AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 12th October 2017
Venue – Birmingham Research Park
Vincent Drive, Birmingham, B15 2SQ

PRESENT:

Dr Lisa Brownell	BSMHFT (Chair)
Prof Mark DasGupta	Birmingham CrossCity CCG
Satnaam Singh Nandra	Birmingham CrossCity CCG
Elizabeth Walker	Sandwell & West Birmingham CCG
Dr Gwyn Harris	Sandwell & West Birmingham CCG
Kate Arnold	Solihull CCG
Dr John Wilkinson	Solihull CCG
Mary Johnson	South East Staffordshire & Seisdon Peninsula CCG
Prof Jamie Coleman	UHB NHS FT
Dr Emma Suggett	UHB NHS FT
Tania Carruthers	HoE NHS FT
Carol Evans	HoE NHS FT
Dr Sangeeta Ambegaokar	Birmingham Women's & Children's Hospitals NHS FT
Dr Angus Mackenzie	Sandwell & West Birmingham Hospitals NHST
Maureen Milligan,	The ROH NHS FT
Ravinder Kalkat	Midlands & Lancashire CSU
Isabelle Hipkiss	Midlands & Lancashire CSU

IN ATTENDANCE:

Sharon Coane for item 1017/08	Solihull CCG
Tanith Palmer, observer	Sandwell & West Birmingham CCG, PH Registrar

No.	Item	Action

1017/01 Apologies for absence were received from:

Dr Paul Dudley, Birmingham CrossCity CCG
Prof Robin Ferner, Sandwell & West Birmingham Hospitals NHST, deputy attended
Inderjit Singh, UHB NHS FT, deputy attended
Dr Timothy Priest, HoE NHS FT
Nigel Barnes, BSMHFT
Dr Neil Bugg, Birmingham Women's & Children's Hospitals NHS FT
Yusuf Asif, Birmingham Women's & Children's Hospitals NHS FT
Jeff Aston, Birmingham Women's & Children's Hospitals NHS FT
Melanie Dowden, Birmingham Community Healthcare NHS FT
Jonathan Horgan, MLCSU

It was confirmed that the meeting was quorate.

1017/02 Items of business not on agenda (to be discussed under AOB)

- Prescribing of NOACs/ DOACs in Primary Care
- Formulary updates
- Enoxaparin supply issues

1017/03 Declaration of Interest (DoI)

It was confirmed that the APC secretary has only recently requested the committee members to complete their annual declaration of interests. There are some outstanding and members were reminded to submit these at the earliest opportunity. Two members declared attending an educational event run by GSK more than 12 months ago. There were no other interests to declare relating to items on the agenda.

1017/04 Welcome and Introductions

The Chair welcomed everyone to the meeting today. Introductions around the table were carried out for the benefit of new attendees.

The Chair reminded members, that 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.

1017/05 Primary Care Antimicrobial Guidelines– Updated and revised by BAAG following PHE latest update

The Birmingham Antibiotic Advisory Group (BAAG) has revised and updated the Primary Care Antimicrobial Guidelines developed in September 2015 following the latest update from Public Health England (PHE) to their Management and Treatment of Common Infections guidelines, which was published in September 2017.

The APC secretary ran through a summary of the main changes since the 2015 version.
New additions were:

- FeverPAIN Score in the acute sore throat section
- Scarlet Fever

- Gonorrhoea
- Genital herpes
- Tick bites
- Mastitis
- Blepharitis
- Link to TARGET Urinary Tract Infection (UTI) information leaflet
- Link to Recurrent UTI flowchart

Main changes were:
- Clarithromycin to replace erythromycin in most cases
- Nitrofurantoin suspension (for children) removed due to cost - £446.95 for 300ml (Oct Drug Tariff)
- *H pylori* – bismuth salt change following discontinuation of De-Noltab
- Travelers' diarrhoea – change from ciprofloxacin to azithromycin

A member queried the figure for local rate of infection with *Borrelia burgdorferi* (cause of Lyme disease) quoted in the tick bites section as it appeared to be quite high (over 20%). The APC secretary will check with BAAG to confirm this is correct. A couple of typos were also identified and it was noted that the contact details for the duty microbiologist covering Birmingham Women's and Children's Hospitals NHSFT needed to be added to the front page.

It was agreed that subject to those corrections, the Primary Care Antimicrobial Guidelines (full document and summary table) were endorsed by the APC.
A member requested that the committee relayed their thanks to BAAG and the primary care individuals who had spent a significant amount of time to produce this useful document and summary table.

A member went on to suggest that the APC would be interested to hear from its members on how these guidelines would be implemented across the health economy as , although they are aimed at Primary Care, they have applications in other care settings such as Accident and Emergency, out-patient clinics and in community care. The secondary care representatives reassured the member that links to these guidelines would be added to electronic prescribing systems, discussed at various educational events throughout the year, included in the main repository for internal policies and would be part of the junior doctors' induction programme.

The APC secretary shared the sad news of Dr Das Pillay's passing; he was the chair of BAAG and had supported the recent update to the antimicrobial guidelines. The members acknowledged that he had been a valuable contributor to the committee's work around the harmonisation of the wound management formulary, specifically around the antimicrobial dressings. BAAG is in the process of appointing a new chair.

ACTIONS:

• **Relay committee's thanks for an excellent piece of work**	**APC sec**
• **Check with BAAG local rate of infection with *B burgdorferi* is indeed over 20%**	**APC sec**
• **Relay comments on minor changes to be made to final document**	**APC sec**
• **Upload final document to APC website**	**APC sec**
• **Write to the Director of Infection Prevention and Control at HoE FT to relay Committee's sincere condolences following the news of Dr Pillay's passing.**	**APC sec**

1017/06 Relvar® Ellipta® DPI for use in Asthma- Abbreviated application form

The APC secretary reminded the members that Relvar® Ellipta® (fluticasone furoate 92mcg/ vilanterol trifenalate 22mcg inhalation powder) was approved onto the formulary in February 2017 for COPD.

The Pan-Birmingham Respiratory Clinical Network have recently updated their Asthma guidelines which make reference to Relvar® Ellipta® and therefore submitted an abbreviated application form to extend the indication approved on the formulary and include asthma. It was not deemed necessary for a clinician to attend to discuss this application.

The APC secretary summarized the main points from the application:

- Relvar® Ellipta® offers an option for once daily treatment which will improve adherence in some patients.
- Relvar® Ellipta® offers an alternative ICS/LABA combination to the existing formulary options which include Fostair® (beclomethasone/formoterol), Symbicort® (budesonide/ formoterol) and Flutiform® (Fluticasone/ formoterol).
- The Ellipta® device represents a valuable option for some patients who struggle with currently available devices.

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

- Relvar® Ellipta® is the lowest acquisition cost ICS/LABA dry powder inhaler (DPI) and would provide a cost-effective option.
- A member commented that the price of Symbicort® DPI is due to drop on 1st January 2018 and would be expected to match the price of other ICS/LABA DPI products.
- A member pointed out that Symbicort® Turbohaler had been removed from the formulary for COPD during the rationalisation of devices available. It was therefore suggested that the same approach be taken for asthma.
- However, a member commented that Symbicort® Turbohaler® was the only DPI licensed for single inhaler maintenance and reliever therapy (SMART). Fostair® MDI is also licensed for MART, but the NEXThaler® is not.
- Although the members acknowledged that they would normally request a new formulary option to replace an existing product to keep the range of devices to a minimum and optimise familiarity with these, it was recognised that in this case the addition of a cost-effective DPI option would be beneficial. This could be reconsidered once the price of Symbicort® Turbohaler® drops or there is a change in the MART licence for any of the inhalers on formulary.

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

Patient Safety: No issues.

Clinical effectiveness: Both strengths licensed in Asthma, equivalent to established products.

Strength of evidence: Moderate.

Cost-effectiveness or resource impact: Currently lowest acquisition cost ICS/LABA dry powder combination.

Place of therapy relative to available treatments: In line with current ICS/LABA options on formulary; treatment pathway outlined in Asthma guidelines. Offers a once daily dosage regime.

National guidance and priorities: ICS/LABA combination inhalers are included in the BTS/SIGN guidelines last updated in 2016 and support the step-wise approach to the management of asthma. NICE guidance on management of asthma is expected at the end of October 2017.

Local health priorities: CCGs supportive

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: Minor amendment to the Asthma Guidelines to reflect the formulary status of Relvar® Ellipta®

Decision Summary: Approved as GREEN for use in Asthma.

ACTIONS:

- **Relay decision to Col Duncan Wilson by Thursday 19th October.** **APC sec**
- **Add Relvar® Ellipta® (both strengths) to APC formulary as Green for Asthma.** **APC sec**

1017/07 Pan-Birmingham Respiratory Clinical Network Asthma Guidelines

In view of the decision to accept Relvar® Ellipta® onto the formulary, the Asthma guidelines circulated for the meeting were now in need of revision.

A member suggested to proceed by thanking the Respiratory Clinical Network (RCN) for their hard work in producing these guidelines, to congratulate them on the clarity and quality of the document and supporting appendices, to relay the decision to approve Relvar® Ellipta® on the formulary and to request some minor amendments to accurately reflect the status of Relvar® Ellipta® before these are published on the APC website. It was also suggested that the RCN consider extending the review date from the current date of March 2018.

It was agreed that subject to these minor amendments, the guidelines and supporting appendices (e.g. plan on a page and step-down guidance) were endorsed by the APC.

ACTIONS:

- **Relay feedback from APC members to the Respiratory Clinical Network** **APC sec**
- **Request minor amendments to the guideline to reflect approved formulary status of Relvar® Ellipta® and suggest extending the review date.** **APC sec**
- **Once finalised, upload the guidelines and supporting appendices to the APC website.** **APC sec**

1017/08 Blood Glucose Monitoring- Review process by DMMAG

The chair informed the members present that a sub-group of the Diabetes Medicines Management Advisory Group (DMMAG) is planning to review the Blood Glucose Meters and Testing strips' guidance, approved by the APC in April 2015. This review will also include needles, lancets and lancing devices

The sub-group is very aware of the sensitive nature of this review and the attention it will no doubt draw from the Pharma Industry. It has therefore drawn up an outline of the process to be undertaken to ensure transparency and governance. The question has arisen as to whether this process needs to be signed off and by whom.

It was agreed that as the APC will ratify the output of this review, it would be sensible to sign-off the process to be undertaken. This will also ensure that where a cut-off price for the testing strips has been set, this needs to be ratified by the APC as this will have an impact on the health economy and pre-determine which meters will be recommended.

A number of documents were circulated with the agenda for the meeting; these included a flow chart of the proposed process, terms of reference of the sub-group, a comprehensive list of all the meters and compatible testing strips currently listed in the Drug tariff.

Feedback from various manufacturers following the previous review highlighted concerns around the process and criteria considered.
The sub-group has therefore drafted a very comprehensive evaluation form which lists review criteria for the meters, strips, needles, lancets and lancing devices, together with a draft sample letter.

The process would therefore involve sending this letter and evaluation form to all the manufacturers and ask them to complete this form within 4 weeks of receipt. The data submitted by the companies will be quality assured and discarded if incorrect. The evaluation forms will be collated centrally by DMMAG and scored against a pre-agreed scoring system.
Based on the scoring, a shortlist of products will be drawn up and agreed by the sub-group and agreed by DMMAG. The shortlisted products will then be sent to a patient group for user evaluation, in collaboration with Diabetes UK. These evaluations will be assessed by DMMAG with formal recommendations to be put forward to the APC for ratification.

Once these are approved by the APC, the applicant company will be informed, DMMAG will be updated and the APC formulary will be updated. It is also proposed that each member Trust updates their formulary accordingly as part of local clinical governance process.

It was noted that an appeal process has been requested and will be added to the draft process. It was suggested to use the same appeal criteria outlined in the APC policy.

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

- A member suggested adding a box at the bottom of the evaluation form; "For office use only. Quality assurance check by" This would make it clear to the manufacturers that the evaluation forms will be quality assured.

- The members commended the sub-group on the quality of the documents produced and the comprehensive and detailed approach to this task.
- A member of DMAAG sub-group clarified that the patient group would include type 1 and type 2 patients across a range of ages. Their feedback would be collated in the form of user questionnaire.
- A member referred to the terms of reference of the sub-group and requested that the members of this sub-group complete a thorough declaration of interest form to come to the APC for scrutiny; this would ensure transparency and mitigate any complaints or appeals.
- The sub-group would appreciate it if the process flow chart and evaluation form could be uploaded to the APC website in a non-editable format; the website would also need to sign post any request for the evaluation form to an email so that read receipts and date stamps can be applied for audit purposes.
- It was confirmed that, subject to the minor amendments discussed, these documents were approved by the APC and the review process could start.

ACTIONS:

- **Finalise documents to incorporate amendments agreed and send to APC secretary.** — **DMMAG sub-group**
- **Upload to APC website in PDF format and signpost to generic email address to request editable version of evaluation form.** — **APC sec**
- **Pencil in consideration by APC for January 2018 agenda.** — **APC sec**

1017/09 FreeStyle Libre® Flash Glucose Monitoring- BSSE APC Position statement

As discussed under Any Other Business at the September meeting, the commissioners have been made aware that, from 1st November 2017, the Freestyle® Libre® glucose monitoring system will be included in the Drug tariff, will therefore be reimbursable on NHS prescriptions and would produce a significant and unplanned cost pressure on their prescribing budgets.

The member CCGs have reviewed the information available on Freestyle® Libre® and have unanimously agreed to issue interim guidance to their GPs advising them NOT to prescribe the new flash glucose monitoring (fgm) system in advance of a formal statement from the APC with input from DMMAG to identify the patient cohort this will benefit the most. Depending on the size of this identified cohort, it may need to go to the CCGs for prioritisation.

A draft APC statement has been produced for consideration and circulated with the papers for the meeting; this is largely based on a document from the East of England Priorities Advisory Committee.

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

- A member wanted to thank all those involved in producing this document in such a short period of time as it turned out to be a significant piece of work.

- Recognising that this is going to be a very contentious issue, it was agreed that the statement needs to be carefully worded to avoid any potential difficulties.
- As already noted, this draft APC document is largely based on the EoE Priorities Advisory committee guidance statement on Freestyle® Libre®

glucose monitoring system which was published before information on the NHS price was available. It was therefore suggested to leave the website price in place, making it clear that this is for self-funding patients, however the document should have the NHS cost immediately adjacent to it, along with the statement that the meter and first sensor will be made available free of charge to the NHS. This is largely covered in the text currently at the bottom of page 2, but needs to be moved.

- The first sentence in the second box on page 2 would benefit from re-wording.
- The text in relation to the "real world evidence" needs to make clear that this is unpublished and not peer reviewed. It was proposed to remove it as the members do not have assurance of how it was collected and the criteria used to collate it. This was agreed.
- A member was uncomfortable with publishing the manufacturers' views on the place in therapy in what will be a public document, as the APC would wish to make their own justified and justifiable decisions. Publishing this could inappropriately raise expectations.
- A member has grave reservations about including the section on page 3 referring to US literature and a product available in the US with a similar but different name. Unless the APC can be absolutely sure that this is the same product as the UK version and has received clarification in writing from the manufacturer around the statements made in relation to the US product, the APC could be open to the reputational risk of having to issue a retraction, let alone possible litigation.
- There is some useful information on page 4 of the full EoE document referring to diabetes distress, hypoglycaemic fear behaviour and worry scores not being improved in patient using this system, as well as adverse events relating to the sensor, which might be useful to include to strengthen the APC's position statement.
- It might also be useful to add some more information about the limits of the studies in children.
- A member suggested strengthening the statement on the front page of the draft document by rewording as : "To ensure equality of access and in line with the statutory duty of commissioning organisations to ensure that funding is allocated fairly and appropriately, with due regard to the competing demands on their available funding it is advised …."
- A member recommended removing any individual's name from the footer of the document.
- The members approved all of the recommendations made and requested that it was made clear that this is an interim position statement.
- It was also suggested that this document be circulated to the clinicians in secondary care.

ACTIONS:

- **Update document with all recommendations/ suggestions to produce a final version.** **APC sec**
- **Recirculate final version to APC members for internal dissemination and communication.** **APC sec**
- **Upload to APC website.** **APC sec**

1017/10 Vortioxetine RICaD- for ratification

The APC secretary reminded the members that vortioxetine was added to the formulary as a Grey RAG status drug following NICE TA367 recommendation in November 2015.

In February 2016, the APC discussed a draft position statement from BSMHFT which placed vortioxetine as a restricted medicine and an alternative treatment option when combinations of antidepressants are being considered. This led to a proposal of Amber with RICaD for the formulary status but that it would remain as Grey until the RICaD was available.

The draft RICaD being considered at this meeting has been already been discussed at BSMHFT's PTC and circulated for consultation across the member organisations; a number of comments have been received. These included:

- A number of GPs were not happy to initiate this treatment in view of the potential serious side effects and monitoring required but would consider picking up prescribing following specialist initiation, up titration and full stabilisation after 6 months. This seems to be more aligned with shared care (ESCA) than a RICaD. However shared care implies that a patient can never be discharged.
- A number of members pointed out that a RICaD implies specialist initiation but recognized that this was not clear in this draft document and needed clearer wording to avoid any misinterpretation.
- GPs would support any document, whatever its title, as long as it was clear who does what, for how long and confirm effectiveness and stabilisation before asking GP to pick up the clinical responsibility associated with prescribing.
- It was acknowledged that the discontinuation criteria needed further clarification as lack of efficacy was too vague.
- A member commented that a RICaD was initially suggested as this was a NICE approved drug and a RICaD would give assurance to the GP that the specialist had initiated this drug in line with the Technology Appraisal, and communicated the rationale for choosing this particular drug over the other formulary options without restrictions.
- A member highlighted that specific ongoing monitoring was not required for this drug.
- A member asked if patients with major depressive episodes whose condition has responded inadequately to two antidepressants were likely to discontinue treatment after 6 months or 12 months.
- The NICE guideline for depression is currently out for consultation and the recommendation to continue treatment for 6 months after consolidation of the antidepressive response has been taken out current which would imply that patients who may be treatment resistant could be on lifelong treatment. So it would be unusual for these individuals to discontinue after 6 months, and the psychiatrists would expect these patients to remain on therapy for a couple of years.
- The chair summarised the discussion so far as: this is a NICE approved drug that needs to be available on the formulary, the specialist would initiate the drug, stabilise the patient and ensure it was suitable and effective before asking a GP to pick up prescribing. It was agreed that the RICaD did not add anything to the information accessible from the summary of product characteristics (SPC).

- It was agreed therefore to review the proposed RAG status and change it to Amber, specialist initiation and stabilisation, and remove the need for a RICaD.

ACTIONS:

- **Update formulary entry for vortioxetine to Amber, specialist initiation and stabilisation, no RICaD**. **APC sec**

1017/11 APC Policy- Draft revised policy- For ratification

The APC secretary stated that the current APC policy has been in place since 2014 and was in need of a refresh to reflect additions to the APC documentation such as the abbreviated application form and the development of the Regional Medicines Optimisation Committees (RMOCs). The appeal section has also been revised and new sections in relation to guests at meetings and appropriate behaviour have been added.
The draft policy document was circulated with the agenda for the meeting and was brought for ratification.
A flow chart detailing the pathway and rationale for resubmission or appeal had been suggested but this was still in progress.

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

- A member commented that a flow chart was no longer required as the policy was much clearer in its definition of resubmission or appeal processes. This was agreed unanimously.
- A member suggested a slight revision of the second sentence in section 8.2.1 Appeals process to read: "It exists to give those clinicians who feel that the BSSE APC decision may result in a compromise in care to patients, an opportunity to make their case for the decision to be reviewed where it is felt that the APC has either not followed due process or that the committee has not given appropriate consideration to the evidence."
  This was agreed unanimously.

It was agreed that, subject to the changes discussed, the APC revised APC policy was ratified.

ACTIONS:

- **Make agreed changes to the policy, and upload to APC website.** **APC sec**

1017/12 Minutes of the meeting held on Thursday 14th September 2017 – for ratification

The minutes of the meeting held on Thursday 14th September 2017 were discussed for accuracy.

- A member highlighted a number of pages where comments were attributed to a certain representative when it had been previously agreed that the comments noted in the minutes should not be attributable. However the actions listed in the action table could be attributable.

- Page 10: the APC secretary commented that the decision summary should reflect that the oral presentations of brivaracetam were approved as Amber with ESCA, but that the injection (which was also included in the application) should be Red. This has been confirmed with the clinician who submitted the application. The cohort of patient defined in the discussions to be clearly reiterated in the decision summary.

- Page 14, item 0917/11: rephrase the third sentence to read " This included

2 clinical pharmacologists, representatives from Mental Health, pharmacists from secondary care, primary care and community services, 2 patient representatives and 4 GPs with experience of working on APCs.
- Page 15: under matters arising 0717/05, change the title to Prof Martin.

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

Following on from the review of the minutes, a number of questions were raised relating to brivaracetam:
- A member commented that the current ESCA for eslicarbazepine included a requirement for DTC (or equivalent decision making body) approval before it could be initiated by the specialist, and it was therefore asked whether this would also need to be included in the ESCA for brivaracetam as both drugs were deemed to be in the same tier of formulary options. It was agreed to remove the requirement for DTC approval from the eslicarbazepine ESCA, as it was deemed to be bureaucratic.
- The APC secretary requested clarification from the members on the appropriate RAG status to allocate to brivaracetam on the online formulary recognising the fact that the ESCA is still being developed. It was agreed that the ESCA should be ratified by the APC before allowing any prescribing to be transferred to GPs; this would ensure that the cohort of patients was clearly identified within the ESCA before any patients can be initiated on it. It was suggested to make it Red until the ESCA was approved, but this could result in a number of patients being initiated on it which didn't meet the criteria set out in the shared care document. It was therefore agreed to publish it as Black awaiting ESCA.
- It was also suggested that, as this drug would only be initiated by tertiary centre epilepsy specialists, it would be useful if they developed the ESCA together as this could speed up the approval process by removing the need to consult with the specialists before circulating it for internal consultation to member organisations.

ACTIONS:
- **Remove requirement for DTC approval before initiation from eslicarbazepine ESCA and upload revised version to APC formulary.** **APC sec**
- **Add brivaracetam to the APC formulary as Black awaiting ESCA, Initiation by Tertiary Epilepsy Specialist only.** **APC sec**

1017/13 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:

- 0917/07 Emollin® 50/50 spray abbreviated application: seek clarification on issues raised by members. Update: A member contacted the manufacturer to enquire on the expected number of doses or applications the spray delivers. The information provided states that it is a constant spray and that it provides 3.2 times the coverage of a normal tub of emollient. Further discussions ensued on what teachers are allowed to do or not, recognising that it varies depending on the school, the age of the child and the parent's views but it became apparent that a care plan would have to be completed for the child whether it was a spray being used or an emollient cream being

rubbed in. The rationale for the application was that teachers would not need to touch the child to apply the emollient. It was decided that the application was declined until there was definitive evidence that confirms applying emollient during the school day is necessary and that teachers are not allowed to touch the child.

ACTION: **Notify the clinician that Emollin® 50:50 spray is not approved and the rationale**. **APC sec**

- 0917/08 Toujeo® insulin glargine 300units/mL RICaD – add links to the risk assessment tool Update: The APC secretary is finalising the risk assessment tool developed by DMMAG and once uploaded to the APC website, the link to this document will be added to the RICaD and also uploaded to the website.

- 0917/10 Oral antipsychotic drugs ESCA - guidelines for monitoring developed by CrossCity CCG to be brought to APC with a view to add as an appendix, and add symptoms of hyperprolactinemia to the ESCA. Both actions are outstanding.

- 0917/13- Matters arising - circulate results of consultation on DMARD ESCAs' to APC members to reach decision on future format by email. Action is outstanding.

- 0917/16 NICE TA Checklist - Draft a RICaD for eluxadoline for IBS with diarrhoea- Action is outstanding.

- 0717/05 - Nebivolol 5mg tablets NDA- feedback from Prof Martin on questions raised at July meeting - Action is outstanding.

- 0717/07- ESCAs - drugs for ADHD - Make changes to atomoxetine and dexamfetamine documents. Update: the revised documents are awaiting final sign off. Further discussion around the different commissioning arrangements across the BSSE footprint followed, specifically regarding the fact that some GPs in Birmingham are willing to prescribe these agents with an ESCA. Some GPs around the University have inherited young adults on these agents and are asking for the ESCAs but more as a reference document for the monitoring. It became apparent that a document outlining the monitoring requirements would be useful but that the commissioning discussions still need to take place. A member pointed out that from a patient's perspective it was difficult to transition from attending a paediatric service until 18 years of age to an adult mental health service just to get repeat prescriptions. To avoid any confusion, it was agreed to list the ADHD drugs as Red in Sandwell and Birmingham CCGs (awaiting commissioning discussions) and Amber with ESCA for Solihull CCG. It was also recognised that the commissioning discussions were outside of the committee's remit but that it might help catalyse these discussions if the Joint chairs wrote to the Mental Health commissioners outlining the committee's discussions to date, the frustrations felt by the members of the APC that this issue isn't being resolved and that this health economy is out of kilt with the rest of the country. The same applies to dementia drugs.

ACTIONS:

- **Write to the Mental Health Commissioners outlining the APC discussions to date and frustrations at the delay in resolving the** **Joint chairs/ APC sec**

historical commissioning arrangements for ADHD and dementia services.

- **Differentiate RAG status for ADHD drugs into Red for Birmingham and Sandwell CCGs, Amber with ESCA for Solihull CCG.** **APC sec**

➢ 0617/11 Urinary incontinence appliances review- Provide usage figures in June 2017. Update: The members agreed that this would require a significant amount of time to correlate prescribing data to formulary status and would not really add anything useful. It was therefore agreed to close this action.

➢ 0317/AOB – Buprenorphine patches RICaD- develop a RICaD for buprenorphine patches. Action is outstanding; one of the CCG's medicines optimisation team will pick this up in view of the safety risks these patches pose as they are available in 3-day, 4-day and 7-day patches.

➢ The APC secretary updated the members on progress with forming a palliative care formulary review sub group; a couple of pharmacists working in local hospices have offered to support this piece of work and will contact the Palliative care clinicians put forward by the member Trusts.

1017/14 NICE Technological Appraisals (TAs)

In September 2017, there were 3 TAs published; of these, 2 are NHSE commissioned and 1 is CCG commissioned. See below.

- Dimethyl fumarate for treating moderate to severe plaque psoriasis (TA475): This technology is commissioned by clinical commissioning groups. Providers are NHS hospital trusts and primary care providers.

The APC secretary stated that this is an oral presentation known as Skilarence® and is available as 30mg and 120mg gastro-resistant tablets. It is different to Tecfidera® which is licensed for use in multiple sclerosis (MS) and is available as 120mg and 240mg gastro-resistant hard capsules.

NHSE's resource impact assessment stated that it did not expect this guidance to have a significant impact on resources; that is, it will be less than £5 million per year in England (or £9,100 per 100,000 populations). It also noted that, using the list price, dimethyl fumarate is cost saving for the NHS compared to biological treatment options and cost incurring compared to non- biological treatments.

A discussion ensued regarding the appropriate RAG status for this drug:

- A member commented that treatment with Tecfidera® in MS was associated with Progressive Multifocal Leukoencephalopathy (PML) and that careful monitoring of lymphocytes must be performed every 3 months.
- The summary of product characteristics (SPC) for Skilarence® confirmed that it is intended for use under the guidance of a physician experienced in the diagnosis and management of psoriasis. The special warnings and precautions for use section of the SPC state that Skilarence® may decrease leucocyte and lymphocyte count, and that a complete blood count with differential should be performed every 3 months during treatment.
- In view of the potential serious side effects and careful monitoring, the members agreed that a Red status was appropriate.

ACTION:

- **Update APC formulary with decisions on NICE TAs.** **APC sec**

Any other business:

1. **Prescribing of NOACs/ DOACs in Primary Care**.
   Following a debate on whether these agents should be referred to as NOACs (novel oral anticoagulants) or DOACs (direct oral anticoagulants), a member confirmed that the approved nomenclature has reverted back to was NOACs but that the acronym stood for non-vitamin K antagonists (non-VKA) oral anticoagulants; this was confirmed in recent European guidance.

   The APC has developed RICaDs for these agents and a member provided feedback on emerging issues in Birmingham, specifically around the initiation of NOACs. Concerns are being raised that monitoring of NOACs is not being done in line with BNF recommendations, specifically around renal function monitoring. A GP pointed out that, in order to adequately assess the renal function before initiating a NOAC in patients, a clinician needs to use the estimated Creatinine Clearance (CrCl) and not estimated glomerular filtration rate (eGFR). The RICaDs are correct in respect of continuation and discontinuation criteria in terms of CrCl, but the pre-treatment results the specialists have to enter on the RICaD refer to eGFR. There is some audit evidence building that these agents are being initiated at CrCl levels that would usually preclude using NOACs and this is making GPs nervous.
   There is an observation that it might be more cardiologists rather than haematologists that are not using CrCl.

   It was also pointed out that initiation of NOACs requires an assessment of HASBLED scores and CHA_2DS_2-VASC scores which are also not currently part of the RICaDs, neither do they ask for evidence of LFT values.

   It was therefore suggested that the NOAC RICaDs are in need of review to ensure that they were fit for purpose, and that some of the information has changed since these were drafted such as the availability of an antidote for one of them.

   The APC secretary asked the members if combining the 4 NOAC RICaDs into a single document would be appropriate as they were being reviewed anyway. A member thought this would be useful but another member felt that it would be difficult as there was little congruence between some of these agents with regards to monitoring. Some agents require concomitant heparin during initiation, the others don't.

   A member also queried whether RICaDs were still required as these were now established treatment modalities, and it may be more useful to have simple monitoring guidance.

   It was agreed to bring this back to the January 2018 agenda to allow a more in depth discussion.
   ACTION: add NOAC RICaDs to December 2017 agenda **APC sec**

2. **Formulary updates**
   The APC secretary updated the members on a couple of formulary updates:
   - There are now a number of licensed formulations of magnesium glycerophosphate but the formulary currently has a note that it is unlicensed. The secretary has removed this note but left the RAG status as Red.
   - Obeticholic acid was approved by NICE in April 2017 (TA 443) for biliary cholangitis. It is NHSE commissioned but as it is an oral formulation it should be listed on the formulary as Red and GPs may want to record it on their clinical system as a third party prescribed medication.

3. Enoxaparin supply issues
   The APC secretary has been made aware that supply issues with enoxaparin are ongoing and likely to be long term and that Trusts are moving over permanently to tinzaparin. It is not currently listed on the formulary as it was identified as a hospital only drug during the harmonisation of chapter 2. However, in view of the change in use, it was agreed to list tinzaparin in the same was as enoxaparin.
   ACTION: list tinzaparin on APC formulary with same RAG status as enoxaparin. **APC sec**

The Chair thanked the members for their input today. The meeting closed at 16:50

Date of next meeting: Thursday 9th November 2017 14:00 – 16:45
Birmingham Research Park