AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 14th November 2019
Venue – Birmingham Research Park
Vincent Drive, Birmingham, B15 2SQ

PRESENT:

Dr Lisa Brownell	BSMHFT (Chair)
Dr Paul Dudley	Birmingham and Solihull CCG
Prof Mark DasGupta	Birmingham and Solihull CCG
Nilima Rahman-Lais	Birmingham and Solihull CCG
Liz Thomas	Birmingham and Solihull CCG
Dr John Wilkinson	Birmingham and Solihull CCG
Dr Nashat Qamar	Birmingham and Solihull CCG
Hannah Peach	Sandwell & West Birmingham CCG
Satnaam Singh Nandra	Sandwell & West Birmingham CCG
Nigel Barnes	BSMHFT
Dr Sangeeta Ambegaokar	Forward Thinking Birmingham Partnership
Emily Horwill	Sandwell and West Birmingham Hospitals NHS FT
Dr Angus Mackenzie	Sandwell and West Birmingham Hospitals NHS FT
Gurjit Sohal	UHB NHS FT
Inderjit Singh	UHB NHS FT
Dr Mark Pucci	UHB NHS FT
Carol Evans	UHB NHS FT/Birmingham and Solihull CCG
Prof Jamie Coleman	UHB NHS FT
Ravinder Kalkat	Midlands & Lancashire CSU
Kuldip Soora	Midlands & Lancashire CSU

IN ATTENDANCE:

Elizabeth Bradley for item 1019/05	UHB NHS FT
Dr Tahir Shah for item 1019/05	UHB NHS FT

No.	Item	Action

1119/01 Apologies for absence were received from:

Jonathan Boyd, Sandwell and West Birmingham CCG, deputy attended
Dr Sonul Bathla, Sandwell and West Birmingham CCG
Melanie Dowden, Birmingham Community Healthcare NHS FT
Alison Tennant, Birmingham Women's and Children's NHS FT

It was confirmed that the meeting was quorate.

1119/02 Items of business not on agenda (to be discussed under AOB)

- Cannabis-based medicinal products and upcoming TAs
- Prescribing of NOAC agents

1119/03 Declaration of Interest (DoI)

The Chair reminded members to submit their annual declarations of interest to the APC Secretariat.

1019/04 Welcome and Introductions

The Chair welcomed everyone to the meeting today.

The Chair reminded members, the meeting is digitally recorded for the purpose of accurate minute taking and once the minutes are approved, the recording is deleted by the APC secretary.

1119/05 Nutrizym 22® gastro-resistant capsules – new drug application

The Chair welcomed Dr Tahir Shah, Consultant hepatologist and transplant physician, lead clinician neuroendocrine services, UHB NHS FT and Elizabeth Bradley, Specialist dietician – liver, UHB NHS FT to the meeting and invited them to present the application for Nutrizym 22®.

Elizabeth explained Nutrizym 22® is intended to be used for the small cohort of patients who cannot tolerate Creon®.

Dr Shah went on to explain Creon® is the default pancreatic enzyme used for pancreatic exocrine insufficiency. Patients are assessed by the specialist dietician for intolerance to Creon®, before being recommended Nutrizym 22®.

<u>The Chair invited questions or comments from members. Discussion points/concerns raised included:</u>

- A member asked how those patients who are intolerant to Creon® are being managed currently. Elizabeth explained these patients are prescribed Nutrizym 22® or Pancrease™ HL by their GP. There is no alternative treatment to Creon® on the formulary and these patients would be left untreated, to experience the various symptoms of pancreatic exocrine insufficiency.
- A member noted from experience some patients with pancreatic exocrine insufficiency suffer its effects and are not compliant with taking their pancreatic enzyme supplement. Therefore, how does the team assess whether the patient is intolerant to Creon® or patients who generally feel unwell and are not getting symptomatic treatment.

- Elizabeth explained she would firstly assess the patient for pancreatic exocrine insufficiency before assessing if there is a genuine intolerance to Creon®.
- A member asked why Nutrizyme 22® is preferred to Pancrease™ HL. Pancrease™ HL is another pancreatin replacement therapy. Elizabeth has found Nutrizyme 22® is more readily available and from experience, patients better tolerate Nutrizyme 22®.
- A member asked if Pancrex V has been considered. Elizabeth explained Pancrex V powder is used for administration via enteral feeding tubes.
- A member noted some patients are prescribed up to twenty Creon® capsules per day therefore treatment cost can be elevated compared to the standard dose outlined in the Summary of Product Characteristics (SPC) and enquired whether there is a maximum dose. Elizabeth explained the dose regimen for Nutrizym 22® is comparable to Creon®, patients would rarely go above thirty capsules per day.
- A member noted a recent supply issue with the availability of certain strengths of Creon® capsule. Would Nutrizym 22® be used as an alternative? Elizabeth confirmed this would be the case.
- A member asked how the Creon® intolerant patient presents in clinic. Elizabeth responded the patient typically presents with nausea and vomiting, flatulence and bloating.
- A member queried the differences between Nutrizym 22® and Creon® which makes one more tolerable than the other. Elizabeth believes the pH at which the pancreatin is activated is slightly different as well as the time of release within the digestive system. The patients individual gut pH and motility may affect tolerance.
- A member enquired regarding the suggestion that Nutrizym 22® is less safe in children than Creon® as stated within the application. The applicants did not have further information to hand however intend to use Nutrizym 22® within the adult cohort.
- It was confirmed Nutrizym 22® is being proposed as Amber specialist recommendation on the BSSE APC formulary and a shared care arrangement is not deemed appropriate.

The Chair thanked Dr Tahir Shah and Elizabeth Bradley for attending the meeting, for answering all the questions from the APC members and advised them that the decision would be relayed within 5 working days, in line with APC policy.

Further discussion points in the absence of the representatives included:

- A member added supply problems should not be factored in when assessing formulary applications as they are outside of APC control. Appropriate alternative arrangements are made when supply issues arise.
- Colonic damage has been reported in patients with cystic fibrosis taking an excess of 10,000 units of lipase/kg/day.

The Chair directed the members to the Decision Support Tool for completion:

Patient Safety: No different to Creon® within adult population

Clinical effectiveness: Equal to Creon®

Strength of evidence: Equal to Creon®

Patient factors: A small number of patients are intolerant to Creon®

Cost effectiveness or resource impact: Similar costs and small cohort of 10 patients per year anticipated

Place of therapy relevant to available treatments: Second line

National guidance and priorities: N/A

Local health priorities: CCGs supportive

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: None required

Prescribing data: N/A

Decision Summary: Approved as Amber specialist dietician recommendation

ACTIONS:

- **Add Nutrizym 22® to the formulary as Amber** **APC sec**
- **Relay decision to applicants by Thursday 21st November 2019** **APC sec**

1119/06 BSSE APC Primary Care Clinical Pathway for Atrial Fibrillation Detection and Management

The Chair directed members to an updated version of the Primary Care Clinical Pathway for Atrial Fibrillation Detection and Management.

Cardiologist feedback relayed at the October APC has been incorporated by Dr Mark Pucci, UHB NHS FT.

Reference to Paroxysmal Atrial Fibrillation (PAF) has been added to state if there is suspicion of PAF then ambulatory ECG monitoring is required. This may require referral to secondary care.

The layout has been streamlined.

The Chair invited questions or comments from members. Discussion points/concerns raised included:

- Under symptom management a member suggested diltiazem and verapamil are specified as the rate limiting calcium channel blockers.

ACTIONS:

- **Amend as discussed and publish pathway to formulary website** **APC sec**

1119/07 BSSE APC Anti-dementia treatments ESCA

The Chair directed members to the BSSE APC anti-dementia treatments ESCA developed by BSMHT team. An overview of the ESCA was given by the Trust representative Nigel Barnes.

- The patient is seen at the memory assessment clinic and if diagnosed with dementia will undergo trial donepezil treatment.
- The patient is reassessed some months later regarding on-going treatment.
- Specialists continue to assess patient's mental state and advise on prescription changes.
- Once a patient is stabilised and ready for transfer, the GP should consider accepting prescribing responsibility, look after the patient's physical health and work alongside the specialist in terms of managing their dementia.
- Dementia services will not discharge the patient and will continue to monitor and assess the patient and work with the GP.

The Chair invited questions or comments from members. Discussion points/concerns raised included:

- A member asked if patients continue donepezil at end of life. The BSMHT representative stated cessation of treatment would be determined by the specialist, old age psychiatrist.
- A member suggested community mental health team (CMHT) is replaced by the term 'specialist'.
- It was clarified the APC formulary status for anti-dementia drugs within Birmingham and Solihull CCG area is currently Red due to commissioning arrangements, however, the APC's view is that on clinical grounds, the status of drugs for dementia should be amber, with a framework in place in primary care before transfer.
- The commissioning arrangements for anti-dementia treatments within Sandwell and West Birmingham CCG differ and the ESCAs they use are already linked to BSSE APC formulary entries.

Decision summary: The ESCA is approved subject to commissioning arrangements to allow safe transfer of patient care for BSOL CCG only.

ACTION:

- **Inform APC of changes to the commissioning of anti-dementia medicines** **BSol CCG**

1119/08 Antidepressants in 16-18 years old – shared care arrangements

A CAHMS service in Solihull have highlighted to the BSMHFT representative they are unable to transfer prescribing of anti-depressants within the 16-18 year old cohort to GPs and ask whether the APC would consider producing an ESCA for this cohort. The antidepressant agents are currently on formulary as Green for the adult population.

The Chair invited questions or comments from members. Discussion points/concerns raised included:

- A member highlighted the guidance on the formulary regarding the informed 'off-label' use of medicines in paediatric practice and asked if additional guidance is necessary for antidepressant agents.
- A member noted a study on anti-depressants and suicide risk patients under the age of 25 and felt the reluctance to prescribe within primary care may be associated with this. A BSMHFT representative noted the

increased risk is now considered for patients up to 30 years of age.

- Members discussed the implications of changing the RAG status of the antidepressants for the paediatric cohort.
- A member queried whether the guidance for medicines for physical conditions and psychiatric medicines should differ, and if this would be the case if the RAG status is amended for the use of antidepressants in paediatrics.
- It was unclear how many Decline to Prescribe forms had been received.
- Members agreed Trusts should refer primary care clinicians to the guidance on Prescribing in Children on the formulary website.

1119/09 BSSE APC Methotrexate in Rheumatoid Arthritis and Psoriatic Arthritis ESCA

The Chair directed members to the draft Methotrexate ESCA for use with Rheumatoid Arthritis and Psoriatic Arthritis which has been updated following feedback received upon consultation with member organisations. The feedback received and amended ESCA were circulated with the papers prior to the meetings.

- The lower neutrophil range has been amended to 1.6x109/l.
- A member relayed feedback from a GP asking the ESCA indicates a maximum interval for monitoring as per the BSR recommendations. It has been noted by Care Quality Commission (CQC) a maximum interval for monitoring is not included.

Decision summary: The ESCA is approved subject to the addition discussed

ACTION

- **Amend as discussed and publish ESCA to formulary website** **APC sec**

1119/10 Ranitidine supply shortage

- Birmingham Children's Hospital NHS FT are reviewing patients currently prescribed oral ranitidine and other acid suppressants such as proton pump inhibitors (PPIs) to establish whether ongoing treatment is still required and discontinuing treatment when appropriate.
- If treatment is still required, omeprazole or lansoprazole are recommended in line with the Trust guidance on management of gastro-oesophageal disease.
- Omeprazole is listed in the BNFC as unlicensed in children but some manufacturer's SPC specify the product is licensed in children. Orodispersible lansoprazole may be used.
- A representative for UHB NHS FT - HGS, stated omeprazole MUPs are used in the paediatric population at the Trust.
- Nizatidine is the alternative agent being procured at UHB NHS FT; prescribing is restricted to consultants only however some patients may filter into primary care on discharge requiring further supplies.
- Birmingham and Solihull CCG have disseminated guidance to GP practices regarding the shortage, outlining step down and alternative treatment.

1119/11 Branded generics product recommendations on formulary

A member asked APC to consider adding a statement onto the formulary that expresses in order to optimise market forces or supply chain problems that the CCG recommendation might deviate from the brand stipulated on the formulary.

The Chair invited questions or comments from members. Discussion points/concerns raised included:

- A member noted the statement would need to be caveated to exclude drugs where it is important the patient is prescribed a specific brand, such as modified-release branded preparations where the rate of absorption can vary between brands.
- Members agreed instead of a statement on the formulary, when the CCG recommend a brand change it should be brought to APC for information.
- In addition, when approving a branded product onto formulary the committee should decide whether the note 'or equivalent generic' should be added to the formulary entry.

1119/12 RMOC recommendations

The Chair directed members to the RMOC advisory statement Sodium oxybate in adult patients.

A business case is required for sodium oxybate for commissioning consideration within each CCG within BSSE. There are a small number of patients who receive sodium oxybate based on individual exceptional circumstances.

1119/13 Minutes of the meeting held on Thursday 10th October 2019 – for ratification

The minutes of the meeting held on Thursday 10th October 2019 were discussed for accuracy.

- Page 3: Reword to "Renapro shot is described as low fat, high protein and low carbohydrate…"

It was confirmed subject to the above amendments the minutes are approved, can be uploaded to the APC website and the recording deleted.

1119/14 Matters Arising

The Chair moved onto the action table for comments and updates:
(See separate document attachment for updated version). Consider actions closed if not discussed.

The outstanding actions include:

- 1019/07 - BSol CCG policy Items which should not be routinely prescribed in primary care - Add hyperlinks to BSol policy from relevant formulary entries.

- 0919/05 - Chapter 11 Eye - Formulary chapter review - Trust to

complete drug application form alongside ophthalmology specialists.

- 0919/07 - BSSE APC Management/Development meeting proposals - Amend Amber RAG status on APC formulary.

- 0919/09 - Items which should not be routinely prescribed in primary care - Develop RICaD for amiodarone and review aliskiren RICaD in line with NHSE guidance.

- 0919/AOB - Matters arising - Dental products on formulary - Schedule away day for the review of dental products

- 0719/05 - BAAG Chapter 5 Infections review and documents - Formulary Chapter 5 Infections to be amended as per discussion.

- 0719/05 - BAAG Chapter 5 Infections review and documents - *C.Diff* pathway to be reviewed by CCG Infection control team prior to uploading to APC website.

- 0719/06 - BSSE Away day documents - Trusts to develop report on LMWH prescribing.

- 0619/AOB - Azathioprine for haemolytic anaemia - Produce Azathioprine ESCA for haemolytic anaemi.

- 1118/AOB - Identified issues with shared care documents Sodium clodronate, denosumab, degarelix and apormorphine ESCAs to be reviewed by secondary care. Update: Denosumab ESCA with nurse specialist for review.

1119/15 NICE Technological Appraisals (TAs)

In October 2019, there were 6 TAs published; of these, 1 is NHSE commissioned, 2 CCG commissioned and 3 are not recommended.

The CCG commissioned NICE TAs are:

- Rivaroxaban for preventing atherothrombotic events in people with coronary or peripheral artery disease [TA607]

Amber status agreed

- Xeomin (botulinum neurotoxin type A) for treating chronic sialorrhoea [TA605]

Red status agreed

ACTION: Update APC formulary with decisions on NICE TAs. **APC sec**

Any other business:

1. Cannabis-based medicinal products and upcoming TAs

A member queried the commissioning arrangements for the cannabis based medicinal products, Sativex® and Epidiolex®. It was acknowledged NICE TAs

for these products are upcoming. A CCG representative advised Sativex® is CCG commissioned and would require an APC application with cost information and patient numbers detailed within the application. The application is likely to require CCG approval via the CCG prioritisation process at Birmingham and Solihull CCG. Epidiolex® is NHSE commissioned.

2. Prescribing of NOAC agents

Members agreed to remove the "preferred agent" recommendations on the APC formulary for the NOAC agents. The APC no longer recommends "preferred agents" on the formulary and the status of the NOAC agents reflects national guidance. Clinicians may refer to local guidance on choice of NOAC agent.

ACTION: Remove 'preferred agent' recommendations for NOACs on APC formulary **APC sec**

The Chair thanked the members for their input today. The meeting closed at 15:45.

Date of next meeting: Thursday 12th December 2019
Birmingham Research Park.