AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 10th October 2019
Venue – Birmingham Research Park
Vincent Drive, Birmingham, B15 2SQ

PRESENT:

Dr Paul Dudley	Birmingham and Solihull CCG (Chair)
Prof Mark DasGupta	Birmingham and Solihull CCG
Nilima Rahman-Lais	Birmingham and Solihull CCG
Liz Thomas	Birmingham and Solihull CCG
Dr Neil Bugg	Birmingham Women's and Children's NHS FT
Alison Tennant	Birmingham Women's and Children's NHS FT
Dr Sangeeta Ambegaokar	Forward Thinking Birmingham Partnership
Christina Wilson	Sandwell & West Birmingham CCG
Satnaam Singh Nandra	Sandwell & West Birmingham CCG
Maureen Milligan	Royal Orthopaedic Hospital NHS FT
Inderjit Singh	UHB NHS FT
Dr Dhiraj Tripathi	UHB NHS FT
Dr Mark Pucci	UHB NHS FT
Carol Evans	UHB NHS FT/Birmingham and Solihull CCG
Ravinder Kalkat	Midlands & Lancashire CSU
Kuldip Soora	Midlands & Lancashire CSU
Daya Singh	Midlands & Lancashire CSU

IN ATTENDANCE:

Ruth S. Chinuck for item 1019/05	UHB NHS FT
Dr Matthew Armstrong for item 1019/05	UHB NHS FT

No.	Item	Action

1019/01 Apologies for absence were received from:

Dr Lisa Brownell, BSMHFT
Nigel Barnes, BSMHFT
Prof Jamie Coleman, UHB NHSFT, deputy attended
Jonathan Boyd, Sandwell and West Birmingham CCG, deputy attended
Dr Angus Mackenzie, Sandwell & West Birmingham Hospitals NHS FT
Emily Horwill, Sandwell & West Birmingham Hospitals NHS FT
Dr Sonul Bathla, Sandwell and West Birmingham CCG
Dr Nashat Qamar, Birmingham and Solihull CCG
Dr John Wilkinson, Birmingham and Solihull CCG

It was confirmed that the meeting was quorate.

1019/02 Items of business not on agenda (to be discussed under AOB)

- Ranitidine shortage
- Decline to Prescribe form

1019/03 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. Introductions around the table were carried out for the benefit of a new attendee.

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.

1019/05 Dieticians subgroup recommendations

The Chair welcomed the representative of the dietician's subgroup Ruth S. Chinuk, Clinical lead - Dietetics, UHB NHS FT and Dr Matthew Armstrong, Consultant Liver Medicine to the meeting and invited them to present the recommendations for Renapro® Shot and Meritene® Shake.

Renapro® Shot and Meritene® Shake are currently assigned a Red RAG rating on the BSSE APC formulary. The dietician sub group propose a change to Amber, dietician specialist initiation or recommendation. The products would be used to treat specific patient populations at UHB NHSFT- QE; highly specialised patients who need specific nutrition treatment.

The two cohorts are hepatobiliary pancreatic (HBP) and renal dialysis patients. The HBP surgical patient cohort size being treated at the QE is Approximately 1000 patients between 2018 and 2019. 217 liver transplants occurred in years 2018 to 2019. There are over 1000 patients within the renal dialysis cohort.

Ruth Chinuck has observed specific patient safety and clinical risks may be associated with the current RAG rating. There are very specific nutritional challenges for HBP and renal dialysis patients.

The HBP cohort of patients are constantly catabolising energy and have very high calorie requirements. These patients have difficulty absorbing fat which leads to debilitating diarrhoea. These patients require high protein content. Many patients in this cohort have ascites and sarcopenia. Frailty a disability from sarcopenia can have a large impact on the outcome of a liver transplant and overall mortality. An effective treatment for sarcopenia is nutritional supplementation.

Renal dialysis cohort are also catabolising energy at a high rate, but these patients will also lose protein through kidneys. A high protein, low salt supplement is required. Currently available products are very high in fat which is not tolerated. Small volume, high protein, low fat is beneficial.

Renapro® Shot was evaluated by the dietitian subgroup against Renapro® powder which is Amber on formulary. Renapro® Shot can be administered via an enteral feeding tube unlike Renapro® powder. Renapro® Shot has shown patient acceptance and tolerability when given orally. Renapro® Shot is cost neutral to Renapro® powder.

The applicants highlighted the stated population figures per annum are an estimate based on community prescriptions. The data, particularly around indication is currently not collected. Applicants expect 1 renal dialysis patient per week and 8 HBP patients per week to be treated.

The nutritional profile of Renapro® Shot is described as low fat, high protein and low carbohydrate which is important for patients who are at risk of steroid induced diabetes and must manage very high or unpredictable blood sugar levels. The smaller volume of Renapro® Shot at 60ml is useful for patients with ascites who cannot tolerate large volumes. It also has a low electrolyte content. Both the Renapro® Shot and Renapro® powder are well accepted products however, Renapro® Shot is a more flexible preparation and fits the patient profile and their nutritional requirements very well. The dietician's subgroup propose Renapro® powder is retained on the formulary.

The nutrient content of Meritene® Shake is described as low in fat, high protein and moderate calories. The patient evaluation shows patient acceptance, and tolerability. The taste is superior to Aymes® Shake, regardless Aymes® Shake is not suitable for the described patient cohorts due to the higher fat content. Patients with encephalopathy have difficulty making up their own fortified milkshakes and patient acceptability and tolerance is low; therefore, this is not considered a suitable alternative treatment.

The dietician's subgroup expressed patient safety concerns as specialised products are unavailable. There is inappropriate prescribing of Aymes® Shake and fortified milkshakes which are unacceptable to patients. Patient centred treatment is compromised, and practice is not in line with the emerging evidence-base. In 2018, The European Association for the Study of the Liver (EASL) published the nutrition requirements for the chronic liver disease population. There is also a case study presentation for Meritene® Shake and Renapro® Shot in compensated and decompensated cirrhosis.

The clinical risks associated with non-specific nutritional treatment are malnutrition, frailty, sarcopenia, leading to more outpatient appointments, and readmissions affecting the health economy.

Alongside a proposed Amber rating, prescribing criteria should be outlined.

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

- A member asked if Renapro® Shot is advocated for all dialysis patients. Renapro® Shot is recommended for specific haemodialysis patients. Renapro® Shot is not a first line product for the renal dialysis cohort.
- A member asked how many patients within BSSE would require Renapro® Shot. Minimum of 20-45 patients per annum for renal dialysis cohort for the UHB NHS FT - QE sites.
- A member asked if the patients who are being declined these products from primary care are receiving supplies from secondary care? Dieticians provide a small amount of supplements for the patients to try in an outpatient setting but they do not provide a complete course. The most common scenario is patients are given a suboptimal prescription such as Fortisip® compact or Ensure®. Patients may be readmitted with symptoms due to inadequate nutrition, they may be suspended on liver transplant waiting list, and require readmission for an enteral feeding tube.
- A member queried how often this situation occurs? Dr Armstrong estimated weekly but highlighted the transplant unit treats patients from across the country. Secondary care doctors and dieticians liase with GPs to stress the importance of specialised nutrition, to prevent these scenarios.
- If Renapro® Shot is available is it likely to solve the discussed problem or is there a cohort of patients who simply do not like to take supplements. Dr Armstrong explained patients are initially given a small number of supplements and are regularly monitored via dietician specialist led clinics and telephone reviews. Objective measures indicate if nutritional improvements are being made. Patient compliance is considered. Supplements are discontinued when appropriate and this is also monitored via the multidisciplinary team.
- The liver team support patients through reasons why they may not be complying with supplementation.
- It was clarified renal dieticians are supportive of the recommendations.
- Ruth added the products are likely to be used first line in the HBP population. They would not be recommended first line for the renal dialysis population.
- A member asked if any other renal units and liver units have implemented these products. Dr Armstrong explained as one of the largest in the UK, the liver unit at UHB NHS FT is the leader within the area and the team here advises other centres; some areas have adopted the products. This is the first liver unit to have a prehabilitation centre with dieticians and physiotherapists working together.
- It was reiterated data on efficacy has not been published yet. Frailty markers are being used to assess nutrition and exercise management.
- European and international guidelines recommend 1.5g/kg protein daily.
- The obese population is increasing, and the products are beneficial for this cohort.
- A member asked how patients would be managed if Meritene® Shake and Renapro® Shot are not approved. Ruth confirmed dieticians would use more Renapro® powder which is less cost effective than Meritene® Shake. There is likely to be increased instigation of enteral tube

feeding. The group aim to propose the products are embedded in NHSE specialised funding, so centres across the country have access to the same products.

- A member stated the evidence of superiority appears to be the volume and composition of the products. Can the success observed be wholly dependant on the products or as a result of the overall management at the UHB NHS FT liver unit. The National Institute for Health Research (NIHR) were approached regarding a study on high protein low volume products and the response was the recommendations from guidance states a high protein, low volume diet therefore a study is not necessary. The applicants have chosen a product that best fit the European recommendations.
- Meritene® Shake is not listed in the Drug Tariff or Advisory Committee on Borderline Substances (ACBS) indicated. There was a discussion surrounding whether Meritene® Shake is prescribable and whether pharmacy supply is reimbursed within primary care.

The Chair thanked Ruth Chinuck and Dr Matthew Armstrong 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.

<u>Further discussion points in the absence of the representatives included:</u>

- Members discussed whether Meritene® Shake is reimbursed on an NHS prescription.
- Meritene® Shake is commercially available in supermarkets.
- No patient safety issues are identified with Meritene® Shake.
- With regards to clinical efficacy of Meritene® Shake, the product contains the stated amount of nutrients per the European guidance.
- There is no clear alternative treatment. There are patients that do not have the appropriate supplementation which can lead to suspension on the transplant waiting list or readmission for an enteral feeding tube.
- Nutrient composition is correct for a select group of patients who are closely monitored by the liver unit.
- A member raised there could be possibility of creep in prescribing outside of the defined cohort if Meritene® Shake is made widely available.
- A member questioned whether APC should see data backing up the product's clinical efficacy.
- A member raised if Meritene® Shake is not accessible in primary care yet if it approved on the formulary, there could be an increase in decline to prescribes.
- Members agreed there was a question regarding clinical efficacy of the product as there was no trial evidence or data presented. Members acknowledged the product fit the European recommendations.
- Another concern is whether Meritene® Shake is reimbursable on an NHS prescription and therefore accessible to the patient cohort.
- A member raised if a doctor prescribes Meritene® Shake there is more control on quantity given compared to if the patient is asked to purchase over the counter.
- A CCG representative added, having looked at data, there is a substantial amount of prescribing occurring of Meritene® Shake in primary care.
- APC would like assurances that if Meritene® Shake is approved it

would be accessed by the appropriate cohort as it is available to buy and there is potential for creep in prescribing. A protocol for use such as a RICaD is considered necessary. This would also give clear direction on when product should be discontinued.

Decision Summary: Request RICaD for Meritene® Shake outlining product's use, continuation and discontinuation criteria.

- Members moved on to assess Renapro® Shot. Renapro® Shot is cost neutral to Renapro® powder following a recent reduction in cost.
- Members agreed Amber rating for Specialist dietician recommendation.
- Low volume of the product is vital to patients who are fluid restricted.
- Renapro® Shot Place in therapy is 2nd or 3rd line
- CCGs supportive of the addition of Renapro® Shot to formulary.

Decision summary: Renapro® Shot approved as Amber Specialist dietician recommendation. Relay need for a RICaD for Meritene® Shake for APC consideration.

ACTIONS:

- **Update formulary with Renapro® Shot Amber Specialist dietician recommendation** — **APC sec**
- **Relay decisions to dietician subgroup by Thursday 17th October 2019** — **APC sec**

1019/06 Diabetes Medicines Management Advisory Group recommendations

Updated Type 2 diabetes guidance

The Chair directed members to the updated Type 2 diabetes guideline for the choice of oral and non-insulin antidiabetics agents for adults produced by the Diabetes Medicines Management Advisory Group (DMMAG). Ertugliflozin and semaglutide have been added to the guideline following their approval on the formulary.

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

- A CCG member relayed comments received from the CCG diabetes pharmacist.
- Page 8 Point 4 regarding pioglitazone and dapagliflozin co-prescribing was recently removed from the SPC.
- Page 8 Point 8 Addition of note to read alogliptin is not licensed for monotherapy.

NICE TA 597: Dapagliflozin with insulin for treating type 1 diabetes

The Chair directed members to DMMAG recommendations for the SLGT2 inhibitors.

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

- DMMAG recommended dapagliflozin with insulin for treating type 1 diabetes remains Red under specialist use.

- A member added the recommendation is a result of the increased risk of diabetic ketoacidosis (DKA) with dapagliflozin.
- Members agreed with DMMAG recommendation that dapagliflozin remains Green for type 2 diabetes.
- The formulary should note that prescribing in line with NICE TA 597: dapagliflozin for type 1 diabetes with insulin should be undertaken in specialist centres only.
- The formulary should note none of the SGLT2 inhibitors should be prescribed in primary care for type 1 diabetes until further local guidance becomes available.

ACTIONS:

- **Relay amendments to Type 2 Diabetes guidance to DMMAG** **APC sec**
- **Update formulary in line with discussion** **APC sec**

1019/07 BSol CCG Policy Items which should not routinely be prescribed in primary care – for information

The Birmingham and Solihull CCG policy reflects the national guidance which was bought to APC in September 2019.

- The current aliskiren and amiodarone RICaDs are being reviewed by UHB NHS FT.
- It was clarified patients on amiodarone who are stable and whose care falls under primary care would not be repatriated by Trusts.
- The formulary should be annotated to indicate patients who are established on amiodarone should continue their prescriptions as normal. The guidance applies to new patients only.
- A member noted there is an exception for lidocaine for treatment of neuropathic pain in adults. It was clarified this indication is noted on the formulary entry for lidocaine plasters.
- A member raised there is also an exception listed within the guidance for liothyronine use. Members noted liothyronine is RED and an abbreviated application is forthcoming.

ACTION:

- **Add hyperlinks to BSol CCG policy from relevant formulary entries** **APC sec**

1019/08 BSSE APC Primary Care Clinical Pathway for Atrial Fibrillation Detection and Management

The Chair directed members to the Pathway and specialist feedback

- A member raised the feedback regarding using Modification of Diet in Renal Disease (MDRD); this equation adjusts for African-Caribbean patients and would not be suitable for the entire population.
- Members clarified creatinine clearance should be used to estimate renal function as it is specifically stated in the Summary Product Characteristics for the non-vitamin K antagonist oral anticoagulants (NOACs).
- A piece of feedback asked why a beta-blocker has been highlighted as the rate control agent. Members agreed the guidance does not mandate beta-blockers, they are given as an example. Beta-blockers are the most likely rate control agent initiated in primary care.
- A piece of feedback states 'CHA_2DS_2-VASc cannot be accurately

calculated without an echo or other imaging so "consider" an echo seems out of place'. Members disagreed. In addition, many GPs are not able to request echocardiogram. The NICE guidance does not advocate this. Requesting an echo at this stage could also lead to delay in patient receiving appropriate treatment.

- Members agreed with the feedback suggesting cardiology referral for patients with heart rate >110bpm and this would be incorporated.
- The pathway is intended to replace the NOAC RICaDs and primarily targeted at GPs.
- A member added the guidance states users should be aware of the local anticoagulation pathways.

ACTION:

- **Amend AF pathway in line with discussion surrounding specialist feedback** — **UHB NHS FT**

1019/09 BSSE APC Toujeo® RICaD – for ratification

The Chair directed members to the enclosure for the BSSE Toujeo® RICaD which has been updated to reflect the availability of the new Doublestar pen device.

- A member noted reference to Semglee®, the insulin glargine biosimilar, should be included.

Decision summary: Toujeo® RICaD is approved subject to the above amendment

ACTION:

- **Amend as discussed and publish Toujeo® RICaD** — **APC sec**

1019/10 NHSE policy update: Cinacalcet for complex primary hyperparathyroidism

The Chair directed members to the updated implementation guidance for cinacalcet.

UHB NHS FT – HGS site are anticipating an abbreviated application and draft ESCA forthcoming to APC for consideration requesting a change in status from Red to Amber.

1019/11 Edoxaban anti-coagulant choice for atrial fibrillation UHB NHS FT - for information

An application form was circulated from UHB NHS FT cardiologists requesting edoxaban replace rivaroxaban as the preferred once a day NOAC agent for non-valvular atrial fibrillation (AF). The application includes an AF pathway for anticoagulant choice.

- A member raised the antidote andexanet alfa for reversal of anticoagulation is not licensed for use with edoxaban. However, it would be used in life-threatening situations.
- A member noted warfarin is not included in the anticoagulant choice pathway for AF. UHB NHS FT representative noted the pathway is for use with NOACs and the title will be amended.
- Rivaroxaban cannot be initiated in patients who are nil-by mouth for

example post ablation; it must be taken with food to optimise bioavailability.
- There are still a number of patients established on warfarin.

ACTION:
- **Update formulary to reflect APC preferred agents for AF are apixaban and edoxaban** **APC sec**

1019/12 Declines by Trust Drugs and Therapeutics Committee – for information

Members discussed the validity of raising declined applications from individual trust DTC as a standing agenda item at APC. Trusts are currently working together to share information regarding drug applications therefore this information is not required at APC.

1019/13 RMOC recommendations

There were no RMOC recommendations published during September 2019

1019/14 Minutes of the meeting held on Thursday 19th September 2019 – for ratification

- Page 5 Omit sentence. A member noted the national guidance for over the counter medication should not influence applications for specialist supported drugs.
- Page 10 under Decline to Prescribe omit bullet point 2.
- Page 16 0619/AOB A member noted the Hydroxychloroquine Royal College of Ophthalmologist guidance for screening requires highlighting on the formulary entry for hydroxychloroquine.

ACTION: Add hyperlink to Royal College of Ophthalmologist guidance for screening to formulary entry for hydroxychloroquine **APC sec**

The minutes of the meeting held on Thursday 19th September 2019 were discussed for accuracy.

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

1019/15 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:

- 0919/05 Chapter 11 Eye Formulary chapter review Trust to complete drug application form alongside ophthalmology specialists

- 0919/06 Dieticians subgroup recommendations Publish updated guidelines or Prescribing Specialist Infant Formula in Primary Care to APC formulary – awaiting updated document

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

- 0919/07 BSSE APC Management/Development meeting proposals - Electronic process for transfer of ESCA/RICaDs to be discussed at future APC Management/development meeting

- 0919/07 BSSE APC Management/Development meeting proposals - Further discussion on CCG delegated limits at future APC Management/development meeting-

- 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 review of dental products Update: Will be scheduled for Jan/Feb 2020

- 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

- 0719/AOB Acenocoumarol and phenindione Clarify commissioning arrangements across BSSE area Update: Close Action

- 0619/AOB Azathioprine for haemolytic anaemia Produce Azathioprine ESCA for haemolytic anaemia In progress

- 0419/AOB Matters arising- mexiletine Further discussion required between CCGs and Trusts regarding potential arrangements for mexiletine supply In progress Update: Close Action

- 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

1019/16 NICE Technological Appraisals (TAs)

In September 2019, there were 5 TAs published; of these, 1 is NHSE commissioned, 1 CCG commissioned and 3 are not recommended.

The CCG commissioned NICE TA is:

- Sodium zirconium cyclosilicate for treating hyperkalaemia [TA599]

RED status agreed

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

Any other business:

1. **Ranitidine shortage**

Zantac® has been discontinued by the manufacturer. Patients at Birmingham Children's hospital are being switched to lansoprazole or omeprazole. Patients on proton pump inhibitors (PPIs) are also being reviewed for discontinuation. Where possible the fast tabs are preferred however in some cases a liquid special is necessary. Lansoprazole and omeprazole orodispersible preparations are not licensed for use in children so the Trust anticipates decline to prescribe forms will be received from GPs. However, these preparations are listed in the BNF for Children. The Trust representative would like to propose an amendment/wording to be added to the formulary website.

ACTION: To provide further information and discussion at November APC **BWCH NHS FT**

2. **Decline to Prescribe form**

A Trust representative raised a DtP form was sent incorrectly to the Trust and this is a potential breach of confidentiality.

The Chair thanked the members for their input today. The meeting closed at 16:45.

Date of next meeting: Thursday 14th November 2019
Birmingham Research Park.