NHS
Barnsley
Clinical Commissioning Group

Minutes of the meeting of the AREA PRESCRIBING COMMITTEE held on Wednesday, 8th August 2018 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)
Alison Evans	Clinical Quality and Development Lead, Public Health Nursing 0-19 Service (BMBC)
Dr Rebecca Hirst	Palliative Care Consultant (Barnsley Hospice)
Sarah Hudson	Lead Pharmacist (SWYPFT)
Dr Jeroen Maters	General Practitioner (LMC)
Dr Abdul Munzar	General Practitioner (LMC)

IN ATTENDANCE:

Nicola Brazier	Administration Officer (Barnsley CCG)
Deborah Cooke	Lead Pharmacist (Barnsley CCG)
Anila George	Junior Pharmacist (BHNFT)
Joanne Howlett	Medicines Management Pharmacist (Barnsley CCG)
Umar Patel	Senior Pharmacist - Formulary / Interface (BHNFT)
Jackie Senior (for item 164 only)	Clinical Lead Speech and Language Therapist (SWYPFT)
Gillian Turrell	Lead Pharmacist (BHNFT)

APOLOGIES:

Caron Applebee	Lead Pharmacist (Barnsley CCG)
Dr Kapil Kapur	Consultant Gastroenterology (BHNFT)
Mike Smith	Chief Pharmacist (BHNFT)

ACTION BY

APC 18/160 QUORACY

The meeting was quorate, however due to the meeting overrunning; GP representatives were not present for a number of agenda items. Any items requiring ratification would be circulated to them by email. **NB**

160.1 <u>APC Annual Report 2017/18</u>

The APC Annual Report was taken to the Quality & Patient Safety Committee meeting which was well received but there was concern in respect of the number of non-quorate meetings and maintaining work coming through the Committee. It was agreed that any future non-quorate meetings would be escalated to the Q&PSC. **CL**

APC 18/161 DECLARATIONS OF INTEREST RELEVANT TO THE AGENDA

There were no declarations of interest to note.

APC 18/162 DRAFT MINUTES OF THE MEETING HELD ON 11th JUNE 2018

162.1 <u>Page 4, Ticagrelor</u>

The Chair provided an update on guidance being followed at neighbouring CCGs and she would continue to liaise with them to possibly agree a South Yorkshire collaborative approach.

It was noted that 'DRAMA' criteria have been referenced in letters from BHNFT to Barnsley GPs advising that if patients meet at least one of the 'DRAMA' criteria then extended therapy would continue.

Agreed action: -

- The Lead Pharmacist, BHNFT would check what criteria local teams, including Sheffield were using. **GT**

162.2 Page 6, APC 18/138 should read 'Breathe Team'.
162.3 Page 7, APC 18/142 spelling correction in title.
162.4 Page 9, APC 18/147.2 MucoClear® should read 'formulary entry needs amending, formulary traffic light status green'.

Subject to the above changes, the minutes were accepted as an accurate record of the meeting. **NB**

APC 18/163 MATTERS ARISING AND APC ACTION PLAN

163.1 Trimovate®

Following discussion at the last meeting, primary care prescribing data, up to January 2018, had been obtained confirming that there was prescribing in primary care. Following a significant price increase, a number of neighbouring organisations have developed guidance with other possible alternatives to consider and BHNFT confirmed that similar guidance is used within the Trust and it was agreed that this would be brought to the September APC meeting for consideration and approval.

It was agreed that Trimovate® would be classified grey on the formulary traffic light list.

Agreed action: -

- Guidance with possible alternatives to Trimovate® would be brought back to the September APC meeting. **GT/UP**

163.2 CAMHS – Prescribing for ADHD (transition from paediatrics to adults)

The Chair confirmed that the issue had been escalated to the Head of Contracting and Head of Quality (Deputy Chief Nurse) and was awaiting a response.

163.3 Colesevelam

The Lead Pharmacist, BHNFT confirmed that a new product application and guidance would be brought back to the Committee, possibly in December 2018. In the meantime, the Committee agreed that colesevelam would be classified non-formulary provisional Amber G.

163.4 NICE TA (June 2018)

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

- TA524 Brentuximab vedotin for treating CD30-positive Hodgkin lymphoma
- TA217 (updated from March 2011) Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease

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

- TA217 (updated from March 2011) Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease (also applicable to SWYPFT)

Post meeting note: *The Lead Pharmacist, BHNFT confirmed that the following Fast Track Appraisal was applicable for use at BHNFT:-*

- FTA521 Guselkumab for treating moderate to severe plaque psoriasis

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

- TA522 Pembrolizumab for untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable
- TA523 Midostaurin for untreated acute myeloid leukaemia
- TA525 Atezolizumab for treating locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy
- TA526 Arsenic trioxide for treating acute promyelocytic leukaemia
- TA527 Beta interferons and glatiramer acetate for treating multiple sclerosis

Action Plan – other areas

163.5 Inflammatory Bowel Disease and Autoimmune Hepatitis Shared Care Guideline – monitoring audit

The Chair reminded the Committee that the audit being undertaken was to establish if GI patients on DMARDS were being monitored and managed as well as patients on RA. Information obtained via Eclipse Live had raised concern that overall the number of patients up to date with ALL DMARD monitoring was low. RA patients appeared to have a greater proportion of monitoring undertaken than GI, however this could be due to the anomaly that information in the hospital ICE systems was not downloaded but could be seen. The Chair confirmed that the Eclipse team have been asked to run a central extraction to review figures.

It was acknowledged that any monitoring undertaken in secondary care would not show on the Eclipse system and the Lead Pharmacist, BHNFT confirmed that GI patients are monitored in the pharmacy IBD clinic which may explain the low percentage of monitoring shown in GP systems as this is recorded within the hospital system.

Agreed action:-

- It was agreed that a review would be undertaken; looking at possibly 10 patients in 3 or 4 practices and the findings would be brought back to the Committee. **CL/DC**

APC 18/164 PRESCRIBING OF THICKENERS

Jackie Senior, Clinical Lead Speech and Language Therapist, SWYPFT was present to support this agenda item and a nil declaration of interest was noted.

Speech and Language Therapy (SALT) had advised primary care that they were considering moving from starch based thickeners to gum based thickeners which were preferred above the starch based preparations as they are safer and more palatable.

Advantages of gum based thickeners were shared and include: -

- Not broken down by amylase
- Improved stability so no change to consistency over time
- Not affected by changes in temperature and keeps intended consistency
- Visual appearance remains clear when added to water
- More palatable
- Smoother texture
- No oral residue post swallow
- Safer

SALT support the gum based products due to the advantages listed.

Jackie provided an overview of the products referring to the International Dysphagia Diet Standardisation Initiative (IDDSI), evidence based framework of new descriptors for food and fluids to be implemented by April 2019. IDDSI is supported by The Royal College of Speech and Language Therapists and The British Dietetics Association and the Barnsley change over date for new descriptor for thickened fluids is planned for October 2018 and therefore it was expected that the change to gum based products would be done in line with this date. It was noted that the company providing the gum based products, Fresenius, are ready to deliver a training package to all ward staff (August/September 2018).

It was noted that gum based products are being used at neighbouring Trusts including Wakefield and Sheffield which could have a potential risk for patients moving between localities.

It was noted that patients in the community would remain on their current starch based thickener due to lack of resource to reassess patients. If admitted to any inpatient facility in Barnsley, patients would be reassessed with the new descriptors and with the new clear product. The potential clinical risk around making up the starch products in line with new descriptors and changes to scoop sizes were discussed.

There were concerns for patients in the community and guidance would need to be shared with carers, care homes and care agencies.

It was noted that the gum based products Nutilis® Clear and Thick and Easy Clear® were slightly more expensive but the Committee felt that there could be less waste and possibly less hospital admissions, less IVIs, reduction in staff time re-making drinks etc by changing to the gum based products given the advantages listed above.

Agreed actions: -

- Prescribing guidelines to be produced. **DC/JS**
- Guidance around the change to be communicated in primary care as soon as possible and a communications plan would be brought back to the September APC meeting. **JS/DC**

APC 18/165 FORMULARY REVIEWS

165.1 Formulary Review Plan
Noted for information.

165.2 Chapter 4 - CNS (Part 2): Pain & Neurology
Item deferred due to time constraints. **NB**

165.3 Chapter 9 - Nutrition
The minor amendments were noted and accepted.

APC 18/166 SHARED CARE GUIDELINES/AMBER G SHARED CARE GUIDELINES

166.1 Shared Care Guideline Draft Approval Process
The development process was presented and approved by the Committee.

166.2 Shared Care Prescribing Guideline for the treatment of children with Recombinant Human Growth Hormone
At the June 2018 APC meeting, Dr Sunil Bhimsaria, Paediatric Consultant, BHNFT informed the Committee about prescribing issues as a result of having no local shared care guidance for paediatrics and it was agreed that guidance would be produced.

As this is a Sheffield service, the shared care prescribing guideline approved by the Sheffield Area Prescribing Group was shared with the Committee to ascertain if the Committee would adopt the Sheffield guidance, which would be hosted on the Barnsley website. **JH**

The Committee agreed to adopt the Sheffield guidance.

166.3 Epilepsy Shared Care Guidelines (Adults)
The collaborative guideline was presented which has been updated to include the recommendations around valproate and the MHRA updated advice about anti-epileptic drugs and switching between different manufacturers products. The main changes were highlighted and it was confirmed that feedback from the specialists had been received and they were happy with the changes.

It was agreed that the process for initiating shared care guidelines at appendix A on page 8 would be included in future full shared care guidance.

The Committee approved the guidance.

166.4 Epilepsy Shared Care Guidelines (Children)
The proposed collaborative shared care guideline, developed and approved by Sheffield APG was presented for possible adoption. Barnsley specialist comments have been received, incorporated and

fed back to Sheffield. It was noted that within the previous draft version there were a number of off label indications and doses for younger children which have been removed as these were not referenced in the Children's BNF. Any shared care arrangements on that basis would be considered on a case by case basis.

The Committee approved the guidance.

166.5 DOAC for DVT & PE Amber G Guideline (update)
The updated guideline was presented and specialist feedback was noted.

The Committee approved the guidance.

***Post meeting note**: a minor amendment has been made to the guidance.*

166.6 Minoxidil Amber G Guideline (update)
The updated guideline was presented with no major changes. It was noted that no feedback had been received from the consultant cardiologists.

The Committee approved the guidance.

166.7 SGLT2 Inhibitor Amber G Guideline (update)
The updated guideline was presented and updated information was highlighted. Feedback from Francis Laverty, Diabetes Nurse was shared and noted. Although he suggested this be classified green, the Committee approved the SGLT2 Inhibitor Amber G Guideline as the classification should not alter the way patients are managed. Amber-G drugs can be initiated in primary care if the prescriber is competent to initiate

The Committee approved the guidance.

Agreed action: -

- It was agreed to raise awareness of initiation in primary care. **JH/DC**

166.8 Acamprosate Amber G Guideline (update)
The updated guideline was presented with minor changes.

It was noted that the SPC recommends that the duration of treatment is 1 year, not 6 months and following discussion, it was agreed that the guideline would be updated to recommend 1 year duration of treatment and returned to Dr Ashby for approval. It was agreed that the length of treatment would be communicated in letters to GPs. **JH**

The guidance updated in this one respect did not need to be brought back to the Committee. **JH**

166.9 Disulfiram Amber G Guideline (update)
The updated guideline was presented with minor changes. The Committee approved the guidance.

166.10 Naltrexone Amber Shared Care Guideline (update)
The updated guideline was presented with minor changes. The Committee approved the guidance.

166.11 Melatonin Amber Shared Care Guideline (update)
The updated guideline was presented with minor changes. The Committee approved the guidance.

166.12 Dapsone Amber G Guideline (new)
The new guideline was presented which has had specialist input. After looking at the monitoring requirements, it was agreed that an Amber Shared Care Guideline should be produced.

Agreed action: -

- An Amber Shared Care Guideline to be produced and brought to the Committee. **UP**
- Dapsone to be added to the specialist drugs scheme. **CA**

APC 18/167 NEW PRODUCT APPLICATION LOG
Noted.

APC 18/168 NEW PRODUCT APPLICATIONS

168.1 Fiasp® (insulin aspart injection)
The application was presented and information from the application form and independent review was discussed.

It was noted that patients treated with Fiasp® will require intense blood glucose monitoring to prevent hypoglycaemia and hypoglycaemia associated complications and therefore this was for use in selective cases. It was noted that some patients need flexibility around timing of the doses and Fiasp® provides that flexibility.

The Committee approved the application for Fiasp® (insulin aspart injection) with an Amber G classification.

Agreed actions: -

- Prescribing data to be monitored over the next 6 months to look at quantities used and why. **DC**
- An Amber G guideline would be produced. **GT**

168.2 Enstilar® Cutaneous Foam
The application was presented and information from the application form and independent review was discussed.

It was noted that this is equivalent to Dovobet® and costs the same but trial data shows that Enstilar® works much quicker and is easy to apply.

The Committee approved the application for Enstilar® Cutaneous Foam with a green classification.

Agreed action: -

- The Lead Pharmacist, BHNFT to check if the dermatologists **GT**

would be happy with the APCs proposal to remove Dovobet® from the formulary.

168.3 Saxenda® (Liraglutide)

The application was presented and information from the application form and independent review was discussed.

This is licensed as an adjunct to a reduced calorie diet and increased physical activity for weight management in patients with a BMI ≥30kg/m^2 or ≥27kg/m^2 with at least one weight related comorbidity. It did not affect any lifestyle change and when stopped, the effects would reverse unless the patient had made diet lifestyle changes.

There was concern raised that it has been identified that an increasing number of patients are being prescribed Saxenda® (Liraglutide) by the specialist weight management service without the submission of a new product application to the APC. All prescribers have signed up to follow the Barnsley area formulary and clinicians appear not be following it, which is worrying and causing confusion to patients. Although prescribing is being held within BHNFT, reports have been received that SWYPFT dietitians have been asked to undertake monitoring and as they are not prescribers, it is understood that GPs would be asked to prescribe.

The Pharmacy Team at BHNFT have escalated the issue to the Medical Director and Clinical Director who have supported the continued use of Saxenda® (Liraglutide) within the Trust by the specialist in the weight management clinic until an application could be brought to the APC for discussion. It was recognised that a specialist within a particular area can prescribe on an occasional basis outside of the formulary but this has been escalated given the considerable increase in prescribing.

There were concerns noted in the safety aspect of the application form that in the study in overweight adults with type-2 diabetes there were 5 severe hypoglycaemic events, and there was a request for more information to be provided in the independent review around outcomes.

The Committee were informed that this has a black classification in a number of areas. It is currently provisional grey in Barnsley and would maintain that classification until discussed at a future meeting.

It was agreed that liraglutide should be prescribed by brand as the two products available have different licensed indications.

Agreed actions: -

- The Chair to escalate issues discussed with the Medical Director at BHNFT. **CL**
- The new product application would be brought back to the next meeting with more detail provided within the independent review document around outcomes and if possible a cost / risk comparison versus other management options i.e. gastric band surgery. **GT/UP**

168.4 VisuXL®

The application was presented and information from the application form and independent review was discussed.

This was for use in a specific cohort of patient in secondary and primary care, during the recovery period following surgery or as an alternative to surgery.

The Committee approved the application for VisuXL® with a green classification.

Agreed actions: -

- The dry eye guidance is due to be updated and the algorithm would be updated to include VisuXL®. **GT**
- Monitor its use over the next 6 months. **DC**

APC 18/169 BARNSLEY APC REPORTING AUGUST 2018

The reports were received and noted.

Agreed action: -

- Meeting dates to be arranged for the sub-group. **CA**

APC18/170 NEW NICE TECHNOLOGY APPRAISALS (JULY 2018)

The Lead Pharmacist, BHNFT would advise if the following NICE TAs were applicable for use at BHNFT:-

- TA528 Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer
- TA529 Crizotinib for treating ROS1-positive advanced non-small-cell lung cancer
- TA530 Nivolumab for treating locally advanced unresectable or metastatic urothelial cancer after platinum-containing chemotherapy
- TA531 Pembrolizumab for untreated PDL1-positive metastatic non-small-cell lung cancer
- TA532 Cenegermin for treating neurotrophic keratitis
- TA533Ocrelizumab for treating relapsing–remitting multiple sclerosis
- TA492 (updated from Dec 2017)Atezolizumab for untreated PDL1-positive locally advanced or metastatic urothelial cancer when cisplatin is unsuitable
- TA522 (updated from June 2018) Pembrolizumab for untreated PDL1-positive locally advanced or metastatic urothelial cancer when cisplatin is unsuitable

170.1 Feedback from BHNFT Clinical Guidelines and Policy Group
Item deferred due to time constraints.

170.2 Feedback from SWYPFT NICE Group
Item deferred due to time constraints.

APC18/171 FEEDBACK FROM THE MEDICINES MANAGEMENT GROUPS

171.1 Primary Care Quality & Cost Effective Prescribing Group
Item deferred due to time constraints.

171.2 BHNFT
Item deferred due to time constraints.

171.3 SWYPFT Drug and Therapeutics Committee
Item deferred due to time constraints.

APC 18/172 ISSUES FOR ESCALATION TO THE QUALITY & PATIENT SAFETY COMMITTEE (Q&PSC)

It was agreed that the following issues would be escalated to the Q&PSC: - **CL**

- Length of the APC agenda
- Prescribing of Thickeners
- Saxenda®

APC 18/173 HORIZON SCANNING DOCUMENT – JUNE & JULY 2018 (not quorate)

173.1 Formulary changes June 2018

Salmeterol/fluticasone (hybrid) 25/125 micrograms, 25/250 micrograms & 25/50 micrograms metered dose pressurised inhalation, suspension. (Combisal®, Aspire Pharma) – **PROVISIONAL GREY**

Insulin lispro (biosimilar) 100 units/ml solution for injection in vial, cartridge or pre-filled pen (Insulin lispro SANOFI®▼, SANOFI) – **PROVISIONAL GREEN**

Glatiramer acetate 40 mg/mL solution for injection, pre-filled syringe (Brabio®, Generics UK T/A Mylan) – **ALREADY RED**

Post meeting note: *NICE TA527 is not applicable to BHNFT (minute 163.4). Glatiramer acetate and beta interferons will be assigned a provisional red (non-formulary) classification.*

Olaparib 100mg and 150mg film-coated capsules (Lynparza®▼, AstraZeneca, UK Limited) – **ALREADY PROVISIONAL RED**

Etoposide (generic) 20mg/mL concentrate for solution for infusion (Etoposide, medac GmbH) – **ALREADY RED**

Dexamethasone (generic) 0.5mg tablets (Dexamethasone, Consilient Health Ltd) **– ALREADY GREEN**

Argatroban 1 mg/ml Solution for Infusion (Exembol®, Mitsubishi Tanabe Pharma Europe) – **ALREADY RED**

Dexamethasone sodium phosphate 1 mg/ml eye drops solution (Eythalm®, Aspire) – **PROVISIONAL GREY**

Betamethasone valerate (generic) 0.1% w/w cream (Audavate®, Accord) – **ALREADY GREEN**

Dolutegravir/rilpivirine 50mg/25mg film-coated tablets (Juluca®▼, ViiV Healthcare) **- PROVISIONAL RED**

Darvadstrocel 5 million expanded adipose stem cells (eASC) per ml suspension for injection (Alofisel®▼, Takeda) – **PROVISIONAL RED**

173.2 Formulary changes July 2018

Trastuzumab (biosimilar) 150mg and 420mg powder for concentrate for solution for infusion. (KANJINTI®▼, Amgen) – **PROVISIONAL RED**

Mesalazine 1g gastro-resistant tablets. (Salofalk®, Dr. Falk Pharma) – **PROVISIONAL GREEN**

Bictegravir/emtricitabine/tenofovir alafenamide 50mg/200mg/25mg film-coated tablets (Biktarvy®▼, Gilead Sciences) – **PROVISIONAL RED**

Ritonavir (generic) 100mg film-coated tablets (Ritonavir, Accord) – **ALREADY RED**

Cyclizine lactate (generic) 50mg/ml solution for injection. (Cyclizine Lactate, Hameln Pharmaceuticals Ltd) – **ALREADY GREEN**

Oxycodone (generic) 10mg/ml and 50mg/ml solution for injection or infusion (Oxycodone, Hameln Pharmaceuticals Ltd) – **ALREADY GREEN**

Nitisinone (generic) 5mg, 10mg hard capsules (Nitisinone Dipharma, Logixx Pharma Solutions) – **PROVISIONAL RED**

Ephedrine hydrochloride (generic) 30mg/ml solution for injection. (Ephedrine Hydrochloride, Hameln Pharmaceuticals Ltd) – **ALREADY RED**

Agreed action: -

- As the meeting was not quorate for this item, the suggested classifications would be emailed to members for ratification. **JH/NB**

APC18/174 MHRA DRUG SAFETY UPDATE (JULY 2018)

Received and noted.

APC 18/175 SOUTH YORKSHIRE AREA PRESCRIBING COMMITTEE MINUTES

The minutes from NHS Rotherham Medicines Optimisation Group (January to May 2018), NHS Sheffield CCG (17th May 2018 & 21st June 2018) and NHS Doncaster & Bassetlaw CCG (28th June 2018) were received and noted.

APC 18/176 ANY OTHER BUSINESS

176.1 Bisphosphonates/Calcium Products

BHNFT were asked if there has been any change with regards to concomitant calcium and vitamin D when bisphosphonates are prescribed as changes have been seen in primary care. It was confirmed that Dr Lee was looking to move away from calcium products due to risks for elderly patients and he was looking towards prescribing vitamin D alone along with bisphosphonates in patients who can have them and this would be incorporated into the guidelines when updated.

There was concern that the evidence base available was around bisphosphates used with the calcium supplementation and this would be taken back to Dr Lee.

Agreed action:

- The Senior Pharmacist (BHNFT) to take this back to Dr Lee. **UP**

176.2 Tadalafil

It was highlighted that primary care are still receiving requests to prescribe once daily tadalafil from secondary care, even though this is a grey non formulary drug and is included within the NHS England guidance 'items which should not routinely be prescribed'.

BHNFT representatives on the Committee requested further information regarding the number of requests received and it was agreed that this information would be obtained and shared. It was agreed that Primacy Care data would be monitored, looking at any new patients initiated and any increase in prescribing.

Agreed actions: -

- The Lead Pharmacist to ask the Medicines Management Team to feedback any future requests received from secondary care and details will be provided to the Senior Pharmacist for investigation. **DC** **DC**
- Primary care data to be monitored for new initiations.

176.3 Sepsis Risk

The Lead Pharmacist, BHNFT had been informed by microbiology of a couple of patients who had been admitted with sepsis that were on dapagliflozin or canagliflozin. It was noted that there is a caution in the SPC about UTIs and following discussion it was agreed that awareness would be communicated in primary and secondary care.

Agreed actions: -

- The Lead Pharmacist, BHNFT to clarify the risks and produce awareness information for circulation to primary and secondary care. **GT**
- Information to be added to sick day rules in primary care. **DC**

APC 18/177 DATE AND TIME OF THE NEXT MEETING

The time and date of the next meeting was confirmed as Wednesday, 12th September 2018 at 12.30 – 2.30 pm in the Edith Perry Room at Barnsley Hospital NHS Foundation Trust.