AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 12h April 2018
Venue – Birmingham Research Park
Vincent Drive, Birmingham, B15 2SQ+

PRESENT:

Dr Lisa Brownell	BSMHFT (Chair)
Dr Paul Dudley	Birmingham and Solihull CCG
Prof Mark DasGupta	Birmingham and Solihull CCG
Satnaam Singh Nandra	Birmingham and Solihull CCG
Liz Thomas	Birmingham and Solihull CCG
Dr John Wilkinson	Birmingham and Solihull CCG
Dr Sonul Bathla	Sandwell & West Birmingham CCG
Hannah Peach	Sandwell & West Birmingham CCG
Dr Angus Mackenzie	Sandwell & West Birmingham Hospitals NHST
Tania Carruthers	UHB NHS FT HGS
Carol Evans	UHB NHS FT HGS
Dr C. Kartsios	UHB NHS FT HGS
Nigel Barnes	BSMHFT
Dr Emma Suggett	UHB NHS FT QE
Prof Jamie Coleman	UHB NHS FT QE
Narinder Rahania	Birmingham Women's and Children's NHS FT
Ravinder Kalkat	Midlands & Lancashire CSU
Kuldip Soora	Midlands & Lancashire CSU
Babatunde Kikiowo	Midlands & Lancashire CSU

IN ATTENDANCE:

Dr Alexandra Sinclair for item 0418/05	UHB NHS FT QE
Prof Wasim Hanif for item 0418/07	UHB NHS FT QE

No.	Item	Action

0418/01 **Apologies for absence were received from:**
Jonathon Boyd, Sandwell & West Birmingham CCG (deputy attended)
Kate Arnold, Birmingham and Solihull CCG (deputy attended)
Dr Neil Bugg, Birmingham Women's and Children's NHS FT
Dr Sangeeta Ambegoakar, Birmingham Women's and Children's NHS FT
Melanie Dowden, Birmingham Community Healthcare NHS FT
Jeff Aston, Birmingham Women's and Children's NHS FT

It was confirmed that the meeting was quorate.

0418/02 **Items of business not on agenda** (to be discussed under AOB)

- Dental prescribing
- Daclizumab MHRA drug safety alert
- APC nutrition formulary update
- Fiasp® feedback on decision
- GPs and ESCA workload
- Suitability of abbreviated applications

0418/03 **Declaration of Interest (DoI)**
There are no outstanding annual declarations of interest from members. The applicant for item 0418/07 has declared interests in Novo Nordisk Ltd.

0418/04 **Welcome and Introductions**
The Chair welcomed everyone to the meeting today. Introductions around the table were carried out for the benefit of the new attendees.
The Chair reminded members, that the meeting is digitally recorded for accurate minute taking and once the minutes are approved, the recording is deleted by the APC secretary.

0418/05 **Flunarizine tablets – New Drug Application –** Janssen-Cilag Ltd
The APC secretariat highlighted that an APC member gave feedback following circulation of the application to all members. They have concerns over flunarizine with GPs not being supportive of prescribing in primary care due to lack of evidence and it being an unlicensed preparation. They are supportive if restricted to hospital prescribing only.

It was established that there were no Declarations of Interests for Janssen-Cilag Ltd.

The Chair welcomed Dr Alexandra Sinclair, Consultant Neurologist, UHB NHS FT QE to the meeting and invited her to present the application for flunarizine tablets.

The Chair also confirmed that Dr Sinclair is proposing that Flunarizine be given an AMBER status to which Dr Sinclair affirmed.
Dr Sinclair explained that the complex tertiary referral headache service within the Trust is the only one within the West Midlands, seeing patients from a large catchment area. Most patients that are seen present with Chronic Migraine. Treatment is guided by the NICE Guideline CG150 document and the profile of the patient. Most patients are treatment-resistant to conventional therapy and find that their migraine is very disabling. It is the second most disabling condition according to WHO, leading to repeated GP visits and missing time off work. This is a loss to the economy and the NHS.

Flunarizine tablets are not licensed in the UK and licensed in Ireland and America. Dr Sinclair explained that flunarizine would be restricted to chronic refractory patients when the treatments in the NICE guideline have been ineffective.

Invasive and non-invasive neuromodulation is another treatment option, however can cost up to £20,000. Flunarizine tablets are established, having been available for a long time with good experience of use in Europe. The most common side effect is weight gain. Flunarizine may exacerbate depression and is contraindicated in Parkinson's disease.

Dr Sinclair continued, stating that there have been two small clinical trials head-to-head with topiramate and propranolol in which flunarizine was proven to show non-inferiority. They are not large enough to do a Cochrane review but there is a Cochrane review in children which showed flunarizine to be effective. She added that there are unlikely to be large trials with flunarizine as it is an older medicine. The cost of flunarizine tablets at UHB NHS FT QE is £15.93 monthly comparable to propranolol at £9 monthly and topiramate can range from £3 to £100 monthly dependant on dose and formulation. Dr Sinclair referred to the NICE Evidence summary ESUOM33, stating that this was a useful reference for prescribers. She went on to say that flunarizine is a commonly used drug in headache services around the UK where the current licensed medications are not effective.

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

- A member asked if in Europe, flunarizine is used in refractory patients or earlier in the treatment pathway. Dr Sinclair explained that it is used earlier as it is well tolerated and inexpensive. She explained that because there is a NICE guideline in the UK, the first and second line options are considered before using the third line agents. Third line agents are for example candesartan which is used off-label for this indication.
- A member asked if a RED formulary status would be acceptable as there may be cost implications in primary care. Dr Sinclair agreed RED was acceptable and indicated that she does not anticipate a large number or patients being prescribed flunarizine, approximately eight to ten patients per year. Other members also confirmed that their primary care colleagues will be uncomfortable prescribing what could not be found in the BNF.
- Dr Sinclair confirmed that she expects flunarizine to be used in a niche group of patients requiring specialist input under the management of her service.
- Another member asked if there are any monitoring requirements. Dr Sinclair said there is no specific monitoring for flunarizine however monitoring of the condition and assessing efficacy of the medication is carried out using headache diaries, headache disability scoring, frequency and duration of pain. A member asked if this requires any specialist input to which Dr Sinclair responded that the service includes a specialist headache nurse, who contacts patients via telephone to monitor their condition. She is not a prescriber however there is currently a nurse undergoing training to prescribe.
- A member enquired how long patients would be taking flunarizine for suggesting that it could be for years. Dr Sinclair confirmed that this is possible as these patients are often refractory to conventional treatment.

She anticipates that if patients are responsive to flunarizine it would be titrated up to therapeutic dose and maintained for 6-12 months. Patients would then be gradually weaned off it.

- A member raised the issue of a patient running out of their medication out of hours. Would community pharmacies be able to procure it? Dr Sinclair stated that her patients are advised that they must indicate one to two weeks before they run out of any medicines. She said from her experience, these patients are very motivated to understand and manage their condition. Dr Sinclair added that from a safety point if a patient misses the mediation for a few days there is no complication.
- A member of the APC asked where else in the UK is flunarizine used. Dr Sinclair stated it is used in London, Stoke and other places. She added that she sits on different specialist committees in the UK and can confirm flunarizine is commonly used. A member of the APC confirmed an internet search showed the medication is used in other headache specialist centres in the UK.
- A member raised that there are lot of options particularly for those drugs that could be used off-label for this indication. Dr Sinclair said that the patients side effect profile would also steer choice of treatment. Different classes of drug are tried and flunarizine being a calcium channel blocker is often effective where patients have not responded to other agents due to its distinct mode of action.

The Chair thanked Dr Sinclair for attending the meeting, for answering all the questions from the APC members and advised her 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 commented that the drug was introduced to the market by Janssen-Cilag in 1968 however it was not clarified for what indication.

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

Patient Safety: Potential for weight gain, extrapyramidal symptoms.
Few interactions noted.

Clinical effectiveness: Unlicensed in the UK. Two small-scale studies indicating non-inferiority to other prophylactic agents.

Strength of evidence: Small scale evidence not deemed robust. Comparable to other preventative treatments for migraine e.g. tricyclic antidepressants based on historical data

Cost-effectiveness or resource impact: Cost per dose is £2.40 per dose at £1,300 for single year treatment before it gets into primary care. Unpredictable in primary care.

Place of therapy relative to available treatments: 3rd or 4th line agent.
Patient to have tried or found to be intolerant to first-line preventative agents.

National guidance and priorities: NICE Evidence summary

Local health priorities: CCGs supportive if restricted to specialist use only

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: Specialist use only

Decision Summary: RED Rationale: Specialist input required. Small patient numbers anticipated.

ACTIONS:

- **Relay decision to Dr A. Sinclair by Thursday 19st April 2018.** **APC sec**
- **Add flunarizine to the formulary as RED** **APC sec**

0418/06 Zindaclin® (clindamycin gel) abbreviated application – Crawford Healthcare Ltd

It was established that there were no Declarations of Interests for Crawford Healthcare Ltd.

The APC secretariat explained that this was an abbreviated application form for clindamycin gel to manage the long-term supply issues with clindamycin 1% solution. Stock of clindamycin solution is not expected until mid-2019. The applicant proposes Zindaclin® gel to replace the current formulary medicine, clindamycin 1% solution as a temporary measure whilst it is unavailable.

The patient group has been defined as patients who would normally be prescribed the topical solution and in whom the lotion is not appropriate.

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

- A member noted that the product was on the APC Primary Care Antimicrobial Guidelines 2017 as a third line agent for acne.
- It was agreed that this was a pragmatic solution to the supply issues.
- A DST was not deemed necessary.

Decision summary: Zindaclin® approved on formulary for acne. To be reviewed in 12 months to assess supply issues with clindamycin 1% topical solution.

ACTIONS:

- **Relay the decision to Dr A Heagerty by Thursday 19th April 2018.** **APC sec**
- **Add Zindaclin® to the formulary as GREEN and review in 12 months.** **APC sec**

0418/07 Tresiba® (insulin degludec) – New Drug Application – Novo Nordisk Ltd

It was highlighted that the applicant has declared interests in Novo Nordisk Ltd. The applicant has stated that for 2016-2017 details of benefit include “Research grant and clinical trial, travel grants and consultancy.”

It was established that there were no declarations of interests from the APC members for Novo Nordisk Ltd.

The Chair welcomed Prof Wasim Hanif, Consultant Diabetes and Endocrinology, UHB NHS FT QE, to the meeting and invited him to present the application for Tresiba®.

Prof Hanif explained the application is to extend the use of Tresiba® to Type 2 diabetics particularly to reduce recurrent hypoglycaemia. Tresiba® is currently AMBER for Type 1 diabetics supported by a RICaD. Further clinical trials have been published recently with regards to this insulin reducing hypoglycaemia. This insulin has a flat profile and Prof Hanif believes this would benefit Type 2 diabetic patients who have severe hypoglycaemia hence reducing hospital admissions. These patients in particular are those who have a hypoglycaemic attack requiring third party assistance and who are admitted more than twice for hypoglycaemia despite being on Lantus® or another long acting insulin.

Prof Hanif stated that hospital admissions from UHB NHS FT QE show more Type 2 diabetics are admitted for severe hypoglycaemia than Type 1 diabetics. Prof Hanif said that Tresiba® is cost neutral to Lantus®. Prof Hanif stated he has data of approximately fifty patients with Type 1 diabetes that were treated with Tresiba® and avoidance of re-admission occurred in fourteen of these patients. Three of these Type 1 diabetes patients avoided treatment with an insulin pump.

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

- A member asked with regards to the SWITCH 2 trial, the application states the results are statistically significant but are the results clinically significant? Prof Hanif stated that he believes the results would be more clinically significant than what is shown in the clinical trial when applied to the real life clinical situation. He stated that his application includes clinic data of 50 patients who showed reductions in hypoglycaemia with Tresiba®. In addition, 14 patients avoided inpatient admission.
- A member commented that in the SWITCH 2 trial the primary end point is severe hypoglycaemia requiring medical intervention however the difference between the two groups was found not to be significantly different. There is no evidence to suggest a reduction in hospital admissions. Prof Hanif replied that the definition of severe hypoglycaemia is of a patient requiring third party assistance. The number of patients within the trial who experienced severe hypoglycaemia was very low therefore not found to be statistically significant. Clinically, the numbers of patients seen who have severe hypoglycaemia or recurrent hypoglycaemia is very high therefore Prof Hanif believes Tresiba® would be beneficial. He referred to his clinic data once more.
- A member wanted to confirm if Tresiba® is equally as potent as the other 100 units/mL insulins. If a patient had a Hba1C within range but was having frequent hypoglycaemia attacks, would the clinician need to initiate Tresiba® by reducing the dose by 8-10%. Prof Hanif agreed that he would reduce Tresiba® then titrate up to be on the safe side.
- A member considered the trial data to show only moderate gains with Tresiba®. Prof Hanif stated that patients' quality of life is severely affected with recurrent hypoglycaemias so despite the trial data he believes Tresiba® will be beneficial.
- A member stated the RICaD should say insulin degludec followed by the brand name in brackets rather than the other way around. Prof Hanif stated that propriety names are more important with insulin preparations due to an increased risk of errors as per the NPSA patient safety alert. It was clarified that if approved, the RICaD would be developed separately as per APC process.

- A member asked with regard to the patient cohort, would nocturnal hypoglycaemia be classified as severe or non-severe hypoglycaemia? The reason asked was for clarity if the two groups; those with nocturnal hypoglycaemia would also come under severe hypoglycaemia or are they two distinct patient groups. Prof Hanif explained that nocturnal hypoglycaemia needs to be defined separately to daytime hypoglycaemia due to for example DVLA guidance. He confirmed that the patient cohort defined relates to nocturnal severe hypoglycaemia, which requires third party assistance.
- A member suggested at the risk of extending the indication, another group of patients at risk of severe hypoglycaemia would be those elderly, housebound patients that rely on a nurse to administer their basal-bolus insulin. Sometimes, these patients aren't admitted when found by the nurse having had a hypoglycaemia attack. However, would Tresiba® benefit them? Dr Prof Hanif agreed and added that due to the longer half-life, Tresiba® would be an advantage as it can be given later in the day. A member stated however, that de-intensifying the insulin is not the answer to hypoglycaemia as this will lead to more cumulative risks. Therefore Tresiba® should be confined to those niche patients with capricious blood glucose control where an alternative agent is required.
- A member asked for clarification regarding patient cohort; are the patients with Type 2 diabetes who have nocturnal or severe hypoglycaemia and the group being readmitted with more than two episodes per year part of the same group or separate? Prof Hanif confirmed these were two separate groups i.e. those admitted with over two episodes per year have not necessarily have severe hypoglycaemia requiring third party assistance.
- A member suggested that Tresiba® is not cost-neutral to Lantus®, it is slightly more expensive. Lantus® is approximately 75% the cost of Tresiba®. Prof Hanif agreed that there was a difference in price and his figures were perhaps not up-to-date. However, if a QALY was undertaken he believed overall, Tresiba® would show cost effectiveness. Prof Hanif clarified that the cost of Tresiba® would be mitigated by fewer hospital admissions.
- A member asked if there was evidence of patients being admitted less frequently with Tresiba® than biosimilar glargine? Prof Hanif referred to his clinic data which showed Type 1 diabetes patients had fewer admissions with Tresiba®.
- A member stated that all the evidence quoted use Relative Risk Reduction (RRR) as opposed to Absolute Risk Reduction (ARR). The RRR values quoted are small. Were ARR available in the trials as they are not stated in the application? Prof Hanif stated that even the smallest ARR is potentially beneficial to this group of patients who are at very high risk of severe hypoglycaemia. The member asked what the Number Needed to Treat (NNT) was to prevent one admission with Tresiba®. Prof Hanif stated that out of fifty Type 1 diabetes patients, fourteen patients avoided inpatient admission. The member asked if this would be the same for Type 2 patients. Dr Hanif stated that it would be as the cohort of Type 1 patients using Tresiba® is similar to those Type 2 patients who would be using Tresiba® i.e. those patients who are having recurrent admissions or those with severe hypoglycaemia.
- A member asked if a patient's social circumstances could lead clinicians to consider Tresiba® earlier in the treatment pathway? Prof Hanif stated that it would depend on what the RICaD is approved for and that only the defined cohort of patients would be considered for Tresiba®.

- A member asked how was the number, fourteen patients who have avoided inpatient admission with Tresiba®, was determined. Prof Hanif explained that Type 1 diabetes patient's admissions were looked at; i.e. compared to preceding period. Also, the number of patient who were going to be considered for insulin pump who were instead initiated on Tresiba®.

The Chair thanked Prof Hanif 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 for Type 2 patients we would not consider avoidance of insulin pump treatment by using Tresiba® as an option like It would be considered in Type 1 patients, therefore the decision to accept Tresiba® for Type 2 diabetics becomes more difficult. From experience more Type 2 patients are being admitted with recurrent hypoglycaemia than before. Tresiba® has a flatter basal profile with a long pharmacodynamic half-life which would logically may benefit these Type 2 patients i.e. those who forget to take their insulin. The SWITCH 2 study states that given the negative consequences associated with hypoglycaemia any basal insulin associated with a better kinetic profile would represent an advance in therapy. A small proportion of Type 2 patients may benefit with Tresiba®.
- A member stated that there are DiCE (Diabetes in Community Extension) clinics where hospital consultants manage difficult diabetes patients in primary care in surgery with the GP. Therefore, will these consultants be able to prescribe Tresiba®. It was clarified that they would be able to if accepted onto the formulary as AMBER, however only for the cohort accepted. The member thought that across primary care availability of Tresiba® could therefore affect many more patients than anticipated.
- The question as to whether a full application was needed was raised; was there enough evidence presented in the abbreviated application? Some members believed that it is unlikely that a full application would have led to more evidence being presented to the APC.
- It was clarified that Tresiba® was being proposed if insulin glargine has been ineffective at reducing hypoglycaemic episodes
- It was raised whether the clinician should be allowed to use Tresiba® in a certain cohort of patients for a certain time period and then invited to present further evidence that Tresiba® reduces inpatient admissions, similar to how this evidence was presented for use of Tresiba® in Type 1 diabetics. Members agreed that the clinic data included in the application does not offer any statistical evidence. A member raised that the numbers that would be given from a single trust would not be significant or provide robust evidence. It was added that hospital clinics are not set up to collect evidence and it may not be appropriate to request this.
- It was agreed that there was insufficient evidence to suggest Tresiba® can reduce hospital admissions. It was added that the application proposed to use Tresiba® in patients with severe hypoglycaemia, however the presented evidence for this indication was also deemed insufficient.
- It was agreed that there was assumption made that the presented data will translate into better quality of life and reduced hospital admissions.
- A member raised whether the defined patient cohort could be made smaller to those who had two episodes per year whilst other data is being

collected to review at a later date. It was agreed that this might encourage patients to visit hospital whereas the aim should be to prevent admissions.

- A member pointed out that the RICaD supporting the application states *Transfer to Primary Care should not happen until specialists can demonstrate reduction in hypos (e.g. after 3-4 months).*
- A few APC members raised concern about creep of prescribing in primary care.
- A member highlighted that there are tools that can mitigate risk of creep including the Decline to Prescribe forms and the supporting RICaD.
- A member proposed to accept as AMBER with RICaD and review the evidence in six months.
- A member stated that we need to review the drug as the data stands currently, i.e. lack of evidence in severe hypoglycaemia. It was added that there are pharmacokinetic reasons to suspect that Tresiba® would be effective.
- A member highlighted that Tresiba® was declined for addition to the formulary for Type 2 diabetics a year ago as there was no robust evidence of a clear benefit.
- A member raised concern that a RED status with a view to review data would not be appropriate. What would patients do if they ran out of insulin out-of-hours? A member said according to the RICaD prescribing would be restricted to secondary care for 3-4 months anyway so the risk is there as well. A member stated that GPs would not refrain to prescribe Tresiba® or any insulin if a patient had run out.
- A member commented that for each individual patient there needs be a n=1 trial that demonstrates it is effective for that patient before it becomes available to prescribe in primary care.
- The Chair concluded that some members viewed that Tresiba® should be non-formulary until more robust evidence comes to light. Another option was to accept as RED and invite the applicant to come back to APC in 6 months with more evidence. AMBER was acceptable by fewer members of the APC due to lack of evidence in this cohort of patients. The decision was put to a vote.

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

Patient Safety: No issues over existing insulin preparations.

Clinical effectiveness: Effective in type 2 diabetes. Evidence of marginal benefit of reduction in hypoglycaemic attacks but no significant difference in severe hypoglycaemia.

Strength of evidence: Well-constructed cross over trial.

Cost-effectiveness or resource impact: 2 per 10,000 patients in primary care. Cost of preparation may increase relative to alternatives available. Lantus® is approximately 75% the cost of Tresiba®.

Place of therapy relative to available treatments: 4th tier for Type 2 diabetes. Recurrent severe hypoglycaemia (requiring third party intervention) where glargine has been ineffective.

National guidance and priorities: Type 2 diabetes high priority.

Local health priorities: Concerns about creep in prescribing.

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: RED specialist use only. Applicant to be invited to provide full application in 6 months with internal clinical data and/or more trial evidence.

Decision Summary: RED status. Rationale: There were concerns over the lack of statistically significant evidence that supported the claim of reduction in severe hypoglycaemia and reduction in hospitalisations. The committee noted that local clinical experience suggests better results than those shown in the trial data.

ACTIONS:

- **Relay decision to Prof Hanif by Thursday 19th April 2018.** **APC sec**
- **Add Tresiba® to the APC formulary as RED for Type 2 diabetes.** **APC sec**

1418/08 APC membership list - For ratification

The APC secretary referred members to the BSSE APC Committee Members document. The APC secretary asked if members would approve the recently updated document. It has been updated due to members leaving and joining the APC. Some members organisation names had been updated following mergers.

- A secondary care representative explained that representation of UHB NHS FT QE and UHB NHS FT HGS should be maintained separately for at least twelve to twenty-four months. Representation for the UHB NHS FT at the APC would need to be considered at a later date.
- A CCG representative echoed this view in respect to the merger of their own organisation.
- Discussions needed to take place about quorum of the APC which would impact on the member list therefore it was agreed that no changes to member organisations should occur at this stage.
- There was further discussion about which members represented which organisation and some omissions of members from the list.

ACTIONS:

- **APC membership list to be approved at a later meeting.** **APC sec**

0418/09 BSSE APC Prucalopride RICaD – For ratification

The APC chair explained that prucalopride was approved for use in men following an abbreviated application in March 2018. The RICaD which originally restricted use to women only has been amended to reflect this decision and now states 'Adults'.

The Chair invited questions or comments from members.

- The RICaD was approved for publication on the formulary website.

ACTIONS:

- **Publish prucalopride RICaD on the formulary website** **APC sec**

0418/10 Minutes of the meeting held on 8th March 2018 – for ratification

The minutes of the meeting held on Thursday 8th March 2018 were discussed for accuracy.

- Page 2, 3 and 4: A member raised that there was inconsistency in titles when referring to individuals.

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

The DSTs for Fiasp® and Velphoro® were also approved for publication.

0418/11 Matters Arising

The Chair moved onto the action table for comments and updates:
(See separate document for updated version). Consider actions closed if not discussed.

The outstanding actions include:

- 0318/09 BSSE APC Cardiology RICaDs due for review. Arrange an away day for members. Update: Doodle poll to be sent to members in the next few weeks.
- 0218/15 Matters arising – Invicorp® NDA: Follow up with clinician again for an updated DOI and highlight next steps to be taken if a response not received within 2 weeks. Update: DoI received within two-week time frame.
- 0318/AOB – Black Country Partnership ESCAs for ratification Update: proposed actions have been postponed due to additional information became available. Update: It was clarified that the Black Country Partnership Trust falls under Sandwell and West Birmingham CCG. Solihull CCG had some ESCAs approved by BSSE APC therefore it is proposed that the BCP NHSFT ESCAs are also ratified by ACP. To be discussed outside of the APC meeting.
- 1216/11 Matters arising – enoxaparin Update: No further progress has been made regarding a business case from Trusts however now trusts have merged this should be more forthcoming.

0418/12 NICE Technological Appraisals (TAs)

In March 2018, there were 7 TAs published; of these, 5 are NHSE commissioned, 1 is not recommended and 1 is CCG commissioned.

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

Any other business:

1. Dental prescribing
It was proposed that for rarer dental items ESCAs should be created by condition rather than for each individual drug. Members agreed this was reasonable. It was raised that these ESCAs would have to be streamlined in a way that the drugs they encompass should have the same monitoring requirements as well as some other criteria.

2. Daclizumab alert

Daclizumab is currently listed as a RED agent on the formulary. NICE have withdrawn the NICE TA441 because the company have withdrawn marketing authorisations of daclizumab. It was agreed that Daclizumab status should be amended to BLACK.

ACTION

- **Amend daclizumab formulary entry to BLACK** **APC sec**

3. ONS update email

The APC secretariat has received an update regarding the nutrition formulary which was relayed to members.

4. Fiasp® feedback on decision

Feedback from the applicant for Fiasp®, which was accepted as RED on the formulary following the March meeting, was relayed to APC members. It was agreed that this discussion would be deferred to the next meeting as there was limited time available.

5. GPs and ESCA workload letter

UHB NHS FT QE received information from epilepsy specialists saying that drugs that had already been initiated and maintained with ESCAs in primary care had been discontinued which may lead to significant harm. CCG representative to action outside of APC.

6. Suitability of abbreviated applications and full applications

ACTION

- **Add as agenda item at the Away day.** **APC sec**

0418/12 NICE Technological Appraisals (TAs)

In March 2018, there were 9 TAs published; of these, 5 are NHSE commissioned, 3 is not recommended and 1 are CCG commissioned.

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

The Chair thanked the members for their input today. The meeting closed at 17:15.

Date of next meeting: Thursday 10th May 2018 14:00 – 16:45
Birmingham Research Park.