AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 8h February 2018
Venue – Birmingham Research Park
Vincent Drive, Birmingham, B15 2SQ

PRESENT:

Dr Lisa Brownell	BSMHFT (Chair)
Dr Paul Dudley	Birmingham CrossCity CCG
Prof Mark DasGupta	Birmingham CrossCity CCG
Satnaam Singh Nandra	Birmingham CrossCity CCG
Kate Arnold	Solihull CCG
Dr Gwyn Harris	Sandwell & West Birmingham CCG
Jonathon Boyd	Sandwell & West Birmingham CCG
Tania Carruthers	HoE NHS FT
Carol Evans	HoE NHS FT
Nigel Barnes	BSMHFT
Melanie Dowden	Birmingham Community Healthcare NHS FT
Dr Neil Bugg	Birmingham Women's and Children's NHS FT
Dr Sangeeta Ambegaokar	Birmingham Children's Hospitals NHS FT
Dr Emma Suggett	UHB NHS FT
Dr Mark Pucci	UHB NHS FT
Yusuf Asif	Birmingham Women's and Children's NHS FT
Narinder Rahania	Birmingham Women's and Children's NHS FT
Ravinder Kalkat	Midlands & Lancashire CSU
Isabelle Hipkiss	Midlands & Lancashire CSU
Kuldip Soora	Midlands & Lancashire CSU

IN ATTENDANCE:

Dr Rahul Mukherjee for item 0218/05	HoE NHS FT
Sara Connor for item 0218/06	Sandwell and West Birmingham Hospitals NHST
Rakhi Aggarwal for item 0218/06	Birmingham CrossCity CCG

No.	Item	Action

0218/01 Apologies for absence were received from:

Professor Jamie Coleman, UHB NHS FT (deputy attended)
Dr John Wilkinson, Solihull CCG
Inderjit Singh, UHB NHS FT (deputy attended)
Mary Johnson, South East Staffordshire & Seisdon Peninsula CCG
Maureen Milligan, The ROH NHS FT
Dr C. Kartsios, HoE NHS FT
Jeff Aston, Birmingham Women and Children's NHS FT

It was confirmed that the meeting was quorate.

0218/02 Items of business not on agenda (to be discussed under AOB)

- Edoxaban on APC formulary
- Guidelines for management of menopause
- Cardiology RICaDs due for review

0218/03 Declaration of Interest (DoI)

There are no outstanding annual declarations of interest from members and there were no interests to declare relating to items on the agenda.

0218/04 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, 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.

0218/05 Circadin® (melatonin modified-release) tablets – Abbreviated application form – Flynn Pharma Ltd

It was established that there were no Declarations of Interests for Flynn Pharma Ltd.

The Chair welcomed Doctor Rahul Mukherjee, Consultant Physician, HoE NHS FT, to the meeting and invited him to present the application for Circadin®.

Dr Mukherjee began by stating that the main issue he faces as a sleep and general physician is that when he initiates patients on melatonin they need to come back to the hospital for continuation of supply as Primary Care clinicians are not advised to pick up ongoing prescribing. Therefore, he reviewed the evidence and submitted this application to make Circadin® suitable for maintenance prescribing by primary care clinicians. He clarified that the application was for the elderly population.

The APC secretary reminded members that when this chapter was harmonised, Circadin® was agreed to have RED status (Specialist only) for all indications.

Dr Mukherjee went on to say that the higher cost of acquiring melatonin as a 'Special' in primary care could be avoided by using licensed Circadin® and this issue has been raised by his GP colleagues.

He explained that when the Rapid Assessment Interface and Discharge (RAID) team initiate Circadin® for patients under his care, he gets repeat prescription requests for months after initiation. As Circadin® is mainly prescribed for primary insomnia, these patients then need to attend his clinic for a review to enable him to asses and if appropriate continue their supply. He stated that this is inconvenient for these patients as well as costly to the health economy and would be more suitable if these patients were reviewed in primary care.

The largest group who will benefit from review of the formulary status will be the elderly, frail and those with conditions such as dementia. Dr Mukherjee explained that his elderly care colleagues had particular interest in this application as they are interested in using it from a falls prevention perspective.

Dr Mukherjee said that Birmingham CrossCity CCG has identified Falls prevention as part of their Aspiring to Clinical Excellence (ACE) programme. A CCG representative reminded members that the ACE programme only applies to part of the APC geographical footprint.

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

- A member asked if Dr Mukherjee could clarify the cohort of patients Circadin® is being proposed to be used in, bearing in mind that Circadin® costs roughly 14-20 times more than a benzodiazepine and significantly more than other potential interventions. Dr Mukherjee described the proposed cohort as patients aged over 65 years, known to have had falls, i.e. those with a FRAT (Falls Risk Assessment Tool) score of 2 or more, those who have already had a fragility fracture and have diagnosis of primary insomnia. A rarer cohort of patients would be those people with circadian disorders, who are referred to the sleep clinic.
- A member asked, with regards to the former group, roughly how many people would this be? Dr Mukherjee has been informed that around 30 patients per month are seen at HoE NHS FT who fit this criteria i.e. those with a FRAT score over 2 and aged > 65 with insomnia. He anticipates that this number would tail off as these patients are repeat attenders.
- A member stated that if Circadin® was Green RAG status on the formulary, any patients who fit these criteria in primary care would be eligible for Circadin® and asked if Dr Mukherjee could estimate how many patients this would be. Dr Mukherjee stated that he didn't anticipate there would be many more patients as those with a high FRAT score are already seen in hospital.
- Most patients with a high FRAT score will have had a fall already.
- A member asked the clinician if he would consider AMBER status instead of the proposed GREEN RAG status. A member raised the concern that clearer guidelines for specialist initiation may be necessary therefore an AMBER RAG status would be more appropriate. Dr Mukherjee agreed that this was reasonable as it still allows maintenance prescribing in primary care, and allows specialist to make recommendations.
- A member asked about the efficacy of Circadin®, whether it works or whether it is used as an alternative to Z drugs. Dr Mukherjee stated that in his experience it works if a careful history has been taken, other factors have been excluded and patient has been diagnosed with primary insomnia.

- A member asked how long patients are usually prescribed Circadin® for. Dr Mukherjee stated that after 6 to 8 weeks, patients are in a rhythm with regards to their sleep patterns and Circadin® can be stopped. Dr Mukherjee has not seen Circadin® being used for longer than 6 months for insomnia in the cohort of patients in his sleep clinic.
- A member was keen to understand the number of patients likely to be seen in Primary Care because if Circadin® was added onto the formulary as GREEN this would lead to a change in the current treatment pathway as it is currently not on the formulary. Unfortunately the only data that is currently collected is from the hospital so the assumption has to be made that those patients who are started on Circadin® are seen in hospital following a fall. The Elderly Care physicians quoted a figure of 30 to 40 falls a month in a catchment population of approx.760, 000. But many of these are recurrent attenders, so once these patients are on Circadin®, the number should decrease.
- A member was still concerned that patients over 65, with primary insomnia and a FRAT score of 2 or more was quite a large prospective population. Dr Mukherjee suggested refining the cohort further by including patients on benzodiazepines as well.
- A member asked what the NNT (number needed to treat) for treating insomnia with Circadin® -Dr Mukherjee signposted to the Wade AG *et al*. paper referenced in the MTRAC bulletin which demonstrated efficacy in truly primary insomnia, improved quality of sleep, and reduced sleep latency. Melatonin restored circadian rhythm. He further stated that there were no studies on Z-drugs improving quality of life.
- It was pointed out to the clinician that the MTRAC bulletin had not been submitted with the application, and therefore the members had not had the opportunity to review the evidence it contained.
- A member asked about a proposed prescribing pathway – would Z-drugs be withdrawn first and non-pharmacological approach be tried initially or would patients be switched to melatonin.
- A member asked what evidence there was for use in insomnia patients with dementia. Dr Mukherjee clarified that there was good evidence to support use of Circadin® in insomnia with agitation which affects those with dementia.

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

Further discussion points in the absence of the specialist included:

- A member stated that if a patient is admitted to hospital after a fall on a Z-drug and this is subsequently discontinued, it is likely that insomnia will reoccur. The idea of weaning patient off a Z drug whilst in hospital is unlikely as patients are often not in hospital long enough for this to occur. If melatonin is available in primary care, this is likely to be prescribed as the next option, where other options may be more appropriate. Therefore a GREEN status as proposed in the application would not be appropriate.
- It was highlighted that melatonin had been reviewed by a member trust in the past, where they found little evidence of benefit; therefore it was not included in that trust's formulary. There is occasional use to retrain adult in-patients to sleep, these have not used other hypnotics and have stopped the drug by the time they leave the service.
- A member commented that a literature search and evidence review for Behavioural and Psychological Symptoms of Dementia (BPSD) which

includes insomnia with agitation did not bring up any evidence for melatonin.

- It was stated that the evidence shows it can reduce sleep latency by between 9 and 15 minutes. A member commented that this is not significantly different to hypnotics as they reduce sleep latency by approximately 22 minutes compared to placebo.
- MTRAC commissioning support bulletin (Oct 2013) which was tabled at the meeting positions Circadin® at Q3 (lower place in therapy but stronger evidence) and suitable for prescribing in primary care.
- In 2008, Scottish Medicines Consortium (SMC) did not recommend Circadin® for use in its licensed indication in the absence of a submission from the holder of the marketing authorisation. .
- It was acknowledged that there was little evidence for use of Circadin® in insomnia.
- It was highlighted that it seems Circadin® is used for ADHD more so than its licensed indication within Birmingham.
- A member recently spoke to a community geriatrician who has one or two patients that are in care homes with day-night reversal and she is aware that there are a few psycho-geriatricians who use Circadin® in similar circumstances. In her perspective it would be convenient to have primary care do maintenance of prescribing. The members acknowledged that this was a very small cohort of patients and the risks of prescribing creep outweigh the benefits.
- It was acknowledged that rather than prescribing a medicine with little evidence of effectiveness for treatment of insomnia, there are other non-pharmacological treatments that should be encouraged.
- It was acknowledged that the applicant had expected his sleep clinic patients to be referred to primary care for Circadin® as an advantage of this application. This was not deemed appropriate.
- It was acknowledged that as there is a push to discontinue Z drugs and benzodiazepines for reasons such as falls, it is likely these patients will be prescribed Circadin® as a result, which is not a cost-effective option. It is also not deemed to be a substitute for Z drugs or benzodiazepines.
- A full application would be required that clearly defines the patient cohort more suitably. It was acknowledged that there may be a small cohort of patients in which primary care prescribing would be suitable.

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

Patient Safety: Other hypnotics may be implicated in falls. Little evidence presented beyond this. Third most common side effect of melatonin is listed as dizziness.

Clinical effectiveness: Little evidence presented at the meeting

Strength of evidence: Little evidence presented at the meeting

Cost-effectiveness or resource impact: Significantly more expensive than benzodiazepines and Z-drugs.

Place of therapy relative to available treatments: Not clarified. MTRAC suggest lower place.

National guidance and priorities: NICE CKS guidelines (long term insomnia) and MTRAC support use. SMC did not recommend use.

Local health priorities: Concerns about evidence presented and the cohort of patients not clearly defined. Although the management of frailty and reduction of falls in elderly/frail is a local priority, there was little evidence presented that this would help in this regard.

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: N/A

Decision Summary: To ask Dr Mukherjee to return with a full application with a clearly defined patient population and include the evidence of efficacy. Circadin® to remain as RED status.

ACTIONS:

- **Relay decision to Dr R. Mukherjee by Thursday 15st February 2018.** **APC sec**

0218/06 Stoma appliance review. – for discussion / ratification

The Chair welcomed Sara Connor, Colorectal Nurse Specialist, Sandwell and West Birmingham Hospitals NHST, and Rakhi Aggarwal, Interface Lead/ Prescribing Support Pharmacist, Birmingham CrossCity CCG, to the meeting and invited them to present the Stoma toolkit for adults.

Sara began by stating that this document has been developed in collaboration with representatives from the 3 local Acute Trusts and the 4 local CCGs. This review of stoma appliances started in 2012.
Sara's presentation outlined the rationale behind the Stoma toolkit and the process undertaken for its development.
The review looked at how these products were ordered, the list of products and accessories together with the costs and reasonable quantities to order on prescription. This would support guidance for best practice and include contact details for the colorectal nurse specialists.

There were a number of meetings held between Clinical Nurse Specialist and medicine management representatives with the agreement to standardise the process across the City.
The group looked at pathways which included review of the care given in the acute trusts, hand over to the community services, the role of GP practices and dispensing companies.
They also discussed roles and responsibilities of the patients.

Declarations of Interest were also collated in recognition that some stoma services are part sponsored by stoma care dispensing companies.

Review of current dispensing practice resulted in the standardization of :

- Letters to GP Surgeries.
- Acceptable quantities of products and what action to take if over ordering
- The use of dispensing companies and chemists.
- The requirement for the patient to initiate the ordering
- The understanding that retrospective ordering will not be accepted
- Sign posting guide for patients who are having problems or over ordering

The rationale was:

- To identify patients who may be experiencing problems; this would manifest itself in ordering large amounts of products.

- To reduce waste of equipment, stock piling and unnecessary costs
- To stop standing orders set up unnecessarily by delivery companies.

This generated lots of discussion with regards to both the physical and psychological needs of a patient.

With regards to the stoma products and accessories, an agreement was made that the pouches (bags) would not be rationalised as a "not one fits all" approach was taken; however an agreement was reached with regards to an expected amount of pouches to be ordered per month.
An alert can be raised by the delivery company or GP surgery if a patient goes over the recommended usage and a review by stoma care nurse can then be requested.

The Colorectal nurse specialists (CNS) reviewed all the accessories currently used. A broad range of accessories were chosen taking into consideration a large scope of variables such as:

- Dexterity of patient.
- Skin Types
- Different Skin Conditions.
- Ease Of Use
- Expected amounts needed.
- Expertise / knowledge of CNS
- Evidence
- Cost

This harmonisation focused on rationalizing accessories to 3 products per category. Products were chosen based on evidence, experience, ease of use, and where two products performed equally, a cost effectiveness approach was taken.
Despite some teams being externally sponsored no bias was introduced as per the Nurse Code Of Conduct.

The resulting toolkit also provides definitions of the products and accessories and when they should be used; guidance for practitioners if the patients are having problems in the form of flow charts. It also lists medications that may be needed for patients with a stoma, information on various support groups and Acute Hospitals contact details.

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

- Several members commended Sara on the usefulness and quality of the toolkit presented.
- A member is aware that manufacturers send patients free samples of their new products, and there was also an acknowledgment that there is stockpiling in patients homes due to inappropriate reordering of stoma products.
- A member asked if the layout of the document could be amended so that the clinical information and operational information / practice process sections can be separated.
- It was pointed out that Solihull CCG is following different model.
- One of the flowcharts suggests that any patient who may be experiencing problems should be referred to the Stoma Care Specialist Nurse. A member expressed concerns that there may be an unpreceded number of these patients referred to stoma nurses and whether there was capacity in the teams to see them. Sara responded that telephone consultations may

be appropriate or patients could be seen as a follow-up.

The Chair thanked Sara Connor and Rakhi Aggarwal for attending the meeting, for answering all the questions from the APC members.

The chair asked the members present if they were in agreement to approve the toolkit. It was pointed out that all the items listed were suggested as AMBER, and that the guidance included was very useful.

Decision Summary: Stoma toolkit was approved, on the understanding that the clinical information will be separated from the best practice guidance.

ACTIONS:

- **APC secretary to relay committee's commendation on the toolkit to the working group via Sara Connor.** **APC sec**
  APC secretary to request that the toolkit is separated into 2 sections: clinical information/ product lists and best practice guidance. **APC sec**

0218/07 DMMAG recommendation on Freestyle® Libre® monitoring system

The chair directed the members to a letter written by representatives of the UHB NHS FT Medicines Management Advisory Group (MMAG) regarding the management of recommendations from Regional Medicines Optimisation Committees (RMOCs) and the proposed APC position statement for Freestyle® Libre®**.**

The letter requests that the following issues are addressed by BSSE APC:

- The proposed position statement for Freestyle® Libre® is reworded to remove reference to provision of supply, since the RMOC advice refers only to the collection of audit data by secondary care and does not specify a commissioning stream for the product.
- That the APC gives clear and prompt advice to DMMAG if a full application is required to the Acute Trusts, APC or both, and in what format.
- The APC ensures that the RAG rating for Freestyle® Libre® is based on previously agreed criteria, rather than on a financial foundation.

For the benefit of new members, It was summarised that DMMAG produced a draft position statement for Freestyle® Libre® for consideration as the position by the BSSE APC. In the intervening period RMOC released their position statement on FreeStyle® Libre®. The DMMAG's proposed position statement and recommendations that came to APC at the January 2018 meeting were described as a subset of the RMOC recommendations with a few differences. The DMMAG/APC position statement was discussed in the last meeting and it was decided then that a separate formulary application would be required to confirm RAG rating.

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

- A member explained that Diabetes clinicians were concerned that they had to make two applications: one to the trust's internal DTC and one to APC, having already discussed the position statement at the last meeting. Despite this, there is an expectation that an application is received at MMAG.
- It was stated that acute trusts are currently working together to produce an

application for the APC.

- A member asked the question if a formulary application for Freestyle® Libre® needs to come to the APC, or could it be considered as an exceptional circumstance; there is a wealth of information that already summarises the clinical evidence and cost effectiveness of Freestyle® Libre®. Therefore, can a decision be made regarding APC without a formal application? And if members decide an application is not needed, how is the DMMAG recommendation to be implemented?
- It was acknowledged that there is a need to consider how future RMOC recommendations are implemented locally by APC, and how the information is presented to commissioners for prioritisation rather than each acute trust having to produce applications.
- A member agreed that the statement "It will be provided by the specialist team on a 3-6 month trial basis" in the interim APC position statement is removed as this is not included in the RMOC statement. If included, it will have a bearing on where the product sits on the formulary.
- APC members were reminded that patients have the option of buying Freestyle® Libre®.
- A member highlighted that a decision needs to be made regarding the APC position statement; is it to be accepted, rejected or amended? This would be a clinical decision that could impact commissioning decisions. Another member highlighted that there was another option, that is, to revert to RMOC.
- A member confirmed that RMOC provide the national steer however, they are recommendations. If a decision is made to go against RMOC on a local level it would be expected that this decision is fully explained.
- It was confirmed that the 5th bullet point from the RMOC criteria "*Those who require third parties to carry out monitoring and where conventional blood testing is not possible*" was not included in the draft APC position statement following local expert opinion.
- A member asked where this would leave paediatric patients and it was confirmed that a separate application may be required at a later date.

Decision Summary: It was agreed to remove the second statement "*It will be provided by the specialist team on a 3-6 month trial basis"* from the proposed APC position statement. Freestyle® Libre® RAG rating to be decided at a later date.

ACTIONS:

- **Circulate revised APC position statement for members to approve by email**. **APC sec**

0218/08 Nebivolol drug application – feedback from Professor Una Martin,

An application for nebivolol had come to APC in July 2017. The decision was deferred as committee members would require clarification on the patient group as there has been interest from cardiologists for its use in heart failure as well as patients with resistant hypertension. Professor Una Martin (UHB NHS FT) was asked to clarify the patient group this would be used in.

The APC secretary directed members to the Decision Support Tool (DST), extract from the minutes from July 2017 and the recent feedback from Prof. Martin regarding the use of nebivolol by cardiologists for heart failure.

The members felt that the patient cohort still has not been clearly defined.
Dr Pucci requested that the committee considers the application for

hypertension only as this was the only indication included in the original application.

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

- A member commented that the feedback from Prof. Martin does not enable the APC to make a decision as the patient cohort has not been clearly defined.

Decision summary: Not approved. Invite a resubmission of the application with clearly defined patient cohort.

ACTIONS:

- **Relay the decision to Prof Martin** **APC sec**
- **Invite another application to come to APC** **APC sec**

0218/09 BSSE APC Brivaracetam ESCA – For ratification

The chair directed the members to the revised brivaracetam ESCA. The APC secretary commented that she had not received any additional feedback from members.

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

- Regarding point 2 under Tertiary Specialist responsibilities "*Confirm the patient has used levetiracetam (at maximum tolerated dose), responded to treatment but has documentation of intolerance and patient is already using a third line agent (perampanel, zonisamide, lacosamide, eslicarbazepine), which brivaracetam would replace".* A member received comments from the applicant whose feedback was that brivaracetam would not necessarily replace the third line agent and that in a small number of patients, two third line agents may be used.
- However, a member stated that the clinician was specifically asked when the application was presented if two third-line AEDs would be used and the applicant had responded that they would not. As discussed in the last meeting, this would significantly change the cost effectiveness of brivaracetam. As such, the APC secretary confirmed that the wording had been changed to clarify that brivaracetam would replace a third line AED as a result of the last meeting.
- The applicant has commented that there are patients where it would be inappropriate to prescribe levetiracetam as their psychiatric profile is such that this medication would be avoided. A member stated that, from a psychiatric point of view, the evidence is lacking. There is a small amount of evidence in one trial that found that brivaracetam resulted in less agitation than levetiracetam but this was found to be unlikely to be clinically significant. One of the main side effects of brivaracetam is suicidal ideation.
- The member stated that overall, the applicant is happy for the ESCA to be ratified as it is and there are patients who fit the cohort currently described. Any patient that does not fit the cohort can remain within secondary care, as this number has been described as small.

ACTION:

- **Publish brivaracetam ESCA on APC website**. **APC sec**

0218/10 BSSE APC Methylphenidate ESCA – For ratification

The chair directed the members to the Methylphenidate ESCA. The APC secretary explained that she had not received any additional feedback from members.

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

- A paediatric consultant had commented that the wording "*You are invited to participate"* under Areas of Responsibility for Sharing of Care may lead to GP opting out of the agreement. It was confirmed that this is standard wording in all of the ESCA documents. GPs that refuse to participate would need to fill in a decline to prescribe form.
- Point 11 under Specialist responsibilities – *A written summary to be sent promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay.* The consultant expressed concern that they may not be able to complete this within the time frame indicated. It was confirmed that this is wording that is standard across all ESCAs.
- Point 12 *Advise the GP what to do when defined parameters are altered, and when (if at all) an emergency referral should be made back to the specialist service.* The consultant pointed out that clinics are not set up to take emergency referrals, although this may change in future. Again, it was stated that this is standard wording in all of the ESCAs. In addition, it was pointed out that ESCAs may reduce repeat prescribing which could improve capacity of clinics to then take on emergency referrals.
- A member confirmed that currently the ESCA is only valid in Solihull CCG, and they would like this to be reflected in the document itself. It was highlighted that a note had been added on the APC formulary website in line with the other ADHD ESCAs. It was agreed that all the ADHD ESCAs would be amended to reflect information that is on the formulary.

ACTIONS

- **ADHD ESCAs to have additional wording "Approved for Solihull CCG only"** **APC sec**
- **Publish methylphenidate ESCA on APC website** **APC sec**

0218/11 BSSE APC Roflumilast RICaD – for ratification

The chair directed the members to the Roflumilast RICaD. The APC secretary explained that the RICaD had been drafted and sent to the respiratory consultants for review. Positive feedback had been received with some minor amendments. Some last minute feedback had been received stating:

I am still unsure of the requirement for ongoing LFT monitoring. The BNF simply states "Caution in mild impairment. Avoid in moderate to severe impairment."
The RICaD doesn't tell clinicians what to do with abnormal pre-treatment test results (presumably this box should act as a prompt to stop the respiratory specialist going any further with the RICaD if there is moderate to severe liver impairment), or indeed what to do with abnormal LFTs detected at monitoring (presumably to stop Roflumilast if the patients develops moderate-severe liver impairment).

I am also unclear why the LFTs sit in the "Assessment of Efficacy" table.

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

- It was agreed that the discontinuation criteria should include a point about abnormal LFTs detected at monitoring.
- It was agreed to remove LFTs from Assessment of Efficacy table. However it was felt appropriate to leave LFTs in the pre-treatment results as this allows the GP to be aware that the specialist had checked LFTs at the point of prescribing, and act as a baseline should there be any changes that may lead to discontinuation.

ACTIONS:

- **Make amendments as discussed and publish RICaD**. **APC sec**

0218/12 **Summaries for Decline to prescribe –** For information

The APC secretary explained that it had been agreed that Summaries for Decline to Prescribe and DTC Chairs Non-formulary approvals would be collated at six monthly intervals rather than ad-hoc. The APC secretary had circulated a list of dates when these would be on the APC agenda. There was a deadline for submission at the end of January for this meeting.

No Summaries for Decline to prescribe forms have been received from any trusts.

0218/13 **DTC Chairs Non-formulary approvals –** For information

The APC secretary directed members to the Non-formulary approvals that have been received from UHB NHS FT and HoE NHS FT. The APC are expected to have an oversight of these.

0218/14 **Minutes of the meeting held on Thursday 11th January 2018 –** for ratification

The minutes of the meeting held on Thursday 11th January 2018 were discussed for accuracy.

- Page 5: 8th bullet point down; reword to read "It was confirmed that, following a request from secondary care representatives, an application for Freestyle® Libre® would need to go through secondary care's internal Drug and Therapeutic committees for consideration before its formulary status can be confirmed and whether prescribing would occur in secondary or primary care."

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

0218/15 **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:

- 0118/11-Medicines of low clinical value – NHSE recommendations following national consultation-Update APC formulary in line with

recommendations made in NHSE guidance for CCGs. Update: in progress

- 0118/14 Matters arising- Circulate draft Feraccru® RICaD for wide consultation. Update: the secretariat has sent the first draft to Prof Iqbal for initial review. A revised version incorporating the clinician's feedback is now ready for wide consultation.
  ACTION: Circulate draft Feraccru® RICaD for wide consultation **APC sec**
- 1217/07- Invicorp® injection NDA- request a separate DOI form to be filled out by Prof Hackett. Update: Nil to declare was confirmed by Prof Hackett by email. A form would be sent on his return from leave. It was agreed that future applications would not be considered unless a completed DOI form was submitted prior to attending.
- 1217/09- NOAC RICaDs Circulate the 2 page document produced by HEFT with the APC draft minutes. Update: on hold
- 1117/07- DMARD ESCAs revised format- outcome of consultation. Update: APC secretariat working through list of clinicians that responded to consultation and inform of outcome.
- 1117/07 DMARD ESCAs revised format- outcome of consultation Task the CCGs' digital team to develop/ investigate an IT solution to deliver these documents in a concise and simple way. Update: on hold until new infrastructure in place.
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0218/16 NICE Technological Appraisals (TAs)

In January 2018, there were 7 TAs published; of these, 4 are NHSE commissioned, 1 is CCG commissioned and 2 are not recommended. See below.

- Golimumab for treating non-radiographic axial spondyloarthritis [TA497]

This technology is commissioned by clinical commissioning groups. Providers are NHS hospital trusts. RED status agreed.

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

Any other business:

1. Edoxaban on APC formulary

There are currently four NOACs on the APC formulary, all of which have been approved by NICE. APC sought advice from haematology colleagues regarding two preferred agents which are rivaroxaban and apixaban.

The rationale for having preferred agents was to gain experience with a few agents. therefore 2 preferred agents

A member has been contacted by a local cardiologist with a request for the APC to reconsider the preferred agents. Having recently reviewed NOACs data, it was proposed that edoxaban should be the preferred once a day NOAC. This was in light of the fact that rivaroxaban has to be taken with food and a number of patients the consultant sees for cardioversion or ablation have forgotten about this advice, have taken the medication outside meal times and there is then concern about them being fully anticoagulated.

The costs of NOACs are also very fluid and keep changing; edoxaban is currently 5 pence a day cheaper.

ACTION: Contact haematology/cardiology colleagues to review their recommendation and whether 2 preferred agents are still required. **APC sec**

2. Guidelines for management of menopause

A member has been approached by a Solihull GP with personal specialist interest in menopause and its management, with a considerable private practice. This GP has offered to develop clinical guidelines for the management of menopause so that women in the area are treated appropriately.
The member commented that rather than individuals developing guidelines in isolation, it would be better if these were developed by a group with representatives from all the stakeholders, reviewing the NICE clinical guidelines and the formulary.

The APC secretary reminded members that the HRT section of the formulary was not yet published as it was still to be harmonised. Specialists at the Womens' Hospital had been contacted at the time this chapter was harmonised, but the APC secretary had not received any feedback.

A member suggested that it would be useful to initially agree a list of guidelines that would be useful to have on the APC website and to then prioritise them.

Should the APC wish to commission the development of clinical guidelines, it would normally approach a local network/ expertise to develop these.

It was agreed that having the HRT section on the formulary was the initial priority. A member commented that the DTC at the Womens' hospital is aware that this needs urgent review.

ACTION: Request urgent review of HRT section from specialists at Womens' hospital to come to APC for harmonisation/ ratification. **APC sec**

3. Cardiology RICaDs

The APC secretary has produced a table of all the ESCAs and RICaDs currently published on the APC website with their respective approval and review dates.

A number of cardiology RICaDs are coming up to their review dates; the earliest being March 2018 for ticagrelor in Acute Coronary Syndromes (ACS).
The secretary is therefore enquiring how the members wish to proceed with these reviews.

The guiding principles were suggested as :

- Are the RICaDs still required?
- If required, are they still fit for purpose or do they need reviewing/ updating?
- What would the process be for reviewing/ updating these documents?

With regards to ticagrelor, this drug was approved by NICE in October 2011, the APC developed the RICaD in March 2015, and the clinicians/ GPs have been using this drug for 3 years now.

The members discussed the rationale for developing a RICaD in the first place was to support a general practitioner with a drug they may be unfamiliar with but also to provide assurance that the drug has been initiated in line with NICE guidance.

The members felt that the clinical letters coming out of the Trusts were very clear; that after 3 years of use the GPs were familiar with the drug and that a RICaD was no longer required as it did not add anything to the information in the clinical letters.

ACTIONS:

- **Update the website and remove the need for supporting RICaD with regards to ticagrelor.** **APC sec**
- **Bring a list of all ESCAs and RICaDs coming up for review in 2018 to March meeting.** **APC sec**

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

Date of next meeting: Thursday 8th March 2018 14:00 – 16:45
Birmingham Research Park.