**AREA PRESCRIBING COMMITTEE MEETING**
**Birmingham, Sandwell, Solihull and environs**
Minutes of the meeting held on
Thursday 9th November 2017
**Venue – Birmingham Research Park**
**Vincent Drive, Birmingham, B15 2SQ**

**PRESENT:**

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| Dr Paul Dudley | Birmingham CrossCity CCG (Chair) |
| Prof Mark DasGupta | Birmingham CrossCity CCG |
| Satnaam Singh Nandra | Birmingham CrossCity CCG |
| Elizabeth Walker | Sandwell & West Birmingham CCG |
| Kate Arnold | Solihull CCG |
| Dr John Wilkinson | Solihull CCG |
| Melanie Dowden | Birmingham Community Healthcare NHS FT |
| Prof Robin Ferner | Sandwell & West Birmingham Hospitals NHST |
| Prof Jamie Coleman | UHB NHS FT |
| Dr Emma Suggett | UHB NHS FT |
| Katy Davies | HoE NHS FT |
| Carol Evans | HoE NHS FT |
| Dr Neil Bugg | Birmingham Women's & Children's NHS FT |
| Dr Sangeeta Ambegaokar | Birmingham Women's & Children's NHS FT |
| Jeff Aston | Birmingham Women's & Children's NHS FT |
| Nigel Barnes | BSMHFT |
| Maureen Milligan, | The ROH NHS FT |
| Ravinder Kalkat | Midlands & Lancashire CSU |
| Isabelle Hipkiss | Midlands & Lancashire CSU |

**IN ATTENDANCE:**

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| Prof Carl Clarke for item 1117/05 | Sandwell & West Birmingham Hospitals NHST |
| Nilima Rahman-Lais | Solihull CCG |

| No. | Item | Action |
|---|---|---|

**1117/01 Apologies for absence were received from:**

Dr Lisa Brownell, BSMHFT
Inderjit Singh, UHB NHS FT, deputy attended
Tania Carruthers, HoE NHS FT, deputy attended
Dr C. Kartsios, HoE NHS FT
Yusuf Asif, Birmingham Women's & Children's NHS FT
Dr Gwyn Harris, Sandwell & West Birmingham CCG
Mary Johnson SES&S Peninsula CCG
Jonathan Horgan, MLCSU

It was confirmed that the meeting was quorate.

**1117/02 Items of business not on agenda** (to be discussed under AOB)

- Formulary for patients in transition from paediatric to adult services
- ESCAs from another Trust not represented on BSSE APC

**1117/03 Declaration of Interest (DoI)**

There are some outstanding annual declarations of interest and members were reminded to submit these at the earliest opportunity. There were no interests to declare relating to items on the agenda.

**1117/04 Welcome and Introductions**

The Chair welcomed everyone to the meeting today. Introductions around the table were not deemed necessary.

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.

**1117/05 Opicapone (Ongentys®)- resubmission of new drug application-** Bial Pharma UK Ltd

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

The Chair welcomed Prof Carl Clarke, Professor of Clinical Neurology, City Hospital, to the meeting and invited him to present the application for opicapone.

Professor Clarke began by thanking the committee for the opportunity to resubmit an application for opicapone with additional information following the APC's earlier decision in May 2017.

The drug under consideration is used for adjuvant therapy in Parkinson's Disease (PD); patients are initiated on levodopa and doses are titrated up over the years until they develop dyskinesia or end-of-dose motor fluctuations or reach a total dose of 600mg levodopa a day, then adjuvant therapy is introduced.

Adjuvant therapy consists of 3 main drug groups: dopamine agonists, monoamine oxidase B (MAO-B) enzyme inhibitors or catechol-O-methyl transferase (COMT) inhibitors.

There is some yet unpublished evidence from PD MED LATER trial which suggests MAO-B inhibitors and dopamine agonists are more effective, so these tend to be used first. Therefore the COMT inhibitors are used at the end of oral therapy for PD.

In his earlier application, Prof Clarke suggested that opicapone could be used instead of entacapone, but acknowledged the committee's view that the trial evidence only confirmed non-inferiority compared to entacapone, and that the availability of generic entacapone made opicapone a more expensive option.

There is another COMT inhibitor, tolcapone, which is licensed for those who have failed on entacapone, but is associated with liver toxicity and requires stringent monitoring of liver function which makes it costly and limits its use; also it is not on the APC formulary.

Therefore the proposal under consideration at this meeting is for opicapone to be used in patients who have failed to respond to entacapone therapy who would otherwise progress to apomorphine injection or infusion.

With regards to number of patients, the PD MED LATER trial would suggest that around a third of patients on entacapone discontinue the drug after a year due to intolerable side effects or lack of response. The main side effects are diarrhoea (reason for this is not yet understood) and bodily fluids turning bright yellow, so there is a high withdrawal rate for entacapone.

The evidence for the clinical effectiveness of opicapone was discussed at length in May 2017 and referenced in the application. Prof Clarke believes it is safer and has fewer side effects than entacapone and would offer a cost-effective alternative before moving onto apomorphine therapy.

The cost comparisons are detailed within the application: opicapone would cost £84.84 for 28 days at standard dose of 50mg daily; apomorphine 70mg daily would cost £679.84 for 28 days plus cost of connector device for drug delivery. This would present a significant cost benefit for the health economy.

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

- A member requested clarification on the figure of 33% of patients discontinuing entacapone and asked if this was mainly due to the fact they didn't like their bodily fluids turning yellow. Professor Clarke explained that the main cause for withdrawal of entacapone therapy was gastro-intestinal side- effects, primarily diarrhoea.
- The member went on to ask what the comparative figure was for patients on opicapone. Prof Clarke did not have a figure to hand but stated that it was better tolerated than entacapone, did not turn bodily fluids yellow and was not associated with diarrhoea. It was also worth noting that tolcapone does not turn bodily fluids yellow or cause diarrhoea either; so it seems these GI side-effects are particular to entacapone. Prof Clarke reassured the committee members that the trials to date have not flagged up any problems with liver function tests or suggest such monitoring is required for opicapone.
- A member highlighted that the BNF lists constipation as a side-effect of opicapone. The clinician stated that constipation is one of the most common problems with PD and believes this a complication of the condition, not the drug.

- A member asked if there was any evidence to suggest that patients who do not tolerate entacapone would indeed tolerate opicapone and would therefore be a valid cohort of patients for this drug. Prof Clarke indicated that the manufacturer is accumulating such data but he has not received any papers as such; he believes it may only be anecdotal. The trials would have been done on patients who are not on entacapone, so this information cannot be extracted from the trials.
- The clinician commented that the surrounding APCs who have accepted opicapone on their formulary have done so for this cohort of patients who have failed on entacapone, so the evidence base is building up.
- A member asked the clinician for his views on combination products/ triple therapy such as Stalevo® or the equivalent branded generics. Prof Clarke commented that he had a small number of patients who seemed to be doing much better on the combination product than on entacapone and levodopa/carbidopa preparations being given separately. He suggested this could be due to improved compliance as taking all 3 drugs at the same time.
- Prof Clarke added that opicapone is given as a separate single dose at night, does not require titration and is not associated with impulse control disorders such as hypersexuality or compulsive gambling common with dopamine agonists.

The Chair thanked Prof Clarke 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 sought clarification on the reason for not accepting the application in May 2017. It was confirmed that the rationale was the significant cost impact on the health economy with no proven clinical benefit over current formulary option. Apomorphine was not discussed on the first occasion, hence the option to resubmit offered to the clinician.
- A member commented that it was plausible that opicapone would work in patients who did not tolerate or benefit from entacapone and would potentially delay a move to apomorphine therapy but that it was unfortunate that the evidence was not available. It was also noted that delaying progression to apomorphine therapy could have some negative impact on patient outcomes.
- It was recognised that the adverse drug reaction (ADR) profile and GI tolerance were slightly different between entacapone and opicapone although both are from the same class.
- A member acknowledged that treatment emergent severe diarrhoea could be an issue in PD patients unable to mobilise, but that the figure of 33% of patients discontinuing entacapone due to intolerable GI side-effects that didn't settle despite continued therapy and simple measures seemed high and could potentially lead to prescribing creep. A member would also want to be reassured that patients not liking bodily fluids turning yellow would not be criteria for changing to opicapone.
- A member asked if the committee had figures for the local usage of apomorphine; this was uncertain but deemed to be low. However, a member felt that the number of patients ending up on opicapone would be far greater if it was available as it is a much easier step to take than going to injection/infusion therapy.
- A member would have wanted the application to outline the criteria for establishing that entacapone therapy has failed and the rationale for

selecting opicapone as the next step in the treatment pathway.

- A member stated that there wasn't anything presented at this meeting to convince the committee members to change their previous decision; the evidence presented is anecdotal or unpublished.
- Another member was reluctant to reject it a second time without making it clear what information the committee would need in order to make an informed decision; this would include the criteria for selecting patients to go onto opicapone.
- A member noted that the NICE evidence summary and MTRAC commissioning guidance both suggest that opicapone has a place in therapy in the cohort of patients who experience intolerable side-effects on entacapone, but recognises that there is a risk of creep.
- A member suggested to accept it on the formulary as Red to allow PD specialists to gain clinical experience with this agent and gather evidence on ADRs as this can only be collated through clinical use in this small group of late stage PD patients. However a member questioned whether the committee would accept case studies from the specialist as evidence further down the line.
- It was commented that if the committee was to accept it on the formulary as Amber, it would want to be reassured that the patient was benefiting from this drug before prescribing was transferred to primary care which would require at least 3 months under the specialist's care to establish this.
- It would also be useful to have some data on the number of falls or A&E attendances prior to initiating opicapone therapy to establish if this improves following treatment.
- A member asked if it was usual for the APC formulary to only have one agent from a class on the formulary. The clinician had suggested at the previous meeting that opicapone would be used in patients who fail to respond to, or are intolerant of, entacapone, in situations where tolcapone is being considered. However tolcapone is not on the formulary.
- It was agreed that the way forward would be to have a shared care document with a clear decision algorithm outlining the rationale for progressing onto opicapone; prescribing to be maintained by the specialist for at least 3 months to establish patient is benefiting from this therapy and side effects have reduced before transferring prescribing responsibility to primary care.

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

Patient Safety: Slightly different side effect profile and GI tolerance to entacapone. The most common adverse reactions reported were central nervous system disorders with dyskinesia reported as very common. Common ADRs included dizziness, headache and somnolence. No evidence of liver toxicity associated with tolcapone. Black triangle drug ▼, subject to additional monitoring.

Clinical effectiveness: BIPARK I found that opicapone, as an adjunct to levodopa, was more effective than placebo at reducing off time in people with PD (mean difference of 60.8 minutes). Improvements in on time without troublesome dyskinesia were also seen in people treated with opicapone (mean difference of 62.6 minutes compared with placebo). Opicapone was shown to be non-inferior to entacapone for reducing off time. Clinician reported 26mins less off time with opicapone vs entacapone, however trial was under powered to show superiority, and only confirmed non-inferiority.

Strength of evidence: RCTs confirmed non-inferiority compared to entacapone. Data suggesting trend towards superiority is yet unpublished.

Cost-effectiveness or resource impact: Significantly more expensive than generic entacapone. Opicapone only available as a single agent, no combination product; patient would still need to take multiple doses of levodopa.

Place of therapy relative to available treatments: Second-line therapy to entacapone, in patients who fail to respond to, or are intolerant of, entacapone, in situations where apomorphine therapy is being considered.

National guidance and priorities: Updated NICE Guideline (NG71) was published in July 2017 and recommends COMT inhibitors (no differentiation between the 3 available products) as an option alongside dopamine agonists and MAO-B inhibitors for adjuvant treatment of motors symptoms after discussing the potential benefits and harms of the different drug classes (new 2017). MTRAC's opinion is that opicapone would be suitable for prescribing in primary care following initiation in secondary care and that some patients would benefit from the additional option offered by opicapone, especially those in whom entacapone is contraindicated, poorly tolerated or poorly effective.

Local health priorities: CCGs would only support if initiated by PD specialists with clear patient selection criteria and successful review following 3 months' treatment before transferring prescribing to primary care under shared care.

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: Would require ESCA, in line with current formulary option. ESCA should include rationale for patient selection, 3 month's prescribing retained by specialist and successful review before transfer of care.

**Decision Summary**: Approved as Amber with ESCA, Second-line therapy to entacapone, in patients who fail to respond to, or are intolerant of, entacapone, in situations where apomorphine therapy is being considered. ESCA to be developed by PD Specialist.

**ACTIONS:**

- **Relay decision to Prof C. Clarke by Thursday 16th November.** **APC sec**
- **PD Specialist to develop ESCA.** **PD team**
- **Add opicapone (Ongentys®) as Amber with ESCA to APC formulary.** **APC sec**

**1117/06 Ethinylestradiol tablets- new drug application**

Unfortunately, the applicant clinician from UHB NHS FT was unable to attend the meeting to present this application.

The APC secretary gave some background information which led to this application being submitted for consideration at the APC.

Ethinylestradiol is listed in section 6.4.1.1 Oestrogens and HRT of the formulary which was harmonised at an APC away day in January 2015 with

specialist input from the then chair of the Birmingham Women's hospital DTC.

The BWH specialists did not have particular preferences for HRT preparations (oral and transdermal preparations). The original document used for harmonisation had ethinylestradiol listed as amber under City hospital only; however a representative from UHB NHSFT stated at that meeting that their clinicians have used this drug for many years for induction of puberty in female patients. It was therefore agreed that a separate review was required to be brought back to the committee based on prescribing usage (epact), cost and evidence.

A new drug application was submitted and formally discussed at UHB's MMAG in March 2015 to help formalise the Trust's formulary for an off-label use. Both the 2 mcg and 10 mcg tablets were supported and approved at MMAG; however it was deemed appropriate to only recommend to GP's to prescribe the 10mcg tablets once the patients were stable on doses of 5mcg or above. The 2mcg tablets would predominantly be used in-house to titrate the dose and should not be prescribed in primary care as there is a risk they would be prescribed incorrectly as 2 mg. Unfortunately, this application was not forwarded to the APC secretary for further consideration at the APC.

Usage data from Sandwell and West Birmingham hospitals indicated that only 3 prescriptions had been issued in the previous year so it was agreed to remove this drug from the formulary following the APC's harmonisation principles. It is therefore currently listed as non-formulary.

This was brought up again in September 2017 under AOB (refer to minutes of Sept meeting) where it was agreed to defer any decision. In the meantime, the APC secretary had suggested that the application discussed at UHB's MMAG should be submitted to the APC for formal discussion in order to resolve this ongoing formulary issue.

Prior discussion with the applicant clarified that the clinicians use patches where possible however there is a cohort of patients, who may be allergic to the patches that do require these tablets.

A member stated that when this was discussed at UHB, it was recognised that a small cohort of transitional patients who may have had this therapy initiated at the Children's hospital for endocrinopathies associated with delayed pubertal development and hypogonadism would need to continue this therapy into adult endocrine care. It was confirmed that it was currently listed on the Children's Hospital formulary but that the majority of prescribing is retained within the Trust as there is a system in place through the Commissioning and Interface Liaison Team (CILT)

The application under consideration makes it clear that the specialists would use the unlicensed 2 mcg tablets in house for titration of the dose as failure to titrate the dose gradually can result in abnormal breast development. After 6 months, once the dose is increased to 5mcg or above, the prescribing would be passed to the GP as they do not have the capacity to pick up ongoing prescribing of the licensed formulation.

A member raised a question regarding monitoring: the application outlines pre-treatment requirements as baseline blood pressure and liver function tests and six monthly review of progression through puberty. However the member was

unclear as to who would monitor development of secondary sexual characteristics, height, weight etc. and how long this treatment would be required for. It was confirmed that this would be done by the specialist as these patients tend to be seen regularly in out-patient clinics.

The point was then made that, if patients were regularly seen in the out-patient setting, was there a need for GPs to be involved in ongoing prescribing in this small group of patients with a rare condition; the application states that a maximum of 5 patients in a population of approximately 1 million would need this treatment.

The cost of the 10mcg tablets was also noted as £200 for 21 tablets, which represents a significant cost. There is also a risk of prescribing error due to incorrect selection between 10mcg and 1 mg tablets, and would very much depend on how they appear on the clinical system's picking list.
The cost of the 2mcg tablets was uncertain as these are classed as specials.

The consensus view of the committee members is that it is accepted; this drug has a place in therapy and needs to be on the formulary for a specialist group of patients but that primary care clinicians would not accept transfer of prescribing, which would make this a red drug.

However it was agreed that, as the clinician was unable to attend and in view of restricted access to email correspondence, if any relevant information was overlooked or omitted from this discussion, this would be flagged at the next APC meeting.

Post-meeting note: Loestrin® 20 (ethinylestradiol 20 mcg / norethisterone 1mg) is included in the oral contraceptive section as Amber – for pubertal induction in adolescent patient or premature ovarian failure only.

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

Patient Safety: No safety issues relating to the drug; millions of women worldwide use ethinylestradiol in the form of the combined oral contraceptive pill, which has a good safety profile. Adverse drug reactions and drug interactions will be minimal at this dose and for this indication. The main risk is with prescribing due to potential incorrect dose selection from the clinical systems.

Clinical effectiveness: Ethinylestradiol is licensed for short-term treatment of symptoms of oestrogen deficiency, for osteoporosis prophylaxis if other drugs cannot be used (section 6.6) and for the treatment of female hypogonadism and menstrual disorders.

Strength of evidence: Limited formal clinical evidence but established therapy and clinical practice.

Cost-effectiveness or resource impact: Significant cost impact.

Place of therapy relative to available treatments: Second line to patches, if patient is allergic to or cannot tolerate patches.

National guidance and priorities: This drug is included in the British Society for Paediatric Endocrinology and Diabetes (BSPED) in their guidance statement

for Hormone Supplementation for Pubertal Induction In Girls.

Local health priorities: CCGs would not support primary care clinicians prescribing in this very small specialist group of patients.

Equity of access: Testosterone undecanoate capsules are included in the APC formulary as a Red drug for induction of puberty in males.

Stakeholder views: N/A

Implementation requirements: N/A

**Decision Summary**: Both strengths (2 mcg and 10mcg tablets) approved as Red, for induction of puberty in female patients who cannot tolerate or are allergic to first-line patches. Rationale: Safety issues with prescribing in respect of potential for incorrect dose selection from clinical system, rarity of condition and regular specialist follow-up.

**ACTIONS**:

- **Relay decision to applicant by Thursday 16th November.** **APC sec**
- **Add ethinylestradiol tablets (2mcg and 10mcg) to the APC formulary as Red drug.** **APC sec**

**1117/07 DMARD ESCAs revised format- outcome of consultation**

Prior to this meeting, the APC secretary circulated the collated responses from Primary and Secondary Care following the consultation on a proposal to revise the current format for DMARD ESCAs (single agent for single indication).

The options put forward in the consultation were:

a) An ESCA document by condition. I.e. all DMARDS used in Rheumatology in one ESCA, all DMARDs used in Gastroenterology grouped in a separate document etc.
b) An ESCA document for single agents for all licensed indications. I.e. an ESCA for methotrexate for all licensed indications, an ESCA for azathioprine for all licensed indications etc.
c) An alternative option not yet defined.

- 9 responses were received from Primary Care: ESCA by condition received 3 votes; ESCA by drug received 6 votes.
- 9 responses were received from Secondary Care: ESCA by condition received 2 votes; ESCA by drug received 7 votes.

As ESCA by single drug for all specialties' seemed to be the favoured option, the APC secretary had also circulated some examples of combined shared care documents from the Oxfordshire health economy.

However a member pointed out that a group which is reviewing shared care nationally is currently having discussions around looking at shared care from a disease-specific perspective rather than a medicine-specific perspective, and it was suggested that the APC should consider going in the same direction to keep abreast of the national steer.

A member also commented that a local Trust was about to submit some

abbreviated application forms with supporting ESCAs for the APC to consider extending the use of DMARDs to autoimmune neurological conditions. This highlighted the fact that these documents need to be comprehensive about the indications against a particular drug otherwise a number of specialties' could be missed out.

A member stated that the opposite could be said; if the list of drugs for a particular condition was not comprehensive enough, this would also be an issue.

A member's view was that it was more likely to be comprehensive if one focusses on a particular speciality or indication as you would consult with the individuals who treat this condition; if you ask about a drug you can never be completely assured that you have covered all the appropriate stakeholders as you don't know who or what indications clinicians are prescribing it for.

Another member's view, from a practical perspective, was that consultants based in their speciality are more likely to want to refer to an ESCA for the management of a specific condition rather than searching for an ESCA that covers the use of a particular drug. This would also facilitate compliance with these shared care documents.

It was acknowledged that this may make the ESCAs more complex but this could be addressed by simplifying the whole process: uploading the main body of the ESCA to the APC website with links. This would also ensure that the clinicians access the most up to date version of the document.

However it was recognised that the current IT infrastructure did not support an easy IT solution. CCGs' medicines management teams already struggle to get engagement from GPs to participate in shared care with the current format of one drug one indication; any complication in the documentation may lead to further decisions to decline to prescribe.

If the committee was to take a pragmatic view, it should proceed with what works in the local health economy; the current format of one drug one indication seems to work. The exception to this format is the ESCA for oral antipsychotics where the class of agents is grouped in one document but this covers only one speciality and the monitoring is the same for all the drugs included.

A member pointed out that if we were to develop ESCAs for single drugs covering a multitude of indications, these would need to be listed in various sections of the formulary as the current layout is still based on the "old" BNF chapters; for example the ESCA for methotrexate would need to be linked in chapters 1 (for Crohn's disease), 3 (for interstitial lung disease), 10 (for rheumatoid arthritis and psoriatic arthritis) and potentially chapter 4 (for neurology). This seems to be counter-intuitive and complicated to manage.

The secretary reminded the members that the consultation was instigated following an agreement to include dermatology conditions in the rheumatology ESCAs. Further communications from the nephrologists at UHB NHS FT pointed out that the management of patients with connective tissue disease in Birmingham had moved away from a traditional rheumatology-centred approach and delivered by Nephrology specialists; hence the request to include these indications in the shared care documents. The secretary also

pointed out that a lot of work was being held up by the ongoing discussion on the format of ESCAs.

It was therefore proposed that the APC maintains the status quo and continues with the current format of one drug/ one indication as there is no mandate to change it, based on the small number of responses (18 in total).
This was supported in the majority but it was also suggested that the APC should have a strategy to review this in the future.

The question of unlicensed indications was raised such as use by dental or ophthalmology specialists. It was agreed that these would need to be considered through the formulary amendment form / abbreviated application form process to avoid further delay to work under way.

It was also suggested to seek IT specialists' views on the best digital/ electronic solution or format to address the issues raised around practicalities.

**ACTIONS**:

- **Relay APC's decision to keep ESCAs in current format to specialists who responded to the consultation.** **APC sec**
- **Communicate that any new indication for existing formulary options will need to be considered through the formulary amendment/ abbreviated application form process**. **APC sec**
- **Task the CCGs' digital team to develop/ investigate an IT solution to deliver these documents in a concise and simple way.** **Digital team**
- **Provide a live demonstration of the APC formulary website to APC members to ensure the committee is familiar with its functionality.** **APC sec**

**1117/08 FreeStyle® Libre® Flash Glucose Monitoring system**

The APC secretary has circulated the APC interim position statement together with the Regional Medicines Optimisation Committee (RMOC) position statement which was published on 1st November 2017.

As stated in the APC's interim position statement, the committee is waiting for the Diabetes Medicines Management Advisory Group (DMMAG) to review this flash glucose monitoring system to define the patient cohort (both adult and paediatric patients) which is likely to gain most benefit from this new technology.

The next DMMAG meeting is scheduled for 30th November.

It would appear that secondary care clinicians from member Trusts are already discussing this glucose monitoring system with some patients and these patients are now lobbying their GPs to prescribe it. It was commented that ophthalmologists were also recommending this system.

It was acknowledged that the very nature of diabetes meant that it affects many different body systems, and this could potentially mean this technology would end up being recommended by a very wide group of clinicians.

The feedback from clinicians at a local Trust was that if the patients brought up the subject of flash glucose monitoring or if they felt they would benefit from it and are willing to buy it, then they have entered into discussions with these patients, however there has been no direction to approach their GP. The Trust

clinicians would also not feel comfortable in not disclosing an option that the patient could buy that would benefit them.

It was agreed that both primary and secondary care clinicians should stand by the APC' s interim position so that neither are put in the difficult situation of dealing with a patient who has had their expectations raised inappropriately.

From a commissioning point of view, the committee was informed that a policy to fund continuous glucose monitoring (CGM) was agreed between primary and secondary care following a lengthy process. CGM is supported by NICE and there is an evidence base to support the view that this is going to be beneficial in a defined group of patients. However, the Birmingham and Solihull STP can only afford to fund 18 patients for CGM, and the pot of money available for valuable developmental issues is only small.

The commissioners fear that if the use of flash glucose monitoring goes out of control, this would severely reduce the available funding for innovation such as CGM.

The members recognise that the amount of direct marketing going to the patients is unprecedented, and acknowledge the difficult situation the frontline clinicians (both in primary and secondary care) are put in, but would plea with the clinicians that they are consistent with the current recommendation not to prescribe until all the evidence has been considered and a clear patient cohort defined.

It was confirmed that the RMOC position statement was a national statement to be taken into consideration when making a local decision. Commissioners are expected to pay due regard to the RMOC recommendation and have to provide a reason should they decide to deviate from this.

APC representatives will attend the DMMAG meeting on 30th November to ensure the group is aware that it has to reach a decision at that meeting. This will be fed back to APC members at the December meeting.

**ACTIONS**:

- **APC representatives to attend DMMAG Meeting on 30th November** **APC**
- **Add feedback from DMMAG to APC's agenda for December meeting.** **APC sec**

**1117/09** **Minutes of the meeting held on Thursday 12th October 2017 –** for ratification

The minutes of the meeting held on Thursday 12th October 2017 were discussed for accuracy.

- Page 12: under 0717/07: reword second sentence to read: 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.

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, the APC secretary directed the members to page 11, under "Matters arising" and the update on the

abbreviated application for Emollin® 50:50 spray; the committee decided to decline the application; however a Decision Support Tool still needs to be completed.

**ACTION:**

- **Draft DST for Emollin® 50:50 spray to be circulated with draft minutes of this meeting.** **APC sec**

**1117/10 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:

- 1017/05 - Primary Care Antimicrobial Guidelines
  Check with BAAG local rate of infection with *B. burgdorferi* is indeed over 20%. Update: Dr Abid Hussain from BAAG cannot find any evidence of the local rate being 20%. His view is that this figure is unhelpful as there is no denominator. The figures from 2011 suggest a national incidence of 1.73 per 100,000 population, with the estimated cases roughly around 2000 per year. He therefore suggested removing this statement from the guidelines but to keep the antibiotic advice as it is noted.

- 1017/07- Pan-Birmingham Respiratory Clinical Network Asthma Guidelines
  Request minor amendments to the guideline to reflect approved formulary status of Relvar® Ellipta® and suggest extending the review date. Update: The RCN was grateful for the feedback from APC; these amendments are under way.

- 1017/12- Minutes of the meeting held on Thursday 14th September 2017: Remove requirement for DTC approval before initiation from eslicarbazepine ESCA and upload revised version to APC formulary. Update: the APC secretary wanted to confirm this was approved. This can now be revised and uploaded to the website.

- 1017/13- Matters arising: Notify the clinician that Emollin® 50:50 spray is not approved and the rationale. Update: DST needs to be completed in the first instance.

- 1017/13- Matters arising: Write to the Mental Health Commissioners outlining the APC discussions to date and frustrations at the delay in resolving the historical commissioning arrangements for ADHD and dementia services. Update: This action is outstanding; members requested that this be expedited in view of the disparity in commissioning of ADHD services between the member CCGs.

- 0917/10- Oral antipsychotic drugs ESCA- queries/ feedback from practices
  Guidelines for monitoring developed by CrossCity CCG to support the audit to be brought to APC with a view to add as an appendix to the ESCA for oral antipsychotics. Update: this action is outstanding.

- 0917/10- Oral antipsychotic drugs ESCA- queries/ feedback from practices.
  Add symptoms of hyperprolactinaemia to ESCA. Update: Action is outstanding. A member commented that the majority of hyperprolactinaemia cases are asymptomatic.

**1117/11 NICE Technological Appraisals (TAs)**

In October 2017, there were 6 TAs published; of these, 5 are NHSE commissioned and 1 is CCG commissioned. See below.

- Tofacitinib for moderate to severe rheumatoid arthritis (TA480): 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. **Formulary for patients in transition from paediatric to adult services**
   Some patients at the Children's hospital are on drugs that are not currently listed on the APC formulary, and this becomes an issue when they transition to adult services in one of the local Trusts. The hospital pharmacy team has also carried out an audit on the medications prescribed through the Commissioning and Interface Liaison Team (CILT) which has identified a small number of drugs and a small number of patients that will soon be moving to adult services. These patients tend to have rare conditions with multiple co-morbidities, are on a multitude of medications mainly specials. Unfortunately, when these patients transition to adult services, they become caught up in the middle of discussions between the Trusts regarding formulary status and picking up prescribing responsibility and funding.

   The member is therefore asking if the APC has a role in facilitating a resolution to these issues for the benefit of patient care.

   From a commissioner's perspective, a member stated that the CCGs have a policy in place which states that, where responsibility for providing NHS services to the patient has been transferred to the CCG in question, the CCG will, subject to the terms of this policy, honour existing funding commitments made by the patient's previous NHS commissioner. For example if a patient has moved to Birmingham on a treatment initiated by another commissioner, the CCG will pick up ongoing funding for this treatment. This would also apply if the responsible commissioner changed from NHS England to CCG in the case of children becoming adults.
   The difficulty with the Children's hospital is that the responsible commissioner for some of the medicines in question is unclear: for example some of the drugs used in the treatment of a condition for which NHSE is the responsible commissioner are not PbR excluded and deemed in tariff.

   There are also some budgetary issues for Red drugs where the funding does not follow the patient when moving from one provider trust to another.

   It was suggested that a discussion should take place a year before the patient was expected to transition to adult services so that any issues can be flagged up early and resolved, before they attend outpatient clinics in adult services and can get access to their medications in a timely manner.

   It was commented that there are established transitional clinics in place for

a number of specialities such as cardiac and hepatobiliary where the process is very clear and pharmacists from both trusts attend to resolve any potential medication issues.

A member commented that on a recent occasion the contracts' team at the Children's hospital were unclear as to who was funding a particular drug; the example quoted was azathioprine for a neurological condition. This drug would be deemed in tariff, the patient's GP declined to prescribe because there was not a shared-care agreement in place so the CILT at BWCH continued to provide the treatment. This became an issue when the patient, now an adult, attended an out-patient clinic at UHB NHS FT expecting to continue to receive their medication from the Trust.

It was acknowledged that this was a complex issue, and it would appear that there is a disparity in the treatment of patients because of their age.

The question on the table is: does the APC need to be involved in resolving these issues, or is it up to the Trusts to find a solution?

It was suggested that a useful exercise would be to compare the paediatric formularies across the region against the APC formulary with the aim to harmonise them and to highlight any gaps.

It was suggested that red drugs would be a good starting point and determine whether they are applicable to transitioning patients as it was recognised that not all drugs initiated by paediatricians are carried on into adulthood.

It was agreed to convene a meeting between pharmacists from the CCGs and the Trusts outside of the APC.

**ACTIONS**

- **Assess differences between the paediatric formularies (BCH and HoE FT) and the APC joint formulary.** **CCGs/Trusts**
- **Pharmacists from CCGs and Trusts to meet outside of APC** **CCGs/Trusts**

2. **ESCAs from another Trust not represented on BSSE APC**

A member highlighted an issue regarding ESCAs developed by another Mental Health Trust not represented on the BSSE APC, and whether these need to come to this APC to be ratified so that they can be used in practices that have patients under the care of Black Country Partnership Foundation Trust. These are mainly around the use of ADHD and dementia drugs.

A member commented that it would not be appropriate for this APC to start looking at other organisations documentation as this would then apply to Coventry & Warwickshire, Staffordshire and Worcestershire. Sandwell and West Birmingham CCG come under the BSSE APC and their member practices should therefore use the ESCAs developed by this APC.
The complication is that Black Country Partnership FT is also commissioned to provide services to Dudley, Wolverhampton CCGs and parts of SWB CCG. Their ESCAs already go to Dudley's APC and Wolverhampton's APC, but to date these have not come to this APC.

It would be more straightforward if they were to use the BSSE APC

documents for SWB CCG, and this may be facilitated following the forthcoming merger with Birmingham Community Healthcare FT and Dudley and Walsall Mental Health Trust, and will then be part of this APC. The consensus view was that if these ESCAs are to be used in SWB CCG, they should be ratified by BSSE APC.

**ACTION**:

- **Inform Black Country Partnership FT Trust that any ESCA documentation to be used in SWB CCG needs to be considered and ratified at BSSE APC.** **APC sec**

3. **Change of Sandwell & West Birmingham Hospitals NHST APC representative.**
   Professor Robin Ferner announced that this was his last meeting as representative for SWB Hospitals NHST and that he would be replaced by Dr Angus Mackenzie.

   The chair and the members present thanked Prof Ferner for his valuable contribution to the committee since its foundation in June 2014; this was demonstrated by a round of applause.

The Chair thanked the members for their input today. The meeting closed at 16:30.

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