These minutes are in draft form until ratified by the committee at the next meeting on 20th June 2024.

Nottinghamshire Area Prescribing Committee Formulary Meeting

Minutes Thursday 18th April 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: -

Laura Catt (LC) (Chair)	**Prescribing Interface Advisor**	**NHS Nottingham & Nottinghamshire ICB**
Tanya Behrendt (TB)	**Senior Medicines Optimisation Pharmacist**	**NHS Nottingham & Nottinghamshire ICB**
Ann Whitfield (AW)	**Patient Representative**	**Nottingham & Nottinghamshire ICB local population**
David Kellock (DK)	**Consultant in Sexual Health and SFHT DTC Chair**	**Sherwood Forest Hospitals NHS Foundation Trust**
Jennifer Moss Langfield (JML)	**GP**	**LMC Representative**
Deborah Storer (DS)	**Medicines Information Manager and D&T Pharmacist**	**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**
Hannah Godden (HG)	**Principal Pharmacist, Adult Mental Health Community Teams**	**Nottinghamshire Healthcare NHS Trust**
Georgina Dyson (GD)	**Advanced Nurse Practitioner**	**CityCare ICB**

Due to a lack of GP attendance, the meeting was not quorate; however, the minutes were subsequently reviewed and all actions agreed in line with quoracy requirements.

In Attendance:

- Professor Corsetti, Consultant Gastroenterologist, NUH, joined the meeting for agenda item 4(d).
- Jill Theobald, Senior Medicines Optimisation Pharmacist, Nottingham and Nottinghamshire ICB, Zahida Niazi, Nottingham University Hospitals NHS Trust, Jackie Waller and Swathi Krishnan, Nottingham County Council Public Health Team, joined the meeting for agenda item 5.

- Peter Richards, Senior Medicines Optimisation Pharmacist, and Claire McCooey, Medicine Optimisation Pharmacist for Nottingham and Nottinghamshire ICB, joined the meeting for agenda item 6.

Observing:
Trainee Pharmacists from Sherwood Forest Hospitals NHS Foundation Trust:
Charlie Parry, Sadeem Alharbi, Dominic Hanbury-Smith, Abdul Rahman El Saboni and Yasmin King.
Joseph Morris, Assistant Chief Pharmacist – Clinical Services Manager (secondment).

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.
Vimbayi Mushayi (VM), Specialist Medicines Optimisation Interface Pharmacist.
Lidia Borak (LB), Specialist Medicines Optimisation Interface Pharmacist.

1. Welcome and apologies.

The Chair, LC, asked APC members not to admit guests into the meeting; only the Chair will invite guests in from the virtual lobby.

It was noted that the meeting was not quorate, due to having only one GP present, therefore actions will not be confirmed or implemented until agreement from at least one further GP member is received.

2. Declarations of interest.

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

It was noted that the submitter of the formulary request for SimAlvia has declared that they have received an honorarium from Mayoly UK, the manufacturer of SimAlvia, for a two-hour lecture delivered to GPs to update the treatment of IBS.

3. Minutes of the last meeting.

The minutes of the previous meeting were accepted as an accurate record in terms of the meeting actions; however, a grammatically correct version will be uploaded to the APC website.

ACTION: KR to ensure that a grammatically correct version of the APC minutes will be uploaded to the APC website.

4. Matters arising and action log.

Rimegepant
LB provided a brief update following the circulation of the updated headache pathway. No further comments had been received, but feedback from neurology was awaited.

ACTION: LB to finalise and upload the updated headache pathway.

Daridorexant
It was noted that, although the procurement arrangements for a nationally commissioned digital CBTi service were not finalised, Sleepio is now available free of charge to NHS users. This will not

be widely advertised until commissioning arrangements are confirmed. HG suggested that promotion could fit with an update to the local hypnotics guideline due later in the year.

ACTION: LK to add direction to Sleepio to the daridorexant prescribing information sheet.

NICE TA875 – Semaglutide for weight loss.
No further update was available. LK informed members that a NICE TA was expected to be published imminently supporting the use of tirzepatide (Mounjaro®) for weight loss. LK will inform APC members of any future updates regarding weight loss medications.

ACTION: LK will return this item to a future APC meeting as further information becomes available.

Micronised Vaginal Progesterone (Cyclogest®) for threatened miscarriage.
LK explained that financial approval had been agreed by the ICB and the formulary had therefore been updated with the AMBER 2 classification previously agreed by the APC. Discussions around the most appropriate prescribing pathway and communication between Secondary and Primary care were ongoing. JML and DS will update APC members with further information in due course.

ACTION: JML and DS will provide relevant information to the APC members as it becomes available.

NICE TA942 – Empagliflozin for CKD and SGLT2i prescribing pathway.
VM explained that the Midlands Kidney Network (MKN) were updating the prescribing pathway to incorporate empagliflozin. Once finalised, this will be circulated to APC members. In the meantime, empagliflozin had been classified as AMBER 3 in line with the NICE TA.

ACTION: VM to circulate MKN pathway to APC members once finalised.

SimAlvia® (simethicone/alverine) for Irritable Bowel Syndrome (IBS).
Professor Corsetti attended the meeting to discuss the submission for SimAlvia® which had been presented at the previous APC meeting. APC members had discussed previously the possibility of over-the-counter purchasing of the active components; simethicone and alverine. However, this was disregarded as community pharmacists would be unlikely to approve a sale for doses greater than the approved license.

It was noted that evidence for many IBS treatments commonly used is lacking, but, despite this, many patients find treatments helpful and effective. In contrast, there is some supportive evidence for Simalvia and it was therefore felt by the submitter that it should be offered as a treatment option.

After discussion, APC members agreed that an AMBER 3 classification could be supported if a flow chart and guideline were in place indicating its place in therapy, with a supporting patient information leaflet (PIL) detailing alternative lifestyle and dietary measures that should be trialled before treatment initiation. In addition, patients should be encouraged to obtain first-line IBS treatments over the counter.

It was pointed out that, should Simalvia® become unavailable, the prescribing of individual components separately would not be supported as this would not be cost-effective and would be reflected in the Formulary entry.

ACTION: LB and Professor Corsetti will produce guidance and present this to APC members at a future APC meeting for a final classification decision.

Action log:

The action log was noted by APC members. It was pointed out that there had been minimal prescribing of Efmody® in Primary care and it was agreed to remove this from the action log.

5. New applications

a) Cytisine for smoking cessation.

LK presented a formulary submission for cytisine tablets as an aid to smoking cessation. Cytisine has been available in parts of Europe for many years, but was launched in the UK at the end of January 2024. Currently, available pharmacological treatments include nicotine replacement therapy (NRT), bupropion (Zyban®) and nicotine vapes (e-cigarettes). The submission had been received from NUH with support from SFH. There was interest from Public Health in making this available for patients in Primary Care so the submission had been brought to APC for discussion to ensure a consistent approach across the ICS and reduce duplication. It was noted that although APC could endorse the use of this medication, it would be up to individual organisations to implement its use. The smoke-free lead at NottsHC had been contacted about cytisine, but no further information about potential use there had been received prior to the APC meeting.

Available evidence supports efficacy of cytisine similar to varenicline and other smoking cessation aids. However, smoking cessation is most successful if offered alongside behavioural support. If initiated in Secondary Care, patients would be referred to community-based smoking cessation services for this support. The overall cost of cytisine is similar to alternatives, as it is given as a 25-day course. However, if initiated in Secondary Care, the whole treatment cost would be borne by that organisation whereas currently only initial supplies of alternatives would be made in Secondary Care, with smoking support services continuing the treatment. There are some patient groups for whom cytisine is not recommended by the manufacturer due to a lack of data. Women of childbearing potential using hormonal contraception are recommended to use an additional non-hormonal method.

Jill Theobald (JT), Jackie Waller, Swathi Krishnan and Zahida Niazi attended to support the submission. JT explained that within Primary Care, smoking cessation support comes from A Better Life (ABL) and Thrive, neither of which employ prescribers. Although work is underway to address this, it would not be available at present through these services. There would, however, be no expectation for this to be prescribed by General Practice, in line with current commissioning arrangements for smoking cessation.

MC added that there was a paper which suggested a 12-week course of cytisine and it needed to be made clear that any decisions made were for the 25-day course only.

APC members endorsed the decision for cytisine to be available locally as a smoking cessation aid with a RED classification; it would be for individual orgainisations to take forward through their local processes.

ACTION: NUH, SFH and NottsHC to take forward implementation through local processes. LK to provide feedback to APC members regarding any update to availability through Primary Care Smoking cessation services. The smoking cessation position statement will be updated to include cytisine.

6. Formulary amendments

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

- Bowel cleansing preps eg Moviprep®, Picolax®- the Joint Formulary entry has been updated to harmonise the classifications to Red.

GREY

- Ogluo reclassified as supply problems with Glucagen have been resolved.

AMBER 2

- Viridal® duo reclassified due to supply problems with Caverject®.

OTHER

- Insulin levemir® and Insulatard® innolet devices have been discontinued; they will be removed from the diabetes guideline in due course.
- Estriol 0.1%: Ovestin® brand has been discontinued; the brand name has been removed from the Joint Formulary.
- Salbutamol nebules: additional information has been added about actions to take during shortages of 2.5mg/2.5ml nebules.

(b) FOR DISCUSSION

GREEN/GREY changes

- Daily tadalafil: reclassify tadalafil 5mg daily to GREEN for those anticipating sexual activity >2/week (in line with license). This had previously been restricted as it was significantly more expensive than “on demand” options. However the availability of a generic had decreased its cost so it was now comparable with these options and there was already a considerable amount of prescribing locally. The 2.5mg tablet will remain GREY as this is significantly more expensive. It was pointed out that avanafil is no longer more cost-effective than other 2nd - line options and there is minimal usage locally. This will be reclassifed as GREY to simplify treatment options available.

ACTION: The APC Interface Team to update Joint Formulary.

AMBER 2

- Vital 1.5kcal® 200ml sip feed and Peptisip Energy HP®: a request had been made by the Hepatobiliary (HPB) dietician to make these products available for prescribing during times of Pancreatic enzyme replacement therapy (PERT) shortages, as recommended in a national Position statement: Position Statement: Pert Shortage | Pancreatic Society of Great Britain and Ireland (psgbi.org). It had been indicated that any patient requiring such an alternative treatment should be reviewed by the Specialist team so an AMBER 2 classification had been suggested. This was agreed.

ACTION: Interface team to add to the Joint Formulary with an AMBER 2 classification. To be reviewed once the availability of PERT improves.

Other

- Melatonin (Adaflex®): a request to add the 5mg strength had been received from the Medicine Optimisation (MO) Team, as an alternative to the 2mg MR preparation currently listed for use by those with learning disabilities and behaviour that challenges. This would potentially simplify administration for some patients, and costs are comparable. It was suggested that any product addition should be in line with the preparations recommended in the work undertaken by the ICS melatonin workstream.

ACTION: LK to confirm the products recommended for use in the ICS and ensure that any addition is in line with this.

- Intramuscular (IM) Pabrinex is currently classified as AMBER 3 and is included in APC alcohol dependence guidelines. IM Pabrinex has been discontinued and stocks are expected to be exhausted by the end of 2024. HG explained that there may be government intervention related to this so the discontinuation may be reversed. It was agreed that no changes should be made currently.

ACTION: Add to action log. HG will update the APC as further information becomes available.

- Bibecfo® inhaler: Peter Richards and Claire Mcooey attended the meeting for discussions. A request had been made to add Bibecfo® to the formulary as a cost-effective alternative to Fostair for those who do not tolerate Luforbec®. Both Bibecfo® and Luforbec® were priced-equivalent and there had been reports of patients not tolerating Luforbec® and requesting a switch back to Fostair®. The Trust representatives present stated a preference for rationalising options due to issues with stocking multiple inhalers.

ACTION: Bibecfo® will be added to the formulary as a cost-effective alternative to Fostair® for patients intolerant of Luforbec®.

Goserelin (Zoladex LA®) 10.8mg for breast cancer

- A request had been received from Oncology for the 3-monthly formulation of goserelin to be added to the Joint Formulary as per the updated product license. Although this was slightly more expensive than the currently used monthly preparation, it offers benefits to patients and reduces workload due to a reduced frequency of administration. APC members supported this. Gonadorelin analogues (GnRH) position statement will be updated accordingly to reflect both Zoladex® and Zoladex LA® formulations.

ACTION: Interface team to update formulary and position statement.

Joint Formulary Review

KR explained that the review of the Joint Formulary is progressing. Chapter 4 has now been reviewed, with updates made to broken website links and out-of-date information. A further progress report will be provided at the June APC meeting.

ACTION: KR to provide an update at the June APC meeting.

7. Horizon Scanning

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

GREY no formal assessment

- Entresto® (valsartan, sacubitril) 15mg/16mg and 6mg/6mg granules in capsules to be opened licensed for children and adolescents aged one year or older, for treatment of symptomatic chronic heart failure with left ventricular systolic dysfunction.

Other

- STRIGOL® Paediatric powder for oral solution, for the treatment of chronic constipation in children 2 to 11 years of age. This product is more expensive than the product currently recommended so no further action is required.
- Ivermectin 3mg tablets for the treatment of scabies; an unlicensed product has been used previously and is classified RED. Now that a licensed product is available, an AMBER 2 classification has been suggested, which may reduce some of the issues experienced previously over obtaining treatment for patients in Primary Care. The scabies guideline will be updated to include supporting information, therefore this classification decision is pending ratification of the updated guideline at the May APC meeting.

Other – the following items will be added to the follow-up action log:

- Adacel® (diphtheria, tetanus and pertussis vaccine) suspension for injection in a pre-filled syringe. Unlike similar vaccines, Adacel® does not contain inactivated Poliomyelitis, but it is not listed in the DoH 'Green Book'. Await the 'Green Book' update for a classification decision.
- Aqumeldi® 0.25 mg orodispersible tablets, enalapril, for the treatment of heart failure in children and adolescents from birth to 17 years of age. Not currently available in the UK and awaiting availability before making a classification decision.
- Sildenafil 100mg orodispersible tablets for adult men with erectile dysfunction : an alternative option for patients who have difficulty swallowing film-coated tablets. Await a price before making a classification decision.
- Vecicom® Prolonged-release Tablets. Tapentadol 100mg, 150mg , 200mg and 250mg for severe chronic pain. Await a price before making a classification decision.

ACTION: KR will update the Joint Formulary and action log.

- **(b) New NICE guidelines**

- Meningitis (bacterial) and meningococcal disease: recognition, diagnosis and management – guidance (NG240). Published March 2024.
- Vitamin B12 deficiency in over 16s: diagnosis and management (NG239). Published March 2024.

APC members acknowledged that the related local guidelines are currently under review by the APC team.

8. Zoledronic acid for osteoporosis – review of evidence for a 4mg dose

LK explained the history behind a request for the APC to review evidence to support a 4mg dose of zoledronic acid for osteoporosis. The licensed dose is 5mg annually, but current practice at NUH and in one of the Fracture Liaison services is to use 4mg. Initially, the change was made at NUH due to supply problems some time ago, but this then became the preferred clinical practice by clinicians who were monitoring the bone markers of patients. Interest in switching to a 4mg dose has also been expressed by orthogeriatricians at SFHT.

During the update of the Nottinghamshire Osteoporosis Guideline, a request was made to reference using the 4mg dose as an off-label option to support its prescribing by non-medical prescribers in the Fracture Liaison services. It has also been requested that reference is added to support use in those with a CrCL <35ml/min; the manufacturer and MHRA advice is to avoid use in those with a CrCl< 35ml/min, but a recently published Position Statement supports its use in those with a CrCl >30ml/min, following individual assessment.

The 5mg annual dose had been chosen for the pivotal trials supporting the license application of Aclasta and these demonstrated reduced fracture rates when compared to placebo. There were no comparative trials of 4mg and 5mg dosing with patient-orientated outcomes such as reduced fracture rates. Studies that have looked at various doses of zoledronic acid have found similar effects on markers of bone turnover, although these studies are small in size. A recently published position statement supports the use of a 4mg dose if resources are constrained. Use of the 5mg product is significantly more expensive than the 4mg.

It was noted that regionally and nationally there was a variation in practice and was acknowledged that lower doses may be sufficient; for example, 5mg every 18 months is an alternative regimen utilised in some areas.

With regards to use in patients with reduced renal function, it was pointed out that this would need to be a clinical decision considering other risk factors a patient may have, but would allow a greater number of patients to receive treatment. Although denosumab is an alternative treatment, this requires referral to an osteoporosis clinic and would introduce a delay.

APC members supported the use of zoledronic acid as requested and agreed that reference could be added to the off-label use in the updated Osteoporosis guidelines.

ACTION: LK to provide feedback to the authors of the Osteoporosis guideline. Interface team to update formulary.

9. Insulin Chapter Formulary review

Work had progressed on reviewing the insulin chapter of the formulary with Tresiba® and Toujeo® being the final insulins to be reviewed. During this work, no major changes were suggested for Toujeo®. However, clinicians had requested a change to the eligibility criteria of Tresiba® 100 units/ml, It had previously been restricted to a defined cohort as it was more expensive than other insulin. The original request was for use in adults; paediatric use had not been considered. However, it has been ascertained that Tresiba is a first-line option for children and young people aged older than 7 years; Levemir® is usually used in younger children. Regarding use in adults, a request has been received to remove the current restrictions on its use in Type 1 diabetes. The clinicians felt that the restrictions on adults with Type 2 diabetes could remain.

VM explained that evidence had not changed since NICE / APC (2013 and 2014 respectively) last reviewed Tresiba® 100 units/1ml use in adults with Type 1 diabetes. However, the restrictions on the

formulary entry for Type 1 diabetes were not in line with current NICE guidelines for adults with Type 1 diabetes, last updated in 2022. The APC recommends initiating Tresiba® 100 units/1ml in Type 1 diabetes currently treated with insulin glargine, with recurrent admissions for ketoacidosis treatment due to insulin omission, OR with recurrent, particularly nocturnal, severe hypoglycaemia. Current NICE guidelines recommends that insulin detemir and insulin glargine remain first line options for basal insulin. However, the guideline advises that Tresiba® can be considered as an alternative in patients where there is a particular concern about nocturnal hypoglycaemia, or for people who need help from a carer or healthcare professional to administer injections. In addition, NICE recommends that other basal insulin regimens should be considered only if the recommended regimens do not deliver agreed treatment goals. Furthermore, NICE advises that the following should be considered when choosing alternative insulin regimens: the person's preferences, co-morbidities, risk of hypoglycaemia and diabetic ketoacidosis, concerns around adherence and acquisition cost.

Tresiba® is not specifically mentioned in the NICE guideline on the management of diabetes in children and young people. However, NICE advises that if a child or young person with Type 1 diabetes does not have optimal blood glucose levels, an alternative insulin regimen (multiple daily injections, an insulin pump, or once-, twice- or three-times daily mixed insulin injections), should be offered.
APC members agreed that the restrictions for Type 1 adults could be removed and entry regarding children added to the formulary. However, members noted that the request for children was for those newly diagnosed and felt that there might be some patients who are already diagnosed who might need to be switched. In addition, the wording of the formulary entry will be clarified, as it was not clear for the different groups, i.e., for Type 1 diabetes the entry stated adults but for Type 2 diabetes the entry does not mention adults.

There was a discussion about whether a review of insulin prescribing across the system was needed. It was agreed that the APC might not be the right place for this review as input would be required from specialists across the system and that LC should highlight this to the ICS diabetes working group.

Other changes to the formulary entries such as the addition of clinical information were agreed.

ACTION: VM to look at the wording on the Tresiba® 100 units/ ml entry with interface team and email to APC. LC to raise to ICS diabetes working group that APC had flagged inconsistency in insulin prescribing.

10. Any Other Business

- Liothyronine position statement- LK informed the APC that it had been questioned whether any update to the liothyronine position statement was required following the publication of NHS E guidance about liothyronine. However, the principles outlined in the position statement are broadly in line and, in the absence of any local clinician request to change practice, it was not felt that an exceptional review was needed.

11. Next meeting dates.

APC Formulary meeting: Thursday 20th June 2024 (2pm to 5pm, Microsoft Teams)
APC Guideline meeting: Thursday 16th May 2024 (2pm to 5pm, Hybrid Meeting)

The meeting closed at: 17:10