These minutes are in draft form until ratified by the committee at the next meeting on 16th February 2022.

Nottinghamshire Area Prescribing Committee Formulary Meeting Minutes

APC meeting 15th December 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 (SFHT)**
David Wicks (DW)	**GP**	**NHS Nottingham and Nottinghamshire ICB**
Esther Gladman (EG)	**GP**	**City PBP, NHS Nottingham & Nottinghamshire ICB**
Debbie Storer (DS)	**Medicines Information Pharmacist**	**Nottingham University Hospitals NHS Trust**
Hannah Godden (HG)	**Principal Pharmacist – Adult Mental Health Community Teams.**	**Nottinghamshire Healthcare NHS Foundation Trust (NHCT)**
Jill Theobald (JT)	**Senior Medicines Optimisation Pharmacist**	**NHS Nottingham and Nottinghamshire ICB**
Laura Catt (LC)	**Prescribing Interface Advisor**	**NHS Nottingham & Nottinghamshire ICB**
Steve Haigh (SH)	**Medicines Information Pharmacist**	**Sherwood Forest Hospitals NHS Foundation Trust**
Katie Sanderson (KS)	**Patient representative**	
Ann Whitfield (AW)	**Patient representative**	
Georgie Dyson (GD). (left at 15:55)	**Advanced Clinical Practitioner (ACP)**	**Nottingham Urgent Treatment Centre, CityCare**
Khalid Butt (KB)	**LMC representative**	**NHS Nottingham & Nottinghamshire ICB**

In attendance:

Prof Hywel Williams, Professor of Dermato-Epidemiology and Co-Director, Centre of Evidence-Based Dermatology for item 5a.

Dr Priya Achar, Consultant ENT Surgeon for item 5b.

Dr Tabitha Randell, Consultant in Paediatric Endocrinology and Diabetes & Deputy Divisional Director for item 5c.
James Sutton, Lead Pharmacist Medicines Finance and Divisional Support, NUH, for item 8.

Observing:
Trainee pharmacists from SFHT; Mary Villegas, Macy Fofulit, Thea Hannigan, Erin Hickey, Katie Glover.

Interface support (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/Formulary Support Technician
Vimbayi Mushayi (VM), Specialist Medicines Optimisation Interface Pharmacist
Irina Varlan (IV), Specialist Medicines Optimisation Interface Pharmacist
Nichola Butcher (NB), Specialist Medicines Optimisation Interface Pharmacist

1. Welcome and apologies

Apologies

Tanya Behrendt (TB), Senior Medicines Optimisation Pharmacist, NHS Nottingham & Nottinghamshire ICB
David Kellock (DK), SFH Drug and Therapeutics Committee, Sherwood Forest Hospitals NHS Foundation Trust
Asifa Akhtar (AA), GP, NHS Nottingham and Nottinghamshire ICB
Lois Mugleston (LM), GP, City PBP, NHS Nottingham and Nottinghamshire ICB
Jenifer Moss Langfield (JML), LMC, GP, NHS Nottingham & Nottinghamshire ICB

To note: the meeting did not have Secondary Care medic representation.

2. Declarations of interest

No declarations were made by APC members or the APC support team.

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

Cavilon: A request to review its inclusion in the formulary had been received as it is currently not listed on the barrier preparations formulary. However, Cavilon film applicators had recently been proposed as an addition to the secondary care trusts' formularies to be supplied by the NHS direct supply chain.
ACTION: LK/ KR to update when further information becomes available.

Agomelatine: HG updated members on the findings of the NHCTs internal audit. The monitoring of LFTs had been recognised as an area requiring improvement, and the Trust is currently completing a quality improvement plan. HG will bring to APC any further information as it becomes available.
ACTION: HG to update APC with further information as it becomes available.

Doxazosin for PTSD: The APC had previously discussed a submission from neurology requesting an AMBER 2 classification for doxazosin for the treatment of nightmares associated with PTSD. As requested at the previous meeting, LK had attempted to investigate treatment options utilised by the Armed Forces for PTSD; however, no information had been obtained. Discussions within NHCT had not indicated sufficient clinician support to pursue a formulary application for alpha blockers for this indication. APC members requested that further information be sought on usage elsewhere and suggested contacting Sheffield Teaching Hospitals Trust (STHT) regarding possible use for this indication as patients with a Functional Neurological Disorder may be referred there.
ACTION: LK to contact STHT and bring back to APC.

Dexcom ONE® for diabetes: LC explained that although this device had been approved at the October APC meeting, it had not yet been added to the formulary due to the predicted costs exceeding the financial mandate. However, Dexcom ONE® has been incorporated into the Freestyle Libre inclusion criteria, and financial approval of the business case is expected to be in place in time for the publication of the guideline.

Shingles vaccines for Rheumatology patients: LK explained that it had become apparent that the previous issues discussed affect a wider patient group than only rheumatology patients and that there are also other vaccines involved. Current advice for some of these patients from the Joint Committee on Vaccination and Immunisation (JCVI) conflicts with the advice listed in the Green Book, so work is in progress to confirm the situation with NHS England.
ACTION: LK to update members when further clarity from NHSE is obtained.

Traffic light classification of medicines for metabolic diseases: LK explained that work was still in progress and requested that this item remain on the agenda for the next meeting.

5. New Applications

a) Tacrolimus ointment (generic) for vitiligo: Professor Hywel Williams, Professor of Dermato-Epidemiology and Co-Director, Centre of Evidence-Based Dermatology (attended at 14:30).

SW presented the tacrolimus ointment for facial vitiligo submission for adults and children. An AMBER 2 classification was being sought by the submitter; Professor Hywel Williams.
Topical tacrolimus is unlicensed for vitiligo. However, the off-label use of tacrolimus ointment is recommended as a 1st line topical treatment for facial vitiligo by the primary care dermatology society and supported by the British Association of Dermatologists in their guideline for the management of people with facial vitiligo, as an alternative to potent or very potent topical corticosteroids. The use of topical calcineurin inhibitors as monotherapy was also recommended by the NICE CKS as an alternative to corticosteroid therapy, owing to their superior short-term safety profile.
SW explained that patient numbers were small, and tacrolimus had a good safety profile, noting that if local skin irritation(s) occur, these will generally be resolved within a week.
Professor Hywel Williams joined the meeting to respond to some of the questions raised by members. He explained that these treatments are regularly prescribed in primary care; however, the primary diagnosis needed to be made via dermatology to differentiate from other dermatological conditions such as Pityriasis Alba. The request was being made for the 0.1% strength ointment, but the lower strength 0.03% ointment was also included in the submission as this could be useful in some cases for maintaining repigmentation once a reasonable repigmentation had been achieved. Compared to potent corticosteroids, there were no blood tests or routine monitoring requirements for tacrolimus ointment. Assessment was suggested for any meaningful repigmentation after at least 6 months, and if the 0.1% strength was ineffective, Professor Williams recommended that the treatment be stopped.
The group approved the submission for AMBER 2, with an information sheet.

ACTION: SW to produce an information sheet and update the formulary with an AMBER 2 classification for facial vitiligo once the APC have ratified the information sheet.

b) Ciprofloxacin 0.3% with Dexamethasone 0.1% ear drops (generic) for ear infections: Dr Priya Achar, Consultant ENT Surgeon (attended at 15:00).

SW presented the formulary submission for ciprofloxacin 0.3%, and dexamethasone 0.1% combination ear drops for acute otitis externa (AOE) and acute otitis media in patients with tympanostomy tubes (AOMT). This is licensed in adults and in children with AOMT from 6 months old and in children with AOE from 1 year old. The request was for AMBER 2 for use as per the licensed indication. The ciprofloxacin with dexamethasone combination ear drops will be a licensed alternative to the current practice of using ciprofloxacin ear drops and off-label dexamethasone eye drops as two separate ear drops.
NHS Scotland recommended the use of ciprofloxacin 0.3% with dexamethasone 0.1% ear drops for AOMT and AOE indications in adults and children and NICE CKS recommends topical antibiotics with or without topical corticosteroids.
Some clinicians felt this product was already being prescribed for recurrent ear infections. Ciprofloxacin 0.2% (Cetraxal®) is currently recommended in the APC Otitis Externa – Acute and Chronic antimicrobial guideline as a second-line option, following specialist advice only.
Dr Priya Achar attended the meeting at 15:00 and explained that the ENT team uses aminoglycoside as per the secondary care antimicrobial guideline. However, gentamicin ear drops may cause ototoxicity and should also not be used if there is an ear perforation. Ciprofloxacin ear drops are non-ototoxic with good coverage for pseudomonas-related ear infections. Dr Achar explained that there was some reluctance in Primary Care to prescribe topical ear drops compared to oral antibiotics. This was agreed by GD, who noted that the Emergency Treatment Centre contacts the specialist for treatment advice for AOE, due to the current formulary classification of ciprofloxacin.
Clinicians at the meeting suggested that an AMBER 3 classification may be helpful, but APC members wished to have microbiology input before a decision was agreed. A request was also made for further information regarding the recommendations for aural toilet use.

ACTION: SW to discuss further with microbiology and the attending consultant, Dr Priya Achar/microbiology/GP members about adding AOMT to the APC guideline and obtaining further information on aural toilet recommendations. SW to update formulary and guideline as appropriate after these discussions.

c) Efmody® (hydrocortisone MR, Diurnal Ltd) for Congenital Adrenal Hyperplasia (CAH): Dr Tabitha Randell, Consultant in Paediatric Endocrinology and Diabetes & Deputy Divisional Director (attended at 15:55).

SW presented the formulary submission. The request was for an AMBER 2 classification for adolescents from 12 years old and for adults with CAH. Use in adults was included in the submission for exceptional cases, for example, in a young woman trying to conceive, where strict compliance to therapy is required. Efmody® is the first hydrocortisone modified-release capsule licensed for CA and is designed to deliver a sustained release of hydrocortisone over 24 hours. The dose is split into two at bedtime and in the morning, making it appealing to school-age adolescents, improving the compliance of young people as it removes the need to take the medication at school.
Efmody® is recommended as an option for use within NHS Wales as a 2nd-line CAH treatment in young people aged 12 years and over and 3rd-line treatment in adults. Hydrocortisone MR is also recommended in the clinical practice guideline for CAH by the Endocrine Society.
Dr Tabitha Randell explained that because of the considerable cost of Efmody it would only be used in exceptional cases and that all monitoring would be provided by secondary care. Currently, prescriptions are provided by the hospital, using an FP10HP. APC members were concerned that there could be a risk of overlooking patient follow-ups due to the small patient numbers. Dr Tabitha Randell noted that Alkindi® also has a small number of patients, but this had not presented any issues. Immediate-release hydrocortisone is also currently being prescribed in primary care by GPs.

SW noted that the hydrocortisone MR tablet, available as Plenadrin®, is currently GREY in the formulary. It is indicated for the treatment of adrenal insufficiency in adults, NOT licensed for CAH, and is more expensive compared to Efmody®.
The MR products are currently available on SystmOne, so inadvertent prescribing could occur, regardless of formulary status. Brand prescribing will be required, and it was requested that this be added to Optimise Rx i.e., prescribe by brand for CAH, following tertiary service initiation.
The APC agreed to classify Efmody® as AMBER 2 for CAH and to revisit this after a year.

ACTION: SW to update the formulary. Add to action log to monitor prescribing in 1 years' time.

d) Admelog® (insulin lispro biosimilar- Sanofi)

LK presented a proposal to include the biosimilar insulin lispro Admelog® in the formulary, with an AMBER 2 classification. Admelog® offers cost savings compared to the originator product Humalog® and it is hoped that its inclusion will help enforce the message of using a biosimilar where one exists. In addition, NICE NG17 and NG 8 recommend using the product with the lowest acquisition cost when starting an insulin for which a biosimilar is available. Furthermore, when patients are already using an insulin for which a lower-cost biosimilar is available, the possibility of switching to the biosimilar can be considered as a shared decision with the patient.
The Admelog® pre-filled pen device is the Solostar pen, which is the same pen device as Lantus® and Trurapi® so there is familiarity locally with using the device.
APC members asked if Diabetic Specialist Nurse (DSN) input had been sought. LK confirmed that there was work ongoing with DSNs promoting the use of several insulin biosimilars within the ICS and this product will be included in this work.

APC members approved the addition of Admelog® to the Formulary, with an AMBER 2 classification.

ACTION: LK to update the Joint Formulary and add to the Diabetes Guidelines.

6. Formulary amendments

a) For Information – Log of minor amendments carried out

Noted and listed below:

GREY

- Prochlorperazine (Stemetil®) 5mg/5ml Syrup – discontinued.
- Cavilon® cream and spray - Not included in barrier formulary but have been used historically in secondary care. Confirmed with Trusts that formulary alternatives are now in use.
- Riboflavin - a food supplement, OTC purchase required for migraine use. NB Riboflavin is also classified RED for the treatment of metabolic diseases.
- Selsun® 2.5% shampoo – discontinued.
- Freestyle® Libre 1 – discontinued.
- Synalar C® ointment (fluocinolone 0.025% with clioquinol) – discontinued.
- Estradiol implants – previously listed on the formulary as GREEN but unlicensed. Confirmed with NUH and SFH that no longer used.
- Insuman® Basal 5ml vial – discontinued.
- Diazepam 2.5mg Rectal tubes – 5mg and 10mg strengths still available.
- Calfovit D3® (Colecalciferol with calcium phosphate) – discontinued.
- Fenbid Forte®- Discontinued. Generic prescribing of ibuprofen 10% advised.

GREEN

- Suprasorb® P Sensitive: Added to formulary. SFH is implementing a switch from Allevyn® gentle border/ Allevyn® adhesive to Suprasorb® P Sensitive, in line with Regional Wound Care Formulary.
- Albustix®: previously restricted on the formulary for SFHT use; restriction removed.
- Pro D3® 2000 units/ ml drops may be supplied as an alternative to Fultium D3® drops during supply problems.

OTHER

- Cefotaxime: Message about supply problems with 1g vials removed as no longer relevant.
- Tranylcypromine entry: wording changed; for use only on recommendation from the Specialist Depression Service at Nottinghamshire Healthcare NHS Foundation Trust.
- Guanfacine: Red classification agreed at Notts HC; for use on the advice of the Neurodevelopmental Specialist Service at Nottinghamshire Healthcare.
- Bismuth subsalicylate (Pepto-Bismol® tablets): Supply issues until June 2023.
- Rivaroxaban suspension (Xarelto®): Formulary entry clarified to avoid patients being given insufficient supply.
- Trimbow® inhaler: All strengths added.

b) FOR DECISION

RED

- Chloral Betaine: Chloral betaine has been discontinued and is only available as a special (which is not listed in the specials tariff). No current patients in primary care. DS requested the reason for the change be added to the formulary as this may be a temporary discontinuation.

GREEN

- Metformin 500mg powder sachets: addition to the formulary agreed, with reference to it being more cost- effective than oral solution. Oral solution to remain as an option for patients with whom the 150ml reconstitution volume required for the sachets is not manageable.
- Luforbec® inhaler 100/6 and 200/6 (beclometasone 100mcg / formoterol 6mcg and beclometasone 200mcg / formoterol 6mcg pressurised metered dose inhalers (pMDIs)). Agreed for use as cost- effective alternatives to Fostair 100/6 and 200/6 pMDIs. Work on primary care implementation and updating of asthma and COPD guidelines in progress by Medicines Optimisation Respiratory Group.

GREY

- iQoro® device: Classify as Grey and add the link to PrescQIPP summary that recommends its non-use.

All agreed as per recommendation, except for the points below:

- Apo-go® POD: This device will replace the APO- go devices currently available and the manufacturer will be initiating a phased switch, with training provided by the company. The apomorphine Shared Care Protocol (SPC) is currently being updated. and the company offers training for the new device. Once the SCP is finalised, an AMBER 1 classification will be assigned.

ACTION: VM to add to updated SCP.

- Glycopyrronium tablets, Assicco®: This offers cost savings compared to current formulations listed on the formulary but will need to be prescribed by brand to achieve the relevant cost savings. It was questioned whether any dose conversion is required when switching formulations. Further work is required to calculate potential savings locally and potential use will be discussed with clinicians.

ACTION: KR/ LK to take forward. ACTION: KR to complete the agreed formulary amendments.

Vortioxetine Traffic light reclassification

HG presented the proposed vortioxetine (Brintellix®) change of traffic light classification from AMBER 2 to AMBER 3. Vortioxetine is indicated for major depression in adults. This proposal is supported by the NICE Guideline 222 for patients who have had no response or limited response to at least 2 previous antidepressants. The safety and side effect profile of vortioxetine is comparable to other SSRIs, and there is local experience of use; EPACT data shows >250 items prescribed in August 22.
NHCT had suggested producing a prescribing information sheet to support the reclassification if the change was agreed in principle.

ACTION: Members agreed an AMBER 3 classification in principle but requested a supporting information sheet. HG to bring the Information sheet to a future APC meeting for agreement of an AMBER 3 classification.

7. Horizon Scanning

a) New publications for review:

GREY – no formal assessment

- Mesalazine. Salcrozine® 500 mg and 1000mg gastro-resistant tablets. Consultation would be required with gastroenterology before considering use. Currently only a small amount of prescribing for the current formulary alternative so unlikely to offer significant savings.

- Drovelis® ▼ (drospirenone & estetrol. 3 mg/14.2 mg tablets): a combined oral contraceptive containing estetrol, a new synthetic version of a naturally occurring oestrogen, and the progestogen drospirenone.

- Lidocaine. Lidbree® 42 mg/mL intrauterine gel: more expensive than current formulary alternatives.

- Humalog (insulin lispro) 100 units/ml Tempo Pen® optional smart button technology. Tempo pen offers no benefits over standard pens while awaiting availability of smart button. *Post meeting note: product currently under development, with no anticipated launch date known.*

- Desmopressin acetate; Demovo® 360 micrograms/ml Oral Solution: Price to be reviewed once product launched, for consideration of use alongside current formulary options.

- Midazolam maleate; Epistatus® 2.5 mg and 5mg oromucosal solution pre-filled syringes: Price to be reviewed once product is launched, for consideration of use alongside current formulary options. Ensure that advice exists on formulary and OptimiseRx for current midazolam prescriptions prescribed by brand as this is a different strength product to Buccolam. Semaglutide. (Ozempic®) 2mg in 0.74mL pre-filled pen: Price to be reviewed once product is launched, for consideration of use alongside current formulary

options.

OTHER

- Lyumjev® ▼ (insulin lispro) Junior KwikPen solution for injection in pre-filled pen: Current formulary approval is for adults only. Remove the statement on the formulary that it is not licensed for children.

NEW PUBLICATIONS

- NICE TA 832- Regololix- estradiol–norethisterone acetate for treating moderate to severe symptoms of uterine fibroids. Under consideration by Trust DTCs.

- Asthma inhalers and climate change: Patient decision aid. NG80, a link has been added to the APC website's Greener NHS drop-down menu.

- Osteoarthritis in over 16s: diagnosis and management. NG226 – noted; no further action

- Subarachnoid haemorrhage caused by a ruptured aneurysm: diagnosis and management. NG228 – noted; no further action

8. Melatonin formulary amendment request

James Sutton, Lead Pharmacist Medicines Finance and Divisional Support at NUH, attended the meeting at 16:00 to present the melatonin formulary amendment request, following discussions at the Nottinghamshire ICS Melatonin Working Group.
James gave a brief background on melatonin and its place in therapy, explaining that suitable licensed formulations exist for use in children, but that introduction of those products will incur a significant cost pressure to the Nottinghamshire health community. Also, unlicensed melatonin products are likely to become unavailable in the near future, causing prescribers to consider switching formulations rapidly, which may lead to adverse outcomes for existing patients.
Various options were considered, and consensus agreement had been reached at the Nottinghamshire ICS Melatonin Working Group, their preferred option was the following:

- Managed introduction of licensed melatonin products in paediatrics within secondary care:
  This option would require the addition of a range of licensed melatonin products to the Nottinghamshire Joint Formulary, with the most cost-effective product being utilised wherever clinically possible. Prescribers, including the Trust Pharmacy team, community paediatricians and specialist nurses, would manage the changeover from unlicensed to licensed products, maintaining and enhancing advice on sleep hygiene, weaning doses, drug holidays and maximum effective doses. Scope supply/delivery service from Trust Pharmacy for SFH patients (removes posting and governance challenges of this).
  Advantages: maintain control of melatonin usage and spending, a decrease of risks surrounding the use of unlicensed products (legal challenge, product quality and availability)
  Risks: Financial (see below), potential loss of clinical effectiveness, due to product change in a challenging patient cohort. Continued governance issues and costs of SFH postal supply route unless this is amended.

It was further noted that licensed oral melatonin products had already been adopted in the vast majority of secondary care Trusts in England (data from DEFINE).

A proposed implementation plan had also been devised by the working group, as follows:

- Communicate change within the pharmacy and relevant directorates – poster/memo
- Set-up new medicine on the pharmacy system, order, update stock lists and decommission use and stocks of unlicensed products
- Update Nottinghamshire Joint formulary to reflect change
- Issue a letter to patients explaining the decision, rationale and timescale
- Inform ICB of cost pressure and impact on planning for future financial years

A request to reclassify melatonin as a P medication had been submitted to the MHRA; however, there was no progress regarding a change of status. RMOC is also considering setting up a Melatonin working group and Nottinghamshire representatives have volunteered to be on the committee.
Acknowledgement of the sleep hygiene service in preventing some of the prescribing was noted; however, this service is only presently available from NUH and did not have the capacity to expand to review the number of patients involved.

ACTION: APC members agreed in principle to this proposal.

10. Testosterone for women: traffic light classification

Testosterone for low libido in post-menopausal women had been approved earlier this year, with an AMBER 2 classification and an accompanying information sheet.
GP members had reported that there had been delays in advice and guidance requests being actioned, with instances of requests being rejected due to excess workload. It was felt that the traffic light status should be reconsidered to allow GP initiation, in line with the previously agreed criteria and monitoring guidance. This would reduce both GP and specialist workload, but when following the current guidance, testosterone should be initiated only in appropriate cases. The change in classification would also ensure equity of access for all patients, as some patients are going to private providers to receive treatment recommendations.

The APC agreed to a reclassification to AMBER 3, for use in line with the current guidance.

ACTION: LK to update formulary and guidance.

11. Continence formulary

JT provided an overview of the continence formulary, which represented the most cost-effective formulary options. It was questioned whether the secondary care continence specialist(s) have been made aware of the new formulary.

The APC agreed to the formulary, subject to confirmation of secondary care approval.

ACTION: JT to seek confirmation of secondary care support and upload document to APC website.

12. AOB

a) Amiodarone shared care clarification: During discussions about implementation of the amiodarone Shared Care Protocol, it had become apparent that there is no directive about whether patients need to receive regular secondary care reviews and there was a differing opinion among clinicians locally. APC members felt that Specialist follow-up was required for a patient being managed under a Shared Care agreement. It was suggested that the RMOC be contacted to ascertain whether this was an oversight when developing the Shared Care Protocol.

b) APC members expressed their thanks, and bid farewell to SM and EG, who were leaving the APC following retirement. Both have been active and valued members for many years and their input has been greatly appreciated. The committee wish them well.

The meeting closed at 17:20.

- **Date of next APC Guideline meeting: Thursday, 19th January 2023, 14:00-17:00 (MS Teams)**
- **Date of next APC Formulary meeting: Thursday, 16th February 2023, 14:00-17:00 (MS Teams)**