheaths are to be added to the formulary as GREEN following the completion of a continence assessment and measurement.
Second line sheaths are listed as AMBER 2 following a recommendation by a continence advisor for new patients, and existing patients can continue with second- line sheaths.
Non-formulary sheaths will NOT be listed as GREY, nor will they be listed on the formulary. A note will be added to the continence section stating that "non-formulary sheaths may be used in exceptional circumstances where none of the formulary options is suitable. Non-formulary sheaths must be recommended and fitted by a continence advisor, and the reason for selection should be documented in the patient's medical record''.

ACTION: SW to update the formulary

9. New applications - SW/LK

a. Rufinamide (Inovelon®, Eisai Ltd) for non- Lennox Gastaut Syndrome (LGS) seizures

LK presented the rufinamide submission. Rufinamide for seizures associated with LGS was discussed at the June APC meeting, and the expansion of its indication to include adults and a reclassification to Amber 2 was provisionally agreed. This was pending further assessment of the cost implications of such a change and potential need for ICB approval. Following this decision, a request to expand the usage to patients with tonic or atonic seizures, but without confirmed LGS was received. This is an unlicensed indication, but in line with recent NICE guidance; NG217: Epilepsies in children, young people and adults. Rufinamide is recommended as an option alongside clobazam and topiramate after treatment with valproate and lamotrigine has been unsuccessful. NICE's review of the evidence concluded that all three options can be effective in the management of tonic and atonic seizures and there was no clear cost-effectiveness evidence of superiority between the different options.

The expansion of the indication to include this patient cohort was not expected to increase potential patient numbers significantly as use other than in patients with LGS is rare. Following discussions at the previous meeting, detailed patient numbers have been requested from NUH in order to assess the potential cost implications of traffic light reclassification.

During previous discussions about rufinamide, concerns were expressed about the pregnancy risks and the need for women of childbearing potential to use adequate contraception. LK had reviewed the pregnancy risk information and found that there was a lack of data on pregnancy exposure to guide advice. DT explained that there was no mandatory advice about use of medications in women of childbearing potential other than for sodium valproate, though discussions were ongoing about this area within the Medicine Optimisation's Safety team.

Members agreed the expansion of the indication approved at the previous meeting to include non- LGS seizures in line with NICE guidance.

ACTION: LK to pursue obtaining more detailed patient numbers for assessment of financial implications and potential need for wider ICB approval.

b. Pridinol re-submission (Myopridin®, Mibe Pharma UK)

LK reminded members about the previous discussions about pridinol and following the publication of new evidence, presented a request to review the GREY classification previously assigned. This evidence had already been reviewed in an unpublished format, prior to the discussions at the April meeting of the JFG. LK explained that, of the two publications submitted, the first was a meta-analysis of 2 trials, one investigating oral therapy and the other intramuscular (IM) therapy. The IM trial was not relevant to this submission and the oral therapy trial had already been considered during the original review of evidence. The second publication was a non- comparative cohort study.

Members felt that as there was still not enough robust evidence to approve the submission, the GREY classification should remain.

ACTION: Not approved. No change required to the Joint Formulary.

C. Ryaltris® (mometasone/olopatadine, Glenmark Pharm Eu Ltd) for allergic rhinitis

SW presented the submission, initially a request for a GREEN classification; however, following discussion about its place in therapy within the Allergic Rhinoconjunctivitis Treatment Pathway, the submitter agreed with a classification of AMBER 3 for the treatment of moderate to severe nasal symptoms associated with allergic rhinitis as per its license indication.

Evidence demonstrated that the olopatadine and mometasone nasal spray was effective and well tolerated compared to the placebo. It has a rapid onset of action of 15 minutes, this significant improvement maintained at all later time points. The combination of topical antihistamine and intranasal steroid is recommended in patients with allergic rhinitis by the BSACI for patients with allergic rhinitis when the symptoms remain uncontrolled with an oral antihistamine or intranasal steroid monotherapy or in combination.

Additionally, both constituents have established use for this condition. Olopatadine has been used as an eye drop and mometasone as a nasal spray. The combination shows synergistic effects in terms of the improvement of allergic rhinitis symptoms. The most commonly reported adverse effects were an unpleasant taste, nosebleed, and nasal discomfort. As with other antihistamines, patients should be cautioned against operating heavy machinery or driving a motor vehicle.

This will be an additional nasal fixed-dose combination of an antihistamine and corticosteroid option under step 4 of the Allergic Rhinoconjunctivitis APC guideline. The alternative is Dymista® (azelastine/fluticasone). There is no head-to-head study of the two, but Ryaltris® is 10% cheaper than Dymista®. DB felt that there was a place for both products on the Joint Formulary due to the number of ongoing supply disruptions.

The potential for a generic version of Dymista® (azelastine/fluticasone) was highlighted as this could potentially elicit a cost reduction. SW was asked to clarify any potential availability of a generic version and email members for approval.

ACTION: SW to clarify the possibility of a generic to Dymista® being launched within the next 6 months and email APC formulary members for final approval.

d) Fibrates (fenofibrate and bezafibrate MR) for primary biliary cholangitis (PBC)

SW presented the submission to the committee. The fibrates in the submission are fenofibrate and bezafibrate. The request was for AMBER 2, following specialist initiation as second-line alternative therapy for primary biliary cholangitis (PBC). The modifying treatments currently available are ursodeoxycholic acid (UDCA) as the first-line therapy and obeticholic acid (OCA), as the second-line option. Fibrates will be offered as a treatment option following specialist (PBC) and MDT discussion for patients intolerant of or unresponsive to obeticholic acid. The treatment will be long-term, and there is no preference between the two fibrates.

The European Association for the study of liver (EASL) guideline recommends fibrates as an off-label second-line therapy. Additionally, the American Association guideline for PBC recommends considering fibrates as an off-label alternative for patients with PBC who have an inadequate response to UDCA.

Evidence includes a phase 3 placebo-controlled, double-blind trial from 2018 and a multicentre observation study conducted in 2021. The evidence demonstrated that these fibrates are safe and can be effective in achieving the normalisation of LFTs in PBC patients. Moreover, cumulative data suggest that fibrates appear to be safe and well-tolerated in patients with PBC, with a low frequency of adverse effects.

The use of fibrates is significantly lower compared to the use of obeticholic acid. Hence, patient numbers are expected to be small. There are currently 30 patients being treated with obeticholic acid and about 5 patients with the potential for fibrate use. Monitoring requirements will be baseline LFTs, U&Es and FBC every 2 weeks for the first 2 months following initiation, and 3- monthly thereafter. Dr Ryder confirmed that initial monitoring would be carried out by secondary care, and that patients are monitored via the Multi-disciplinary Team (MDT)

ACTION: APC formulary members approved the submission. SW to update the Joint Formulary and feedback to clinicians

10. Formulary Amendments
(includes formulary amendments and traffic light classifications)

a. Bupropion

A request was received from Nottinghamshire Healthcare for traffic light reclassification from RED to AMBER 2 for the treatment of resistant/refractory depression. It was explained that this is an off-label indication and would be on psychiatry recommendation only. The reclassification was agreed.

ACTION: HG to update the classification on the Joint Formulary

The log of formulary amendments already completed was noted by members. LK requested that the traffic light classification of arginine and sodium benzoate be looked into further as here had been previous discussions about traffic light classifications of some medicines for metabolic disorders.

Action: SW/LK to review previous discussions about traffic light classifications of medications for metabolic disorders and seek secondary care opinion on the appropriateness of a red classification.

Formulary amendments for discussion:

Morphine sulfate orodispersible tablets, Actimorph®; a request had been made for this product to be added to the Joint Formulary with a GREEN classification as an alternative to Oramorph. The tablet formulation requires less manipulation by patients and may be preferable for those with dexterity issues. It also allows doses to be controlled which is desirable in terms of reducing opioid usage by patients. Actimorph® is a schedule 2 Controlled Drug (CD), whereas Oramorph is a Schedule 5 CD. It was highlighted that the enhanced CD requirements for Actimorph may have implications, particularly in care homes and in Secondary Care. Concerns were raised about safety aspects associated with a lack of familiarity and the potential for duplicate opiate administration.

LK explained that the cost of Actimorph was significantly more than Oramorph in Secondary Care. However, there was interest from the Pain Clinic and the Palliative Care teams.

APC members felt that Actimorph could be useful for some patients, but should be considered as a second line product to Oramorph. It was requested that the interested clinicians provide some clarity on the patient group in whom they would potentially use Actimorph and that the potential implications for Secondary Care and care homes should also be further assessed.

ACTION: SW/ MO to gather further information and bring back to the October APC formulary meeting.

GREY:

Tiotropium (Acopair®) – This offers another tiotropium brand of inhaler but offers no advantage over currently available options. As it is not available as a refill pack, it is less environmentally friendly than alternatives.

Metolazone (Xaqua®) – the licensed preparation has up to a two-fold bioavailability difference compared to currently used unlicensed metolazone preparations. A response from the MHRA regarding the risk when switching from imported metolazone to Xagua® is awaited. It was therefore classified GREY, pending further information.

AMBER 2:

Incontinence products, Efemia®, Contiform®, Diveen®: female stress incontinence products are not listed on the formulary. The continence formulary group request 1st line Efemia®, at lower cost and with least waste due to 3-month usage; 2nd line Contiform®; 3rd line Diveen®. There has been a request for all three incontinence products to be listed as not all devices will suit all women. The Continence formulary group are not expecting any increase in usage, and the ICB Medicines Optimisation team will monitor usage every six months.

AMBER 3:

Rivaroxaban 20mg/15mg Film-coated Tablets Treatment Initiation Pack (Xarelto®) for VTE; instruction to the Optimise team to develop a message to make it clear that the titration pack is for VTE only.

OTHER:

Sacubitril/ Valsartan (Entresto®) - updated with information relating to TA388.

Rivaroxaban 1mg/ml granules for oral suspension (Xarelto®) – updated to include formulations for different weights of children.

Riboflavin oral – clarity added to the indication, ie paediatric metabolic disorders only.

Naseptin cream – formulary updated due to the formulation no longer containing Arachis oil (peanut oil).

Oxybutynin 2.5mg-5mL and 5mg/5mL oral solution –further information added, that some brands contain sorbitol.

Hypromellose eye drops 0.3% - moved to the appliance section of the drug tariff, so all existing generic prescriptions for hypromellose eye drops 0.3% are now non-EPS compliant and are unable to be sent electronically. AaproMel®, Lumecare Tear® or Teardew® are the recommended brands added to the formulary.

Post-meeting note- Lumecare Tear® has been discontinued so not an option for prescribing.

Oxycodone 1mg/mL and 10mg/mL oral solution (Shortec® liquid 1mg/mL and 10mg/mL): Notification from the manufacturer that both strengths will be discontinued on the 30th September 2022. Discontinuation advice added to the formulary entry.

Morphine sulfate 10mg/5ml oral solution – generic version more cost-effective. Formulary to be updated to reflect this.

11. Horizon Scanning

GREY no formal assessment:

Risperidone 75 mg powder and solvent for prolonged-release suspension for injection (Okedi®).

Dexamfetamine sulfate ▼1 mg/ml Oral Solution.

Netilmicin and dexamethasone, 3mg/1mg in 1mL eye drops in a single-dose container. (Netildex®).

Dexamethasone and levofloxacin 1mg/5mg in 1mL eye drops (Ducressa®).

Pyridostigmine 12mg/mL oral solution.

Levodopa, carbidopa, entacapone (Lecigon®) 940mg/235mg/940mg in 47mL Gel.

Hydrocortisone 5 mg/5ml and 10mg/5ml oral solution.
**Post meeting note: Hydrocortisone solution has not been listed as GREY as the unlicensed oral suspension is already listed on the Joint Formulary. The formulary status will be reviewed once the product is available.*

Dexcom ONE.

GlucoRx AiDEX.

Estradiol hemihydrate 10 micrograms vaginal tablets (Gina®).

Beclometasone dipropionate 172mcg, formoterol fumarate dihydrate 5mcg, glycopyrronium 9mcg bromide. (Trimbow®) pMDI

Luforbec®, Beclometasone/ formoterol pressurised metered dose inhaler - more cost-effective than Fostair®. Peter Richards, the MO lead for Respiratory Medicine, has been made aware of the cost efficiencies.

AMBER 2:

Tapentadol prolonged-release tablets (Ationdo®): add to the formulary as a more cost-effective brand. The capsule formulation, Tapimio® offers no advantage over Ationdo® and tablets are preferred for consistency with current usage of Palexia SR®.

OTHER:

Dapagliflozin 5mg and 10mg tablets (Forxiga®): licensing has changed. Now indicated for adults and children aged 10 years and above. Previous license for initiation was only adults between 18 and 75 years.

Semaglutide (Ozempic®) ▼2mg pre-filled pen; price not yet available. Classify as AMBER 2 if cost is neutral with the other strengths of Ozempic® when information is available. Add to the action log to review when price is available.

NICE TA805- Icosapent Ethyl (Vazkepa®, Amarin Pharmaceuticals Ltd)

LK presented the NICE TA for icosapent ethyl; this recommends its use as secondary prevention in patients with raised triglycerides and controlled LDL cholesterol. Lipidologists had suggested a classification of AMBER 2; patient numbers are expected to be small.

The APC agreed an AMBER 2 classification, for use in line with the NICE TA.

Action: LK to update formulary and feedback to clinicians
LK to highlight potential cost implications to finance.

12. AOB

- **For noting - PPL has been updated and ratified by CPMT (21.07.22)**
  Updated as part of the six-monthly review: noted.

- **Dermatophyte Infection of the Proximal Finger or Toenail**

A comment had been received from Paediatric Dermatology Consultants about the recommendation for LFT monitoring in the guideline. It was felt that the small risk of terbinafine associated liver toxicity did not justify monitoring LFTs for all patients, including children. However, it is recommended in the BNF to check LFTs after 4-6 weeks of treatment. The committee felt that this recommendation should remain in the guideline as it is good practice to check LFTs.

- **Steroid card**

LC had sent an updated version via email for ratification. A few questions had been sent via email and AW had previously provided feedback to the author. It was felt that further work was required in order to make the document fit for purpose. DS suggested adding an image of the card to the reworked document as there were other steroid cards in circulation that it could be confused with.

Action: AW to work on the document in conjunction with LC

- HG explained that Notts HCT had developed a new pathway for take-home naloxone from Notts HCT. Communication will be disseminated via the prescribing hints and tips newsletter.

- SW requested the views of the APC regarding secondary care requests for primary care prescriptions of cephalexin to be taken pre-procedure. The APC clinicians felt that these requests were inappropriate and that FP10HP prescriptions should be utilised in this situation.

- KB offered to provide an education session on GP funding. SM agreed that if there was capacity on the agenda, it would be beneficial to reinstate APC training sessions.

The meeting closed at 16:44

Date of next APC Guideline meeting- Thursday 15th September 2022, 14:00-17:00 (MS Teams)

Date of next APC Formulary meeting- Thursday 13th October 2022, 14:00-17:00 (MS Teams)