Nottinghamshire Area Prescribing Committee Formulary Meeting Minutes 20th June 2024: 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: -

Tanya Behrendt (TB) Chair	**Senior Medicines Optimisation Pharmacist**	**NHS Nottingham & Nottinghamshire ICB**
Ann Whitfield (AW)	**Patient Representative**	**Nottingham & Nottinghamshire ICB local population**
Katie Sanderson (KS)	**Patient Representative**	**Nottingham & Nottinghamshire ICB local population**
Jennifer Moss Langfield (JML)	**GP**	**LMC Representative**
Asifa Akhtar (AA)	**GP**	**South Notts PBP, Nottingham & Nottinghamshire ICB**
Tim Hills (TH)	**Assistant Head of Pharmacy**	**Nottingham University Hospitals NHS Trust**
Mark Clymer (MC)	**Assistant Chief Pharmacist**	**Sherwood Forest Hospitals NHS Foundation Trust**
Steve Haigh (SH)	**Medicines Information and Formulary Pharmacist**	**Sherwood Forest Hospitals NHS Foundation Trust**
John Lawton (JL)	**Clinical Pharmacy Services Manager**	**Nottinghamshire Healthcare NHS Trust**
Beth Rushton (BR) (until 3pm)	**Senior Clinical Pharmacist**	**Nottingham West PCN**
Georgina Dyson (GD)	**Advanced Nurse Practitioner**	**CityCare ICB**
Fatima Malik (FM)	**Practice-based pharmacist**	**Nottinghamshire locality**

In Attendance:
Natasha Hudson, Respiratory Specialist Pharmacist, NUH in attendance for agenda item 6.
Dr Jonathan Evans, Consultant Neurologist, NUH in attendance for agenda item 12.

NHS Nottingham & Nottinghamshire ICB Interface Support in attendance:

Lynne Kennell (LK), Specialist Interface & Formulary Pharmacist for SFH.
Karen Robinson (KR), Specialist APC Interface and Formulary Pharmacy Technician.
Lidia Borak (LB) – Specialist Medicines Optimisation Interface Pharmacist.
Nichola Butcher (NB), Specialist Medicines Optimisation and Interface Pharmacist only for agenda items 9 and10.

1. Welcome and apologies.

New APC member Fatima Malik was introduced and welcomed. Fatima is replacing BR as the PCN representative for the APC formulary meetings.
It was noted that APC member Hannah Godden of NHCT had changed her name to Hannah Sisson

2. Declarations of interest

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

3. Minutes of the last meeting

The minutes of the previous meeting were accepted as an accurate record of the meeting subject to minor amendments.

4. FOR DISCUSSION – APC development session update on actions

In Laura Catts' absence, LK presented a progress update on the actions following the development session.

- Management of meeting papers and agendas has progressed, and the format of the submission papers has been reviewed and condensed.
- The APC bulletin will now be published using the Microsoft SWAY application.
- Live APC update webinars are being developed to include contributions from the whole APC team and offer interactivity for users.
- The 10-minute APC learning session will be reintroduced, and LK will be conducting a training needs analysis; members are asked to suggest suitable topics they would like to see included.
- APC membership is being looked at; an NUH medic was still required however there has been interest from Non-Medical Prescribers (NMP) and these new members will be introduced over the next few months.

ACTION: All members are asked to consider what learning topics they would like to see presented at the APC meetings. Please return any suggestions by email to LK.

5. Matters arising and action log.

Melatonin
LK updated members on ensuring brands used on the formulary are consistent across the ICS as raised at the previous meeting. It had been confirmed that the immediate release brand used at NUH was Adaflex® and this will be added as an option alongside the MR prep for the indications that melatonin is classified as Amber 2. It had since been raised by NUH that a cost-effective melatonin liquid preparation was now available as Ceyesto® and this had also been requested for addition eg for those with learning difficulties unable to use crushed tablets.
Members discussed various options and implications but felt predicted patient numbers were required to make an informed decision.
It was noted that James Sutton had stepped down from the melatonin group.

ACTION: LK to request predicted patient numbers and return the item to the APC for further consideration.

(a) **NICE TA875 – Semaglutide for weight loss**

Following on from discussions at previous meetings, LK explained that there was no further update regarding service provision for semaglutide. It was highlighted that the draft NICE Technology Appraisal (TA) for tirzepatide, an alternative medication for weight loss had recently been published and the ICB would be submitting a response to the consultation. Information was provided about how other organisations could contribute to the consultation.

ACTION:LK to update APC with further progress.

(b) **Simalvia®**

APC members previously agreed that an AMBER 3 classification could be supported with a flow chart guideline and patient information leaflet (PIL). Professor Corsetti has proposed an adapted version of the national IBS guidelines from British Society of Gastroenterology to signify the place in therapy and BDA PIL that details lifestyle and dietary advice to support management of IBS. Members discussed the unclear placement of alverine/simeticone within the flowchart and that the document may inadvertently suggest this treatment is specifically recommended in the BSG guideline, making it unsuitable for use in Primary Care in the proposed format. Members felt the language used within the PIL was above the reading level for the local general population and that the guideline would not be workable within Primary Care.
TB as chair requested the item to be returned to a future APC meeting whereby the decision tree should be utilised to make a classification decision.

ACTION: LB will update the submitter and return to the APC for a decision.

(c) **Cytisine for smoking cessation**

LK informed APC members that the smoking cessation position statement had been updated to include cytisine. The Trusts are continuing to implement the prescribing of cytisine via their local processes. SFHT and NUH representatives had met to discuss the implementation of cytisine prescribing and a final decision will be made by the Drug and Therapeutics Committee (DTC). APC members agreed to leave the traffic light indication as GREY until the DTCs had discussed the implementation once the funding and implementation processes have been decided it is likely the classification will be RED.

ACTION: LK to update the Joint Formulary and classify cytisine as GREY with a view to re-classify once the DTC has clarified the funding streams.

All other items are on the agenda, or they have been actioned.

Action log:

The action log was noted by the APC members.

6. New applications

Trixeo® Aerosphere pMDI for COPD (Astra Zeneca)

LK presented the submission for Trixeo® Aerosphere pMDI for COPD. This was a re-submission having previously been discussed at APC in March 22. The reasons given to support the re-submission are:

- Environmental benefits- analysis supports a lower carbon footprint of Trixeo® compared to Trimbow®, partly due to there not being a requirement for cold chain storage and transportation of Trixeo® prior to use. Both inhalers are classified as having a high carbon footprint, but Trimbow®= 14203.2 g CO2e/ inhaler and Trixeo® 13500 g CO2e/ inhaler. Equivalent to 863 miles vs 603 miles per year in a car. Trial data for Trixeo® also supports a reduction in SABA use (equating to a reduction in pMDI use), but this wasn't seen in the equivalent trial for Trimbow®.
- Trixeo® has trial data to support a reduction in all-cause mortality and CV mortality, whereas such evidence does not exist for Trimbow®. These claims are not felt to be supported by evidence currently.
- Unlike Trimbow® the formulation of Trixeo®, does not contain alcohol therefore Trixeo® may be preferred by some patient groups.
- Trixeo® offers a seamless transition for patients on Bevespi®; although the LAMA and LABA components of Trixeo® and Trimbow® are the same, the Aerosphere technology is claimed to result in superior lung deposition than traditional pMDIs.
- Trixeo® is priced equivalent to current LAMA/LABA/ICS inhalers, which are more cost-effective than using a LABA/ICS + LAMA inhaler.

This submission was supported by the ICB respiratory group and SFHT and NUH respiratory clinicians. Natasha Hudson, Respiratory Specialist Pharmacist from NUH attended to support the submission. It was acknowledged that storage space is often an issue for pharmacies, but it would be preferable for both inhalers to remain on the formulary. APC members acknowledged that patients are often reluctant to switch their inhaler device once they are stable, It was highlighted that Trixeo® with the Aerosphere technology had a longer patent expiry than Trimbow®, but patent expiries for both inhalers were many years in the future.

APC members approved the submission with an AMBER 3 classification subject to it's inclusion on the COPD guidelines. Updated COPD guidelines are due to come to July APC meeting, once these have been approved the Joint Formulary will be updated.

ACTION: APC members approved the submission with an AMBER 3 classification, LK will update the Joint Formulary once the updated COPD guidelines are ratified.

7. Formulary amendments

(a) FOR INFORMATION – Log of minor amendments completed.

GREEN

- Zetuvit® dressing has undergone a name change, it is now called Zetuvit Plus Superabsorber®. The District Nursing (DN) Teams and Tissue Viability leads are aware.
- ADACEL® (Tdap), a non-IPV-containing vaccine for injection in pre-filled syringe, this will replace Boostrix-IPV® for vaccination of pregnant women from the 1st July.

AMBER 2

- Pancrex V® - temporarily reclassified as Amber 2 to support the management of patients during significant supply problems with PERT (previously 340mg was non-formulary and 125mg was for NUH use only). The formulary entry will be reviewed once the supply issues are resolved.

OTHER

- Freestyle Libre Plus® and Dexcom One® + The original versions will continue to be available for approximately 12 months. Communication about the change in wear time has been circulated.

- Prostaglandin analogue preservative-free (PF) eye drop section. The brands previously recommended as PF preparations are price equivalent to the generic. The recommendation to use brand names has changed to take advantage of future price decreases.
- Nystaform® ointment and cream are no longer discontinued, the Joint Formulary entry has been updated to reflect this.
- Tirzepatide for the management of Type 2 diabetes: previously this has been available in 2.5mg and 5mg strengths, but the higher strengths have recently become available. Discussions with clinicians involved in the ICS Diabetes strategy group have indicated support for restricting dose escalation above a maintenance dose of 5mg weekly to be done only on specialist advice following a review. In clinical trials, the reductions in HBA1c were not significantly greater with larger doses, yet the cost of treatment is increased. This is consistent with practise in other areas.

(b) FOR DECISION – Suggested amendments

AMBER 2

- RespoSorb® Silicone border for use only on specialist advice, included in the CityCare formulary - available via NHS Supplies for community nursing teams.

APC members approved the formulary amendments.

ACTION: KR to update the Joint Formulary.

8. Horizon Scanning

- **(a) New Horizon Scanning publications for review**

GREY

- Period pain relief tablets
  Evana® (tranexamic acid) 500 mg is available for over-the-counter sale from a Pharmacy.
  Ultravana® 250mg (naproxen) is available for over-the-counter sale from a Pharmacy.

GREY no formal assessment

- Nephrotrans® (sodium hydrogen carbonate) 500 mg gastro-resistant capsules
- Apixaban (Eliquis®) granules in capsules for opening
- Dasiglucagon (Zegalogue®)

Other

- Fludrocortisone acetate 0.05mg tablets (50microgram). The 100mcg tablets are more cost-effective and many brands are scored and can be halved as per their product license additional details will be added to the formulary.
- Aqumeldi® 0.25 mg orodispersible tablets, enalapril, for treatment of heart failure in children aged from birth to <18 years. NUH procurement informed that a price is now available.
- Enalapril 1mg in 1mL oral solution other low-dose formulations are RED for NUH paediatric use only. Highlight to NUH licensed preparations are now available.
- Vibegron (Obgemsa®) for the symptomatic treatment of adults with overactive bladder syndrome [EU]. A TA is expected to be confirmed, await the TA for a classification.
- Quadrivalent Influenza Vaccine Split Virion® Inactivated High-Dose suspension for injection in pre-filled syringe. The influenza formulary section already contains a link to the GREEN book.

Medications awaiting a price before decision making.

- Pylera® 140 mg/125 mg/125 mg capsules (bismuth subcitrate potassium, metronidazole, tetracycline hydrochloride)
- Ozempic® 2mg solution for injection in pre-filled pen (semaglutide)
- Liraglutide biosimilar (Nevolat®) 18mg in 3mL prefilled pen for use as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adults.
- Liraglutide biosimilar (Zegluxen®) 18mg in 3mL prefilled pen for the treatment of adults, adolescents and children aged ≥10 years with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise.
- Escitalopram (Enalto®) 5mg, 10mg, 15mg and 20mg orodispersible tablets.
- Povidone iodine (Betadine®) 5% cream.
- Atropine eye drops.

ACTION: APC members approved the classifications. KR will update the Joint Formulary and add the items awaiting a price to the Horizon scanning follow up log.

- **(b) New NICE guidelines**

NICE TA – Atogepant for migraine prevention in adults – NICE TA973

LB presented the atogepant NICE TA for migraine prevention in adults. The TA was presented alongside a formulary submission request for an AMBER 2 classification.
The TA recommends atogepant as an alternative option to the injectable CGRP monoclonal antibodies for preventing migraine in adults who have at least 4 migraine days per month, only if at least 3 preventive medicines have failed or cannot be tolerated.
Stopping criteria: after 12 weeks if the frequency of migraine does not reduce by:

- at least 50% in episodic migraine (fewer than 15 headache days per month)
- at least 30% in chronic migraine (15 or more headache days per month, with at least 8 of those having features of migraine).

At this point in therapy, atogepant is the only available oral medicine for the prevention of chronic migraine. The costs with atogepant are currently lower than those of all the comparators.
The NUH Neurology team on behalf of both local trusts have submitted a request for the inclusion of atogepant with an AMBER 2 classification in line with the NICE TA. After initiation and following the 12-week efficacy review within Secondary Care, the ongoing prescribing will be transferred into Primary Care with 4 weeks supply prescription to allow transition time.

TB explained that the injectable migraine prevention treatments were subject to Patient Access Schemes, which reduced the list price and were provided by home care delivery. However, as tablets would likely be a preferred patient option for many, it is likely the cost will impact on Primary Care. It was suggested that a pathway for the use of the various options would be helpful to ensure that the most cost-effective options are utilised.

Because of pregnancy toxicity in animal studies, members requested clarity on any relevant preconception advice for women of childbearing potential. LB to discuss this with submitter.

ACTION: Members agreed an AMBER 2 classification in line with the NICE TA. Primary Care prescribing would only take place following a 12-week review and Secondary Care should issue a 4-week prescription to cover the transition period. LB to update the Joint Formulary and Headache pathway to include atogepant and include any pertinent pregnancy precaution information., LB/ TB to feedback to the high-cost medicines pharmacists regarding the request for a high-cost medicine pathway for this area.

9. MRSA guideline update

NB attended to present the MRSA guideline that had been updated to align with the products used for MRSA decolonisation.
The following main changes have been made to the guideline:

- Prontoderm® foam from AMBER 2 to GREEN, but with the restriction that it is second-line for patients where Octenisan® wash isn't suitable. Examples of non-suitability include allergy to Octenisan®, limited washing facilities and restricted washing ability. Prontoderm® foam does not need to be washed off, making it more appropriate for some patients.
- Octenisan® mitts and shower caps from GREEN to AMBER 2. They were previously the alternative for patients who couldn't use Octenisan® wash but are significantly more expensive than Prontoderm® foam, and prescribing will be restricted to patients with an allergy to Prontoderm® foam. Their use will only be on the recommendation of a specialist.
- Chlorhexidine 4% surgical scrub from GREEN to GREY (non-formulary) and remove from the APC MRSA guideline. Previously SFH had this as a treatment option but chlorhexidine 4% has been removed from their MRSA guideline and Octenisan® wash has been added as the first line choice.
- A note has been added that Bassetlaw follow South Yorkshire MRSA decolonisation guidelines and Prontoderm® foam is their first line choice.
- Mupirocin and Octenisan® nasal gel are both now first-line options. NUH recommend mupirocin and SFH recommends Octenisan®. Naseptin® has been retained as third-line option in case of shortages.

APC members requested that the first-line choice should be listed first. The guideline was approved subject to that minor amendment.

ACTION: APC members approved the guideline subject to the minor amendment, NB to amend and upload the guideline and update the Joint Formulary with the changes.

10. Scabies guideline update

NB attended to present the scabies guideline that had been updated to incorporate the use of ivermectin 3mg tablets. The following main changes have been made to the guideline:

- A licensed oral ivermectin 3mg tablet has been released in the UK and the proposal to change the traffic light classification from RED to AMBER 2 was discussed at the April 2024 APC formulary meeting. The traffic light classification decision is pending ratification of the APC Scabies guideline which has been updated to incorporate ivermectin 3mg tablets.
- Definitions of classical and crusted scabies have been added.
- Further information about identifying and treating close contacts has been added.
- Details on when the IPC teams should be contacted about scabies cases have been added.
- Treatment has been categorised into classical scabies and crusted scabies.
- The treatment advice for classical scabies has been updated.
- Ivermectin is available as a 3mg tablet, and the dosage for classical scabies is 200micrograms/kilogram taken as a single dose. A table providing information on the number of tablets required per body weight band has been added from the Summary of Product Characteristics (SPC).

- The guideline has been updated to state that a second dose should be given 7 days later, this is based on the lifecycle of the scabies mite and historical local use of the unlicensed preparation.
- The local advice from Infectious Diseases regarding the unlicensed preparation was to provide a second dose taken one week after the first for patients with classical scabies. The rationale being that oral ivermectin works by paralysing the motile mites but has no effect on eggs. More than one dose is therefore needed to kill motile larvae, nymphs, and adults with the first dose, and then as the eggs hatch kill the next wave of motile mites with a second dose.
- As the burden is much greater with crusted scabies, oral ivermectin at multiple doses may be combined with topical treatment. Specialist advice must always be sought if crusted scabies is suspected.

APC members approved the updated guideline.

ACTION: APC members approved the updated guideline. NB to update the formulary and upload the guideline.

11. <u>Ondansetron for IBS-D prescribing information sheet</u>

LB presented the ondansetron diarrhoea predominant Irritable Bowel Syndrome (IBS-D) prescribing information sheet. Ondansetron was approved as AMBER 2 by the APC members subject to the development of an information sheet to support Primary Care prescribers.

APC members approved the information sheet subject to the addition of pre-conception advice and grammatical corrections.

ACTION: APC members approved the information sheet subject to the minor changes. LB to inform the author and upload the information sheet to the APC website.

12. <u>Opicapone Ongentys (Bial Pharma UK Ltd); proposal for amendment to place in therapy</u>

LK presented the opicapone proposal and gave a brief reminder of previous discussions. Opicapone is a Catechol-O-Methyl Transferase (COMT) inhibitor used for the management of Parkinson's Disease (PD). Historically entacapone has been used first line, but a request has been made by PD clinicians to remove the restriction on opicapone such that either agent can be considered first line at the discretion of the clinician for PD patients with wearing off and motor fluctuations.

Opicapone has been discussed previously through the APC and following those discussions is currently restricted as a 2nd line agent after entacapone, unless the patient has severe or disabling OFF periods or significant pain in the OFF state, and slow dose titration of entacapone is particularly undesirable. It may also be considered first-line for patients on Duodopa infusion.

In clinical practise, many patients fail to tolerate entacapone or combination preparations containing entacapone (usually because of diarrhoea or postural hypotension) and clinical opinion supports superior efficacy of opicapone with a potential for reducing levodopa doses. Clinical reviews in PD clinics are never more frequently than 6 monthly, and there is no longer a PD nurse helpline at NUH. Therefore it is difficult for clinicians to make medication changes outside of these appointments and because of the restriction on opicapone, patients may not be identified as being suitable for opicapone for a significant amount of time.

Since opicapone was discussed previously, its price has decreased so the difference in cost, although still higher than entacapone, is less significant. A retrospective observational cohort study comparing entacapone and opicapone has also been published. This study demonstrated reductions in healthcare utilisation of patients prescribed opicapone compared to those prescribed entacapone in terms of outpatient appointments and Emergency Department visits.

Dr Jonathan Evans, Consultant Neurologist for NUH joined the APC discussions and explained the rationale behind its place in therapy, explaining that it was not the intention to start switching medications of stable patients.

Although it was acknowledged that opicapone remains more expensive than entacapone, it was felt that there was potential for its use to produce efficiency savings from reduced Secondary Care appointment costs and an enhanced patient experience. Discussions were had regarding how generally such system savings can be captured given the increasing scrutiny on medicine spend. It was requested that this should be captured in the next APC annual report.

APC members approved the proposal to remove the restriction on opicapone and requested audit data to be provided in approximately 12 months.

ACTION: LK to update the Joint Formulary, inform Dr Jonathan Evans of the decision and request that audit data is provided in 12 months.

13. Joint Formulary review

KR verbally gave a brief update about the Joint Formulary review which was ongoing with the help of a medicines management technician. Chapters 5 and 6 had now been completed culminating in a review of 364 entries of which 45 required an action. KR will provide another update in October.

14. Any Other Business

- A request had been received from NottsHC to host a COPD action plan leaflet specifically developed for those with learning difficulties. The APC agreed to the request but it was questioned whether there would be any printed copies made available, noting that the majority of printers only print in black and white. In addition, there was a request for the availability of an editable version so that it could be added to SystmOne/EMIS entries and saved to patients' records and then sent to patients electronically.
  ACTION: LK to feedback to the author

- AW requested advice following reports of patients experiencing adverse effects to a vaccine. Information was provided about reporting via the Yellow Card system. This link will also be made available on the patient section of the APC website.
  ACTION: KR to add a link to Yellow card reporting system.

15. Next meeting dates.

- APC Formulary meeting: Thursday 22nd August 2024 (2pm to 5pm, Microsoft Teams)- it was requested that members confirm availability for the meeting so that a decision could be made on whether to postpone the meeting and move the agenda items to either the July or September meeting.
- APC Guideline meeting: Thursday 18th July 2024 (2pm to 5pm, Microsoft Teams)

The meeting closed at: 5pm