Minutes of the meeting of the AREA PRESCRIBING COMMITTEE held on Wednesday, 8th November 2017 in the Boardroom, Hillder House

MEMBERS:

Chris Lawson (Chair)	Head of Medicines Optimisation (Barnsley CCG)
Professor Adewale Adebajo	Associate Medical Director (Medicines Optimisation) on behalf of the Medical Director (BHNFT)
Tom Bisset	Community Pharmacist (LPC)
Sarah Hudson	Lead Pharmacist (SWYPFT)
Dr Kapil Kapur (left after agenda item 210)	Consultant Gastroenterology (BHNFT)
Dr Abdul Munzar (left after agenda item 217)	General Practitioner (LMC)
Mike Smith	Chief Pharmacist (BHNFT)

IN ATTENDANCE:

Caron Applebee	Lead Pharmacist (Barnsley CCG)
Nicola Brazier	Administration Officer (Barnsley CCG)
Lauren Clarke	Pre-registration Pharmacist (BHNFT)
Joanne Howlett	Medicines Management Pharmacist (Barnsley CCG)
Professor Hugh Jones (for agenda item 209 only)	Consultant Physician & Endocrinologist and Hon. Professor of Andrology (BHNFT)
Dr Steve Lobaz (for agenda item 208 only)	Consultant in Anaesthetics and Intensive Care Medicine, Fluid and AKI Lead (BHNFT)
Umar Patel	Senior Pharmacist - Formulary / Interface (BHNFT)
Gillian Turrell	Lead Pharmacist (BHNFT)

APOLOGIES:

Deborah Cooke	Lead Pharmacist (Barnsley CCG)
Dr Mehrban Ghani	Medical Director (Barnsley CCG)
Dr Becky Hirst	Palliative Care Consultant (Barnsley Hospice)
Dr Augustin Iqbal	Consultant Physician (SWYPFT)

ACTION BY

APC 17/203 QUORACY

The meeting was quorate up to APC17/217. Any decisions made after this item would need to be ratified. **CL**

Post meeting note:- decisions made after APC17/217 were ratified by email and documented under the specific agenda items.

APC 17/204 DECLARATIONS OF INTEREST RELEVANT TO THE AGENDA

There were no declarations of interest to note.

APC 17/205 DRAFT MINUTES OF THE MEETING HELD ON 11th OCTOBER 2017

APC183.3 should read …"There could have been a misunderstanding within secondary care in the interpretation of the formulary to suggest that this preparation was on formulary…" **NB**

Subject to the above amendment, the minutes were accepted as an accurate record of the meeting.

APC 17/206 DECISIONS/APPROVALS TO BE RATIFIED FROM 11TH OCTOBER 2017 MEETING

Decisions made at the October 2017 APC meeting relating to the following were ratified: -

- Guidance for GPs on common off-label use of psychotropic medication
- Increased QTc in Palliative Care
- Generic Desogestrel
- Summary of Formulary Choices for BGTS
- DMARD Shared Care Guideline (updated)
- Chapter 9: Nutrition Formulary Review

APC 17/207 MATTERS ARISING AND APC ACTION PLAN

207.1 NICE TAs

August 2017 NICE TAs

The Lead Pharmacist, BHNFT confirmed that the following NICE TAs were applicable for use at BHNFT:-

- TA471 Eluxadoline for treating irritable bowel syndrome with diarrhoea
- TA472 Obinutuzumab with bendamustine for treating follicular lymphoma refractory to rituximab
- TA160 (updated from Oct 2008) Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women
- TA161 (updated from Oct 2008) Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women

The Lead Pharmacist, BHNFT confirmed that the following NICE TAs were not applicable for use at BHNFT:-

- TA463 Cabozantinib for previously treated advanced renal cell carcinoma
- TA465 Olaratumab in combination with doxorubicin for treating advanced soft tissue sarcoma
- TA467 Holoclar for treating limbal stem cell deficiency after eye burns
- TA190 (updated from June 2010) Pemetrexed for the maintenance treatment of non-small-cell lung cancer

September 2017 NICE TAs

The Lead Pharmacist, BHNFT confirmed that the following NICE TA was applicable for use at BHNFT:-

- TA475 Dimethyl fumarate for treating moderate to severe plaque psoriasis

The Lead Pharmacist, BHNFT confirmed that the following NICE TAs were not applicable for use at BHNFT:-

- TA473 Cetuximab for treating recurrent or metastatic

squamous cell cancer of the head and neck
- TA474 Sorafenib for treating advanced hepatocellular carcinoma
- TA476 Paclitaxel as albumin-bound nanoparticles with gemcitabine for untreated metastatic pancreatic cancer
- TA357 (updated from Oct 2015) Pembrolizumab for treating advanced melanoma after disease progression with ipilimumab
- TA366 (updated from Nov 2015) Pembrolizumab for advanced melanoma not previously treated with ipilimumab
- TA428 (updated from Jan 2017) Pembrolizumab for treating PDL1-positive non-small-cell lung cancer after chemotherapy
- TA439 (updated from Mar 2017) Cetuximab and panitumumab for previously untreated metastatic colorectal cancer

207.2 Supply Of Epipens®

It was reported that the current supply issue with Epipens® was causing problems in primary care, resulting in instances where patients that only have 1 Epipen®, are being prescribed 1 Emerade® in order to meet the new recommended guidance to be prescribed/to carry 2 pens.

It was also reported that schools are requesting that 1 Epipen® is kept with the child and 1 is held at reception. This would therefore require children to be prescribed at least 3 Epipens® so that they also had 1 at home.

Agreed action: -

- A reminder to be communicated in Primary Care via the APC memo and Medicines Management Newsletter. **CA**

Action Plan – Other Areas

207.3 Zoladex Amber G Shared Care Guideline

The guidance was currently with specialists for comment. This would be brought to the December 2017 meeting. **CA**

APC 17/208 ACUTE KIDNEY INJURY (AKI) PHARMACIST LIAISON

Dr Lobaz, Consultant in Anaesthetics and Intensive Care Medicine, Fluid and AKI Lead at BHNFT was in attendance and his nil declaration of interest was received.

Dr Lobaz gave an overview to the Committee about his role and his aim to reduce the deaths and morbidity associated with AKI (formally acute renal failure) by moving more resources into the community to make changes to influence hospital outcomes.

He has instigated a number of changes within the Trust already including fluid prescription and balance booklets and the AKI bundle to bring the Trust in line with NICE Guidance for AKI.

He recently received some AKI data for Barnsley in terms of inpatient mortality and length of hospital stay and has also been conducting a monthly rolling AKI audit. The monthly audit was started in June 2017 to look at trends and fluid balance

management and demographics and information has been obtained from Lorenzo to look at mortality and outcome data.

The audit has identified that 60% of AKI cases are present on admission to hospital and is significant in terms of life lost, morbidity and expenses/ cost. He feels the community need to be targeted much more, as simple interventions such as 'sick-day rules' e.g. not taking certain nephrotoxic medications in times of sickness or ensuring the patient is not dehydrated, would potentially have the biggest effect on AKI patient outcomes.

Reference was made to the 'Think Kidney' website and Salford CCG Guidance where further resources are available.

In order to reduce admissions, hospital lengths of stay, cost etc Dr Lobaz was seeking help and support via the APC from the CCG to help promote better links between Secondary Care, Primary Care and community pharmacy to develop an implementation plan.

It was noted that some work had been undertaken in primary care but not as an intensive education campaign for patients.

Agreed actions: -

- Dr Lobaz to share information with the Head of Medicines Optimisation **SL**
- A working group to be formed and information to be brought back from the working group to the Committee **CL**

APC 17/209 FREESTYLE LIBRE® BRIEFING

Professor Jones was in attendance and his declaration of interest was received.

At the October 2017 APC meeting, the Committee approved a position statement which stated: -

- The use of FreeStyle Libre® for all patients with type 1 and type 2 diabetes is not recommended
- FreeStyle Libre® has not been demonstrated to be cost-effective and in the absence of a positive recommendation from a full technology appraisal (TA), produced and published by the National Institute for Health and Care Excellence (NICE), is not recommended for routine funding in primary care

The Diabetes specialist team wanted the APC to reconsider its decision with a view to allowing prescribing for patients who sit within clearly defined patient groups. Professor Jones was in attendance to provide his clinical expertise around the benefits of using the device and to present the advice from the Regional Medicines Optimisation Committee (RMOC).

There was a lengthy discussion about the advice within the RMOC position statement and examples of its use for those in different patient groups were shared by Professor Jones.

It was noted that in addition, all patients (or carers) must be willing to

undertake training in the use of Freestyle Libre® and to commit to ongoing regularly follow-up and monitoring of the 8 areas listed, and the Chair asked if Professor Jones felt that this was something that could be undertaken locally with the appropriate templates to support. He felt it was achievable, noting that if the commitment was not there from patients, then treatment would be discontinued.

Professor Jones was thanked for attending the meeting.

It was thought that this could benefit district nurses in terms of time saved but there were concerns raised around the potential prescribing costs for primary care associated with the device discs.

The Committee supported the RMOC position statement and it was agreed that guidance would be produced to support the process which would provide clarity around initiating responsibilities and patient responsibility, to progress with the trial use of Freestyle Libre®.

Agreed actions: -

- Guidance to be produced to define the patient groups and to provide clarity around initiating responsibilities and patient responsibility, along with specifying the outcomes that must be monitored to ensure use of the device is leading to an improvement in the outcomes. **CA**

APC 17/210 CO-AMOXICLAV USAGE IN SECONDARY CARE

The Define usage data was presented showing: -

- an overall trend of higher usage over the winter months
- usage spike in May 2017 due to a shortage of IV co-amoxiclav, hence the microbiologists were promoting the use of oral co-amoxiclav where appropriate

It was noted that there had been several other national antibiotic shortages over the summer 2017.

It was expected that the usage would start to fall in line with normal winter pressures.

Secondary care representatives did not feel that any inappropriate requests were currently coming out to primary care as a full course of treatment is issued on discharge, however it was decided that the usage data should be reviewed again in 6 months.

Agreed action:-

- Secondary Care co-amoxiclav usage data to be brought back to the Committee in May 2018. **GT**

APC 17/211 COPD ALGORITHM

Produced by Neil Heslop and Jacqui Pollington, the COPD algorithm was brought back for comment and ratification.

The Chair asked that both the specialist nurses and secondary care clinicians were in agreement with the algorithm and the Lead

Pharmacist (CA) would check this for completeness.

The Committee approved the COPD algorithm but queried the number of inhalers still on the formulary e.g. with respect to the LABA/ICS inhalers there are 4 DPIs listed. The Lead Pharmacist (CA) would liaise with Neil Heslop to clarify the reasons for including them.

Agreed actions: -

- The Lead Pharmacist (CA) to ensure that the specialist nurses and secondary care clinicians were in agreement with the algorithm. **CA**
- The Lead Pharmacist (CA) to query the number of DPI's listed on the algorithm/formulary. **CA**

APC 17/212 SHARED CARE GUIDELINES / AMBER G SHARED CARE GUIDELINES

212.1 Ivabradine Shared Care Guideline (SCG)

The Ivabradine Amber G SCG has been updated following changes to the SPC. The following changes have been made:-

- The license for chronic stable angina has changed from patients with heart rate >60bpm to >70bpm
- Doses should only be titrated upwards if resting heart rate is persistently above 60bpm for all indications
- Heart failure patients with a resting heart rate between 50-60bpm should remain on maximum dose 5mg BD
- Combination with verapamil or diltiazem are now contraindications
- The following statement has been added regarding resting heart rate assessment and monitoring: Given that the heart rate may fluctuate considerably over time, serial heart rate measurements, ECG or ambulatory 24-hour monitoring should be considered when determining resting heart rate before initiation of Ivabradine treatment and in patients on treatment with Ivabradine when titration is considered. This also applies to patients with a low heart rate, in particular when heart rate decreases below 50 bpm, or after dose reduction.
- It now states that if there is no improvement within 3 months, treatment should be discontinued.

The Committee approved the Ivabradine SCG.

Agreed action:-

- The approved SCG would be shared with LMC. **CA**

212.2 Epilepsy Amber G Shared Care Guideline (SCG) and review of Briviact®

The Epilepsy Amber G SCG covering the prescribing of anti-epileptics has been updated following a South Yorkshire collaborative approach with local CCGs.

Enclosure H1 summarises the issues to be discussed: -

- Change traffic light status of Brivaracetam (Briviact) from red to amber
- Inclusion of eslicarbazepine (Zebinix®) into the guideline as an amber drug
- Review of buccal midazolam preparations
- Clarification around epilepsy specialist nurses providing advice to GPs

Buccal midazolam preparations are available in 2 formulations including 10mg/ml Epistatus® which is now licensed in patients under 18 years and it was highlighted that the cost of the licence to community pharmacy was more expensive than the 'special' (unlicensed preparation).

The Committee approved the following: -

- Traffic light status of Brivaracetam (Briviact®) to change from red to amber
- Inclusion of eslicarbazepine (Zebinix®) into the guideline as an amber drug
- Buccal midazolam preparations – use Epistatus® as a licenced product, off label use. Buccolam® remains product of choice in paediatric services

Clarification was provided at Enclosure H1 around epilepsy specialist nurses providing advice to GPs.

Agreed action: -

- Scriptswitch to be checked to ensure that prompts are active to ensure that buccal midazolam is prescribed by brand. **CA**
- Following the inclusion of eslicarbazepine (Zebinix®) into the guideline as an amber drug, further information with key points to be communicated to primary care via the APC memo and Medicines Management Newsletter. **CA**

APC 17/213 NEW PRODUCT APPLICATION LOG – noted.

APC 17/214 NEW PRODUCT APPLICATION

214.1 Eslicarbazepine (Zebinix®)

This was discussed at APC 212.2 and the application was approved (Amber) as an alternative option for patients not responding to monotherapy or adjunctive therapy.

APC 17/215 BARNSLEYAPCREPORT@NHS.NET FEEDBACK – follow up actions and outcomes were noted.

APC 17/216 NEW NICE TECHNOLOGY APPRAISALS – OCTOBER 2017

216.1 Feedback from BHNFT Clinical Guidelines and Policy Group

The Lead Pharmacist, BHNFT confirmed that the following NICE TA was applicable for use at BHNFT:-

- TA480 Tofacitinib for moderate to severe rheumatoid arthritis

Feedback on whether the following NICE TAs are applicable for use at BHNFT would be fed back at the next APC meeting: - **GT**

- TA477 Autologous chondrocyte implantation for treating

symptomatic articular cartilage defects of the knee
- TA478 Brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma
- TA479 Reslizumab for treating severe eosinophilic asthma
- TA481 Immunosuppressive therapy for kidney transplant in adults
- TA482 Immunosuppressive therapy for kidney transplant in children and young people

216.2 Feedback from SWYPFT NICE Group
There was nothing relevant to report to the APC and it was confirmed that none of the October 2017 NICE TAs above were applicable for use at SWYPFT.

APC 17/217 FEEDBACK FROM THE MEDICINES MANAGEMENT GROUPS

217.1 Primary Care Quality & Cost Effective Prescribing Group (QCEPG)
- The Group discussed Primary Care QiPP progress, which was on target with the financial QiPP savings. Committee members were thanked for all their help in terms of the decision making process in order to implement the work required to achieve the savings.
- The Group discussed community pharmacy contracts.

Following a discussion around the palliative care stockist scheme and the view that previous proposals and recommendations have not been implemented around increasing the number of pharmacies open extended hours to be included in the scheme, the Head of Medicines Optimisation and Lead Pharmacist, SWYPFT would discuss this further outside of the meeting.

217.2 BHNFT
There was nothing relevant to report to the APC.

217.3 SWYPFT Drugs & Therapeutics Committee (D&TC)
It was noted that the lithium guidelines have been updated and therefore the Shared Care Guideline would be updated and brought back to the Committee. **SH**

APC 17/218 ISSUES FOR ESCALATION TO THE QUALITY & PATIENT SAFETY COMMITTEE (Q&PSC)
AKI and Freestyle Libre® to be escalated to the Q&PSC. **CL**

APC 17/219 HORIZON SCANNING DOCUMENT – OCTOBER 2017
The Committee agreed to classify the new products as follows on the traffic light list (TLL): - **CA**

Ex vivo expanded autologous human corneal epithelial cells containing stem cells 79,000-316,000 cells/cm^2 living tissue equivalent (Holoclar®▼, Chiesi) – **PROVISIONAL RED**
Tenofovir disoproxil succinate (generic) 245 mg film-coated tablets(Dr Reddy's) – **ALREADY RED**
Cladribine 10 mg tablets (Mavenclad®, Merck) – **PROVISIONAL RED**
Raltegravir 600 mg film-coated tablets (Isentress®, Merck Sharp & Dohme – **ALREADY RED**

Methotrexate 100 mg/mL concentrate for solution for infusion (medac GmbH) - **PROVISIONAL RED**
Mercaptamine 3.8 mg/mL eye drops (Cystadrops®▼, Orphan Europe) - **PROVISIONAL RED**
Avelumab 20 mg/mL concentrate for solution for infusion (Bavencio®▼, Pfizer) - **PROVISIONAL RED**
Telotristat ethyl 250 mg film-coated tablets (Xermelo®▼, Ipsen Ltd) - **PROVISIONAL RED**
Atezolizumab 1,200 mg concentrate for solution for infusion (Tecentriq®▼, Roche) - **PROVISIONAL RED**
Bosentan 62.5 mg & 125 mg film-coated tablets (Bosentan Accord, Accord) - **PROVISIONAL RED**
Phenytoin 50 mg/mL solution for injection (Phenytoin Hikma, Consilient Health) – **ALREADY GREEN**

As the meeting was not quorate for this item, ratification would be required from Dr Munzar via email.

Post meeting note:- Dr Munzar confirmed by email that he agreed with the proposed traffic light classifications given above.

APC 17/220 MHRA DRUG SAFETY UPDATE – VOLUME 11, ISSUE 3, OCTOBER 2017

Received, noted and summarised below: -

- Methylprednisolone injectable medicine containing lactose (Solu-Medrone 40 mg): do not use in patients with cows' milk allergy
  Solu-Medrone 40 mg may contain trace amounts of milk proteins. Do not use in patients with a known or suspected allergy to cows' milk.
- Gabapentin (Neurontin): risk of severe respiratory depression
  Gabapentin has been associated with a rare risk of severe respiratory depression even without concomitant opioid medicines. Patients with compromised respiratory function, respiratory or neurological disease, renal impairment, concomitant use of central nervous system (CNS) depressants, and elderly people might be at higher risk of experiencing severe respiratory depression. Dose adjustments might be necessary in these patients.
- Isotretinoin (Roaccutane): rare reports of erectile dysfunction and decreased libido
  Cases of sexual dysfunction, predominantly involving erectile dysfunction and decreased libido, have been reported rarely in patients taking oral isotretinoin for severe acne.
- Clozapine: reminder of potentially fatal risk of intestinal obstruction, faecal impaction, and paralytic ileus
  If constipation occurs during treatment with clozapine (Clozaril, Denzapine, Zaponex), it is vital that it is recognised and actively treated.

APC 17/221 SOUTH YORKSHIRE AREA PRESCRIBING COMMITTEE MINUTES

The minutes from NHS Sheffield CCG (20th July 2017 & 21st September 2017) were received and noted.

APC 17/222 ANY OTHER BUSINESS

As the meeting was not quorate for these items, ratification would be required from Dr Munzar via email.

222.1 Migalastat

The Lead Pharmacist (CA), Barnsley CCG informed the Committee that, although we hadn't received a request to prescribe Migalastat, we have been informed that a patient in Barnsley has been started on this drug by Salford Hospital. Migalastat has a positive NICE highly specialised TA therefore the Committee agreed that this drug would be classified red on the traffic light list with a note stating 'to be prescribed by specialists in inherited metabolic disease only'.. **CA**

Post meeting note:- Dr Munzar confirmed by email that he agreed with the Committees decision.

222.2 Dilzem® Preparations

The Lead Pharmacist, BHNFT noted the current supply problems with Dilzem® preparations and asked the Committee if these could be removed as first line choices as this brand is less cost effective than some of the others on formulary. The Committee approved the removal of Dilzem® preparations from the formulary.

Post meeting note:- Dr Munzar confirmed by email that he agreed with the Committees decision.

APC 17/223 DATE AND TIME OF THE NEXT MEETING

The time and date of the next meeting was confirmed as Wednesday, 6th December 2017 at 12.30 pm in the Edith Perry Room at Barnsley Hospital NHS Foundation Trust.