These minutes are in draft form until ratified by the committee at the next meeting on 15th Dec 2022.

Nottinghamshire Area Prescribing Committee Formulary Meeting Minutes

APC meeting 13th October 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 ICB**
Esther Gladman (EG)	**GP**	**City PBP, NHS Nottingham & Nottinghamshire ICB**
Debbie Storer (DS)	**Medicines Information Pharmacist**	**Nottingham University Hospitals NHS Trust**
Asifa Akhtar (AA)	**GP**	**NHS Nottingham and Nottinghamshire ICB**
Lois Mugleston (LM)	**GP**	**City PBP, NHS Nottingham and Nottinghamshire ICB**
Hannah Godden (HG)	**Principal Pharmacist – Adult Mental Health Community Teams.**	**Nottinghamshire Healthcare NHS Foundation Trust**
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**	

In attendance:
Dr Sumeet Singhal joined the meeting at 14:30 for item 5a.
Natasha Hudson, specialist pharmacist joined the meeting at 15:00 for item 5b.

Dr Buddhike Mendis, NUH consultant and Rosa Bell, specialist pharmacist joined the meeting at 16:05 for item 5c.
Dr Vivian Weston, consultant microbiologist/community infection control joined the meeting at 16:00 for item 7b.

Observing:
Sheena Kothari, Specialist Pharmacist for Therapeutics and Medicine Finance at NUH

Interface support (NHS Nottingham & Nottinghamshire ICB):
Nichola Butcher (NB), Specialist Medicines Optimisation Interface Pharmacist
Lynne Kennell (LK), Specialist Interface & Formulary Pharmacist for SFH
Michalina Ogejo (MO), Medicines Optimisation and Pain Clinic Pharmacist joined the meeting at 15:38 for item 6.
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

1. Welcome and apologies

Apologies

Tanya Behrendt (TB), Senior Medicines Optimisation Pharmacist, NHS Nottingham & Nottinghamshire ICB
Khalid Butt (KB), LMC, GP, NHS Nottingham & Nottinghamshire ICB
Jenifer Moss Langfield (JML), LMC, GP, NHS Nottingham & Nottinghamshire ICB

To note: the meeting had no LMC 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 a minor amendment.

4. Matters arising and action log

Steroid card patient letter

LC and AW updated members on the steroid card letter. Following some issues being raised during the development of the letter, the consultation process will be reviewed, particularly the need for deadline dates for comment. The APC team will act as liaison between authors and patient representatives in future in order to protect the latters' time.

Rufinamide

LK provided an update on the action from the August meeting. Rufinamide had provisionally been given an AMBER 2 classification while awaiting further investigation and clarification on the potential financial implications. NUH have clarified that the current spend is not as high as initially expected and is significantly below the APC's mandated threshold. Therefore, the previous decision to classify rufinamide as AMBER 2 has been actioned.

Guanfacine
LC provided an update on guanfacine as previously a request had been made to move children and adults to shared care arrangements and change the formulary status for both to AMBER 1. Commissioners have been approached as guanfacine is not included in the current shared care Local Enhanced Service (LES) agreement. This is unlikely to change, due to lack of additional in-year funding. Guanfacine is currently RED for children and not on the formulary for adults, although some legacy adults are currently receiving it from Notts Healthcare (patients moving from paediatric to adult services. for example). The clarification of the formulary status for adults is to be deferred to NottsHCT, to go through their DTC process; HG will provide further information when this is available.
ACTION: HG to provide future updates.

Safinamide and opicapone–The APC had previously agreed to extend the indications on the formulary and it had been requested that prescribing be monitored to ensure that it was in line with the agreed use. LK confirmed that ePACT2 data had been reviewed and prescribing had not increased excessively.
ACTION: remove from the action log; no further action required.

Cavilon – currently listed on the Joint Formulary with a GREEN classification, but it is no longer listed on the barrier preparation formulary. Work is continuing in secondary care to review usage.
ACTION: LK/SW to update when further information becomes available.

Lyumjev (insulin Lispro)- a formulary submission had been approved previously, but an audit of usage and outcomes had been requested. Clinicians were unable to produce a comprehensive audit, due to resource constraints, but anecdotal feedback was that beneficial effects had been seen. Monitoring had been completed using ePACT2 data; prescribing has increased but is below predicted levels.
ACTION: LK to update the action log to review ePACT2 data in six months.

Agomelatine – HG advised that prescription numbers were in line with predictions following a traffic light reclassification to AMBER 2. NottsHC are conducting an internal audit on patient monitoring (LFTs) and HG will bring to APC any significant feedback from this audit.
ACTION: HG to feedback anything relevant from the audit once it has been completed.

Cinacalcet – Concerns had been expressed previously about the significant spend on cinacalcet following its reclassification to AMBER 2. ePACT2 data had been reviewed and, although usage had increased, the cost of the medication had decreased so the overall cost remained stable.
ACTION: Remove from the action log; no further action required.

5. New applications - SW/LK

a. Doxazosin for nightmares associated with PTSD.

LK presented a submission from neurology for doxazosin for PTSD. An AMBER 2 classification had been requested.

Currently, the only recognised treatment for PTSD is long-term trauma therapy, but this is not always readily accessible, and some patients are not suitable for it. SSRIs are considered first line pharmacological therapy and antipsychotics may be used, but as they are associated with adverse effects, they are often avoided in younger patients.

NICE guidance on the treatment of PTSD does not contain any recommendations on alpha blockers; evidence for prazosin had been reviewed during the development of the guidance but it was felt to be

insufficient to base a recommendation on. BAP guidance and the Maudsley Guidelines list prazosin as an option.

This condition is also treated by psychiatrists at Notts HC, but their alpha blocker of choice is understood to be prazosin. Further clarification is, however, needed from Notts HC as prazosin is currently classified as Grey.

Both prazosin and doxazosin are unlicensed for this indication. The submitting clinician expressed a preference for doxazosin rather than prazosin, due to its longer duration of action which is useful for controlling nightmares occurring later in the night. Also, doxazosin has greater familiarity among GPs, there had previously been supply issues with prazosin, and doxazosin is less expensive.

Concerns were raised about the lack of supporting evidence for doxazosin, although it was acknowledged that this is a difficult condition to treat and there is a lot of experience of prescribing doxazosin for other indications. Some concerns were raised regarding the likelihood of de-prescribing occurring once prescribing responsibility had been taken over by primary care and it was therefore asked whether there is a need for primary care prescriptions, given that this may be given as short-term treatment. It was highlighted that some patients may need to continue indefinitely and continued hospital prescribing is not ideal, especially as NUH is a tertiary centre.

Dr Singhal Sumeet explained that, from clinical experience, he had found doxazosin to be very effective. Its use in other areas was asked about and it was suggested that it be ascertained whether it is used by the Armed Forces.

ACTION: LK to investigate treatment options utilised by the Armed Forces for PTSD.
HG to take to TMOG at NottsHC.
LK to bring back to December APC.

b. Trimbow® MDI high-strength for asthma

SW presented the submission for high-strength Trimbow® pMDI (179/5/9), which has recently become available in the UK. The submission request is in line with the licensed indication, for maintenance treatment of asthma in adults not adequately controlled with a maintenance combination of long-acting Beta 2 agonist and a high dose corticosteroid and who are experiencing one or more exacerbations in a year. Trimbow® pMDI, (87/5/9) was approved by the APC as AMBER 2 in December 2021. The two strengths of the inhalers can be identified by different coloured caps, together with different coloured label packaging.

The triple combination of ICS/LABA/LAMA is in line with the recommendations from NICE, BTS/SIGN, and GINA guidelines for asthma. High-strength Trimbow® pMDI is the same price as medium-strength Trimbow® pMDI and is more cost effective, when compared to the APC-recommended ICS/LABA dual combination in addition to the LABA Spiriva® Respimat as a second device.

NUH specialist respiratory pharmacist Natasha Hudson joined the meeting and confirmed that a steroid card would be provided for patients starting on high-strength Trimbow®. The triple combination will help tackle compliance issues by using a single device rather than multiple inhaler devices. It will also help patients with increasing costs of living as the triple inhaler only incurs one prescription charge. The place in therapy will be for patients on a medium-strength Trimbow® pMDI or on high dose Fostair® who need a step-up. The committee was reassured that patients would be initiated on this inhaler by a respiratory specialist and counselled on the use of the inhaler. Patients can potentially step down if they gain better asthma control. There is no carbon footprint data available from the manufacturer at present.

Specialist initiation would be required; patient numbers are predicted to be low,10-20 estimated for NUH and 5-10 for SFHT.

The committee agreed with the addition of the higher strength inhaler to the formulary, but felt that the current asthma guideline needed to be made clearer and it was proposed that the ICS respiratory group should review the guideline.

ACTION: SW to update the formulary, highlighting that two strengths are available, with the higher strength for use in asthma only.
LC to request that the asthma guideline is updated by the ICS Respiratory Group.

c. Dexcom ONE® for diabetes

SW presented the submission for this real time continuous glucose monitor (rtCGM). A request for an AMBER 2 classification had been made for the following patient groups in line with the licensed indication:

- all adult patients with Type I diabetes, as per NICE NG17,
- adults with Type II diabetes on multiple daily injections of insulin as per NICE NG28,
- All children with type I diabetes as per NICE NG18, as there may be individual cases where the Dexcom® ONE sensor is appropriate.

Key advantages for Dexcom One® include:

- Sends proactive glucose readings every 5 minutes to a compatible smartphone (receiver). There is no need to scan the device. The company will provide a free reader for patients who do not have access to a smartphone.
- Designed to eliminate the need for finger pricking by using a blood glucose monitor. Note that patients will still require ketone testing strips.
- Empowers patients to control their diabetes by having 24-hour information on blood glucose levels.
- It is licensed for use from 2 years (flash devices are from 4 years of age).

Another type of CGM device available on prescription and listed on the Joint Formulary is the intermittently scanned CGM (is-CGM), also known as "flash". An example of this is the Freestyle® Libre 1 and 2. Flash devices involve scanning the sensor with your mobile phone to see blood sugar levels. Dr Mendis explained that one of the disadvantages of using a Flash device is that data is only available if the device is scanned and therefore is reliant on the patient scanning the device. The Dexcom® ONE transmitter sends proactive glucose readings every 5 minutes, and there is no need to scan the device. The glucose level information appears on the phone automatically.

NICE recommends a choice of real time CGM or Flash as follows:

- Offer adults with type 1 diabetes a choice of real-time CGM or Flash, based on their individual preferences, needs, characteristics, and the functionality of the devices available.
- Offer real-time CGM to all children and young people with type 1 diabetes, together with education to support children and young people and their families and carers in using it. Offer Flash to children and young people with type 1 diabetes aged 4 years and over who are unable to use rtCGM or who express a clear preference for isCGM.
- Offer Flash to adults with type 2 diabetes who meet the criteria. Consider real-time CGM as an alternative to Flash for adults with insulin-treated Type II diabetes if it is available at the same or lower cost.
- Offer real-time CGM to all pregnant women with type I diabetes to help them meet their pregnancy blood glucose targets and improve neonatal outcomes.

NICE found these technologies to be cost effective compared to intermittent capillary blood glucose monitoring.

Dexcom® ONE is designed to eliminate the need for finger pricking by using a blood glucose monitor. However, NICE advises that patients will still need to take capillary blood glucose measurements to

check the accuracy of their CGM device as a backup in cases where the blood glucose levels are changing rapidly or if the device stops working.

Members agreed that Dexcom® ONE should be classified as AMBER 2 for type I diabetes and classified as AMBER 3 for patients with type II diabetes. The difference was due to decision-making on the most appropriate device being more complex for Type 1 diabetics; there may be a potential need for insulin pumps and compatible CGM devices. There is a requirement for Primary care clinicians to register with the manufacturer and complete training on interpreting results from CGM. Links to training packs will be made available.

The annual cost of Dexcom ONE is estimated to be above the APC's financial mandate and will therefore require a business case. LC explained that a regional business case is planned for CGM devices; the Nottingham and Nottinghamshire ICS Diabetes Strategy Group will progress the business case.

ACTION: LC to support the development and submission of the business case to the ICB and to develop prescribing and eligibility criteria for initiation.
LC to feedback at the December APC meeting.

6. Actimorph®

MO joined the meeting to present the Actimorph agenda item. This had been discussed at the previous meeting and further information had been sought.

Concerns were raised about the possible impact of Actimorph if used instead of Oramorph liquid, both in terms of increased costs and enhanced CD requirements. However, it was emphasised that there are cohorts of patients that would benefit from the use of an orodispersible tablet instead of a solid tablet or liquid formulation.

Actimorph was proposed as an alternative for:

1) patients having problems with manual dexterity and/or tremor, where liquid (Oramorph) could be spilled;
2) carers struggling with measuring correct doses of Oramorph;
3) patients showing signs of potential drug overuse (incorrect use of syringes or spoons resulting in over-measuring of Oramorph liquid);
4) when deprescribing opioids under the guidance of a pain clinic clinician.

It was agreed that Actimorph should be classified as GREEN for use in Palliative Care patients and AMBER 2 when used/ recommended by Pain Teams.

The Committee requested a follow up review in 6 months' time to assess the impact of Actimorph on prescribing budgets and to review feedback on its usefulness among patients prescribed Actimorph.

ACTION: KR/ MO to update the formulary.
KR to update the Action log to include a review of the prescribing of Actimorph in 6 months' time.

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

- Vaxelis®, diptheria, tetanus, pertussis (acellular component), poliomyelitis (inactivated) and Haemophilus influenza type b and hepatitis B vaccine suspension for injection prefilled syringe

Vaxelis is an immunising vaccine for infants and toddlers from the age of 6 weeks. It forms part of the childhood primary immunisation regime and subsequent booster vaccinations as recommended in the Green book. The request for the formulary amendment came from NUH neonatal consultants to

ensure an alternative preparation was available in the event of a supply issue, to prevent immunisation delays.

ACTION: Add to formulary with a GREEN classification.

- Chloral hydrate

A request to use an unlicensed chloral hydrate 500mg/5mL liquid came from NUH via DTC. This unlicensed preparation is sugar-free, whereas the licensed preparation contains glucose and glycerol and is therefore generally unsuitable for children, particularly those following a ketogenic diet. It was noted that it is not possible for primary care to specify the unlicensed preparation on prescriptions.

ACTION: Classify unlicensed SF chloral hydrate 500mg/5mL oral suspension as RED for use when the licensed preparation and chloral betaine tablets are unsuitable. NOTE: Chloral betaine tablets may be a suitable alternative for patients who require a ketogenic diet.

- Methenamine

This medication was discussed previously at the APC guideline meeting on 15th September 2022.

Dr Weston joined the meeting and discussed the request for the reclassification of methenamine from AMBER 2 to AMBER 3 as a non-antibiotic prophylactic agent for recurrent UTIs. A change of classification would allow primary care non-specialists to initiate methenamine, as per the APC recurrent UTI guideline in adults. Methenamine will be a first line alternative non-antibiotic option for UTI prevention in women. This offers an option when antibiotics are contraindicated or not tolerated and in patients with resistant infections, thereby reducing the need to move to 2nd line broad-spectrum antibiotics. The pressure of antibiotic resistance in the population is therefore reduced.

Recently published supportive evidence is available from the ALTAR trial and NICE is planning to update its recurrent UTI guideline. This update will focus on methenamine as prophylaxis against recurrent UTIs.

It was asked whether there is a need for acidification of urine to ensure the effectiveness of methanamine. Further guidance on this may be required.

An AMBER 3 classification was agreed for use as a prophylactic agent for recurrent UTIs, in line with the APC recurrent UTI guidelines.

ACTION: KR/ SW to update the formulary.
SW to investigate the need for acidification of urine.

- Pancrex V powder

A request for traffic light reclassification had been received from a specialist dietician at NUH. Currently Pancrex V powder is classified as RED; an AMBER 2 classification had been requested as this is used for patients that need administering via a feeding tube, where capsule formulations are not suitable and long-term use may be required in a small number of patients.

An AMBER 2 classification was agreed.

ACTION: KR/ LK to update the formulary.

- Arginine/sodium benzoate

These medicines are currently unclassified on the Joint Formulary and it had been requested at the last meeting that historical discussions be reviewed as these had been discussed at length some years ago. It appeared from previous meeting minutes that a RED classification had previously been agreed. DS highlighted that NHS England don't routinely commission these medicines so the previous decision may no longer apply. Further detail was requested on the patients currently being prescribed these medicines in primary care so that potential implications of repatriation could be assessed.

ACTION: LK/ SW to investigate further and bring back to the December APC meeting.

- Herpes Zoster vaccines (Shingrix and Zostavax)

LK explained that queries had been received about the administering of these vaccines outside the routine vaccination schedule of adults e.g in rheumatology patients younger than 70 years. Although not advised in the Green Book, there is National Immunisation guidance that recommends that Zostavax may be offered at GP discretion for patients outside the routine schedule who have conditions which increase the risk of shingles. This vaccine is, however, contraindicated in immunocompromised patients and should be given at least 14 days before commencing treatment with biologics. Patients outside the National Programme are not eligible to receive Shingrix on the NHS. It was suggested that administering Zostavax for this patient group may be more appropriate in secondary care, to ensure that timing restrictions with immunosuppressant therapies are followed and treatment delays to biologic therapy are prevented.

Action: Shingrix to be classified as GREY for use outside of routine vaccination schedule.
LK to seek opinion of Rheumatology service regarding acceptability of a RED classification of Zostavax if indicated prior to commencing immunosuppressant treatment.

- Escitalopram oral drops
  These may be indicated in patients discontinuing escitalopram if small dose reductions are required due to withdrawal symptoms.

Action: KR/SW to add to the formulary with a GREEN classification.

Formulary amendments already carried out, noted and listed below:

GREY:

- Similac Alimentum® - product no longer available following a recall in February 2022. Grey classification added to the Joint Formulary
- EleCare® - product no longer available following a recall in February 2022. Grey classification added to the Joint Formulary
- Comfifast® tubular bandage - East Midlands and NHS direct supplies buying group no longer recommend this brand of tubular bandage
- Ranitidine –classification changed from GREEN to GREY; product already had a non-formulary status

GREEN:

- COVID-19 Vaccine (Cominarty®) Original/Omicron Ba.1 15/15micrograms
- Memantine treatment initiation pack
- Fibrates – Joint Formulary updated to add clarity of the GREEN traffic light classification

AMBER 2:

- Oestrogen only HRT tablet - added Amber 2 indication for gender dysphoria
- Oestrogel®- added Amber 2 indication for gender dysphoria
- Oestrogen only HRT patch (Estradot® and Evorel®) - added Amber 2 indication for gender dysphoria
- Testosterone gel – added Amber 2 indication for gender dysphoria

- Testosterone undecanoate (Nebido®) - added Amber 2 indication for gender dysphoria

OTHER:

- Seroxat (paroxetine hydrochloride) 20mg/10ml oral suspension: global product discontinuation – link to discontinuation letter added to the Joint Formulary.
- Glycopyrronium 1mg/5ml – formulary updated to reflect the most cost-effective brand.
- Apixaban – generic product now available, brand name removed from the Joint Formulary.
- Inclisiran – Joint Formulary updated with supplier information; AAH and Alliance are suppliers.
- Metolazone (Xaqua®) – a link to information about the differences between various metolazone preparations and safety considerations has been added to the Joint Formulary.
- Levetiracetam infusion (Desitrend®) – additional information added about the need to prescribe as the Desitrend® brand in Primary Care. This is to aid community pharmacy supply.
- Disopyramide – Standard release capsules discontinued. Noted that disopyramide MR 100mg and 250mg capsules (Neon®) remain available.
- Allergen extract from house dust mites (Acarizax®) – duplicate entry on the Joint Formulary removed.
- Flumetasone 0.02% with Clioquinol 1% ear drops – formulary updated to reflect that supply issues no longer exist.
- Dulaglutide (Trulicity®) - Growing demand cannot be met by current supplies. Manufacturer advises stocks should be reserved for current patients to prevent future unavailability problems. Joint formulary update with this information.
- Buspirone - Removed restriction for use in learning disabilities only - historical restriction, not clinically appropriate, licensed for short term management of anxiety disorders.

8. Horizon Scanning

GREY no formal assessment:

- tixagevimab, cilgavimab. Evusheld®▼ 150 mg / 150 mg solution for injection
- tirzepatide 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg and 15 mg sub-cut injection. Mounjaro®▼
- sufentanil citrate. Dzuveo® 30mcg Sublingual tablet
- teriparatide. Sondelbay®▼ 20 micrograms/80 microliters solution for injection in pre-filled pen. Biosimilar
- Birch bark extract 100mg/g gel. Filsuvez

ACTION: KR to update the formulary.

AOB

- Committee member update- LC informed the committee that, sadly, a former member, Sarah Northeast, had passed away. The committee offered their condolences to her family and colleagues.
- APC development session- LC informed the committee that an APC development session was planned for the New Year. Further information about potential dates would be circulated.

The meeting closed at 17:18.

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