AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 11th October 2018
Venue – Birmingham Research Park
Vincent Drive, Birmingham, B15 2SQ

PRESENT:

Dr Paul Dudley	Birmingham and Solihull CCG (Chair)
Prof Mark DasGupta	Birmingham and Solihull CCG
Satnaam Singh Nandra	Birmingham and Solihull CCG
Dr Nashat Qamar	Birmingham and Solihull CCG
Liz Thomas	Birmingham and Solihull CCG
Dr Sonul Bathla	Sandwell & West Birmingham CCG
Jonathan Boyd	Sandwell & West Birmingham CCG
Dr Angus Mackenzie	Sandwell & West Birmingham Hospitals NHS FT
Carol Evans	UHB NHS FT/ Birmingham and Solihull CCG
Gurjit Kudhail	UHB NHS FT
Jeff Aston	Birmingham Women's & Children's NHS FT
Dr Neil Bugg	Birmingham Women's & Children's NHS FT
Dr Sangeeta Ambegaokar	Forward Thinking Birmingham Partnership
Nigel Barnes	BSMHFT
Dr John Wilkinson	Birmingham and Solihull CCG
Ravinder Kalkat	Midlands & Lancashire CSU
Daya Singh	Midlands & Lancashire CSU
Kuldip Soora	Midlands & Lancashire CSU

IN ATTENDANCE:	
Dr Saiju Jacob for item 1018/05	UHB NHS FT
Marie Orford for item 1018/06	UHB NHS FT
Carolyn Patchell for item 1018/06	Birmingham Women & Children's NHS FT
Prof. Anita Macdonald for item 1018/06	Birmingham Women & Children's NHS FT
Steve Kitchen for item 1018/06	Birmingham Women & Children's NHS FT

No.	Item	Action

1018/01 Apologies for absence were received from:

Dr Lisa Brownell, BSMHFT
Prof Jamie Coleman, UHB NHS FT
Inderjit Singh, UHB NHS FT, deputy attended
Katy Davies, UHB NHS FT
Mary Johnson, SES & SP CCG
Kate Arnold, Birmingham and Solihull CCG

It was confirmed that the meeting was quorate.

1018/02 Items of business not on agenda (to be discussed under AOB)

- GP CQC inspections and shared care arrangements
- Trimovate® cream
- Loperamide melts
- Selegiline oral lyophilisate

1018/03 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.

1018/04 Welcome and Introductions

The Chair welcomed everyone to the meeting today.

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.

The APC would like to thank Satnaam Singh Nandra for his contributions to the committee.

1018/05 Neurology immunosuppressants – application forms – Dr Saiju Jacob, Consultant Neurologist, UHB NHS FT

It was established that there were no Declarations of Interests.

The application forms for the use of azathioprine, ciclosporin, methotrexate, mycophenolate and tacrolimus in neurology indications were circulated with the papers for the meeting, along with draft effective shared care arrangement (ESCA) documents for each drug application.

The Chair welcomed Dr Saiju Jacob, Consultant Neurologist, UHB NHS FT, to the meeting and invited him to present the applications.

Dr Jacob began explaining he aims to gain approval for the use of ESCAs for these agents for neurology indications, so the prescribing is shared with primary care. There is historical use of these immunosuppressants within the neurology speciality. They are currently being used regularly in the neurology clinic at QE and other centres across the region. Dr Jacob explained that azathioprine, methotrexate and mycophenolate are the most commonly used drugs in neurology conditions whereas tacrolimus and ciclosporin are used

less. Dr Jacob mentioned that he receives a phone call or an email from a GP on average every week for an ESCA. He currently understands there are ESCAs in place for these drugs for rheumatology conditions but not for neurological conditions. Dr Jacob understands not all GPs would be willing to participate in the ESCA and for these patients he would continue to prescribe and monitor the patient as he currently does. The most commonly used indication listed is Myasthenia Gravis which is a condition of the neuromuscular junction. Dr Jacob emphasised that the cost of the drugs is not an issue as these drugs are not as expensive as some of the other drugs used in neurological conditions. Dr Jacob explained the biggest problem he faces is monitoring and he is happy to assist primary care colleagues on dose adjustments if they monitor drug levels.

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

- A member mentioned that the ESCAs presented are standardised across the immunosuppressants which is good for training GPs as they will become familiar with the use of these agents.
- A member asked whether the discontinuation criteria for these drugs are the same as when they are used for other indications. For example is the discontinuation criteria for azathioprine the same as when used in rheumatology. Dr Jacob replied that discontinuation criteria would be the same as these ESCAs were adapted from the rheumatology ESCAs.
- A member raised that one of the monitoring requirements for ciclosporin is blood pressure monitoring and urea and electrolytes (U&Es) every two weeks for three months and felt this frequency of monitoring would be challenging for GPs to arrange. It was asked whether this could be changed as it could impact GP workload.
- Dr Jacob explained that during the first three months more frequent monitoring is required until the patient is stable, and this would be within a hospital setting. However, the main issue Dr Jacob faces is the ongoing monitoring beyond three months.
- Dr Jacob explained there are many patients stable on these medicines for approximately ten years but are still seen in his hospital clinic.
- Dr Jacob mentioned that he prescribes for patients all over the country and there are GPs willing to take on the prescribing of these drugs as long as there is an ESCA in place in these regions.
- A member pointed out the tacrolimus ESCA mentions to refer to the clinic letter for monitoring. Dr Jacob replied that monitoring for tacrolimus is predominately secondary care. He would only expect primary care to monitor if the patient was living far away from clinic making it difficult to attend clinic appointments. However, the responsibility of what to do regarding the levels would remain with the secondary care clinician.
- A member asked whether all these drugs are licensed to be used for the conditions as outlined in the ESCAs. Dr Jacob replied he does not expect the agents to be licensed for all of the stated conditions as they are all rare conditions, besides myasthenia gravis.
- A member raised as rare conditions, not all GPs would know what to look out for and GPs would be taking on this responsibility when signing the prescription. Dr Jacob replied that they would not be discharging any of these patients back into primary care. He does not expect primary colleagues to monitor the primary condition but would expect them to monitor the changes in blood levels.

- It was raised that it is easier to monitor disease activity when a patient has flare ups in gastrointestinal disease or rheumatology conditions whereas monitoring in neurological conditions would be more difficult to recognise.
- Dr Jacob was asked how accessible he would be if problems were to occur to which he replied he is very accessible either by phone or email. He mentions the Trust has a specialist nurse who can also deal with any queries.
- A member stated existing ESCAs have been issued for relatively common conditions that are suitable for shared care but the proposed ESCAs are for very rare conditions. In addition, it is more difficult for GPs to take on the shared care and responsibility of prescribing for unlicensed medications as the ethical body requires a GP to be certain that there is an evidence base for the prescribing of unlicensed medicines. Dr Jacob replied he does not mind prescribing these agents; the main difficulty is getting patients to undertake blood tests particularly as some patients travel long distances and he believes this is unfair to patients. Some of these patients are from outside the BSSE area. Dr Jacob stressed that this is the main issue that needs to be resolved.
- A member acknowledged this but asked whether patients within the BSSE area are affected. Issues coming under other areas would need to be resolved with teams in those areas. Dr Jacob replied this problem occurs in all areas. He mentions that GPs are willing to prescribe but ask him for a formally approved document like an ESCA.
- A member raised that a few years ago immunosuppression prescribing and monitoring for solid organ transplantation was brought back into secondary care. As this is a similar theme for rare conditions, what is the difference between the two conditions for this to be managed as shared care whereas the solid organ transplantation cannot. Dr Jacob replied that the side effect profile is different for transplants compared to neurological conditions. Profound neutropenic sepsis is one of the side effects that can occur in solid organ transplant patients compared to neurological conditions where it rarely occurs. The underlying condition does make a difference to the side effect profile.
- A member highlighted that on the ESCA, where it states *Confirm the diagnosis of Autoimmune Neurological Disease (includes among others – Myasthenia Gravis, CIDP…etc*, the term 'etc' after the indications are listed may be unsuitable and cause for concern for GPs taking on the agreement. Dr Jacob replied in the last ten years they have had several new antibodies and are likely to discover more antibodies in the near future. Therefore, changes would need to be made to the indications and the ESCAs would need to be brought back to APC frequently.
- A member asked whether Dr Jacob is aware of any situations where GPs would prescribe tacrolimus or mycophenolate for other conditions in primary care for patients who are managed in secondary care i.e. similar monitoring arrangement to what is being proposed. Dr Jacob responded that mycophenolate is probably used but is not sure about tacrolimus as this is predominately used in the transplant setting. He has a very few patients on tacrolimus but would like to see ESCAs approved for azathioprine, mycophenolate and methotrexate and would be happy to retain tacrolimus and ciclosporin.
- Dr Jacob added that many patients with autoimmune neurological diseases would not be on immunosuppressants for life apart from myasthenia gravis patients.

- A member asked If the secondary care clinician is continuing to prescribe as suggested then is it a shared care agreement or ESCA which is needed? Dr Jacob responded that he would be happy to continue prescribing if primary care colleagues are not and would be happy to advise on dose adjustments if GPs only undertake the monitoring.
- A member asked if the GP takes on monitoring, then how from a practical point of view would you be able to get the blood results? Dr Jacob responded that usually he would ask the patient to take a copy of the blood test results from the GP and ask the patient to bring it in to the clinic appointment.
- It was acknowledged that this arrangement of obtaining blood test results may lead to duplication and mistakes.

The Chair thanked Dr Jacob 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 raised in some areas GPs have declined shared care for all high-risk drugs over Care Quality Commission (CQC) concerns over the local management of these ESCAs. This would be discussed further under Matters Arising.
- A member raised that Dr Jacob stated there are a number of GPs who are willing to take on the prescribing of the drugs, but we have not been able to facilitate this due to not having the ESCAs.
- A member responded to provide consistency within primary care it is understood the ESCAs that have been ratified by the APC have been considered by a group of piers as suitable for primary care prescribing. The range of response from GPs regarding these ESCAs would be much wider due to the complexity of the conditions involved.
- A member raised that some GPs are not participating in shared care with some of the current ESCAs regardless of how common the condition. Therefore, those GPs who would like to participate in shared care arrangements should be enabled to do this perhaps despite the complexity of the condition.
- A member raised further work is needed to help standardise ESCAs to facilitate the training of GPs. The number of patients that on immunomodulators over the coming years will increase.
- A member raised that GPs participate with immunosuppressant agent ESCAs for conditions they recognise such as rheumatoid arthritis and crohn's disease as they can recognise adverse effects. However, the neurology conditions listed are very rare and most primary care colleagues will not recognise them. GPs want to be comfortable and confident with the condition before considering prescribing the treatment.
- It was expressed if more patients are seen in primary care than secondary care with this arrangement there is a chance something could be missed that would perhaps have been picked up in secondary care.
- A member stated that a decision needs to be made regarding who undertakes the prescribing considering both the workloads in secondary care and GPs undertaking work beyond their area of expertise.

- A member raised that it is not always the consultant dealing with the repeat prescriptions in hospital and it is common for highly trained specialist nurse practitioners to be doing so, which is a much more pragmatic solution.
- Members agreed the inclusion of the term 'etc' when describing the indications that could fall under the ESCA needs to be removed to avoid ambiguity. There should be a thought process behind each indication involved in the ESCA.
- A member observed that the applicant stressed patients in other areas were having difficulties and suggested those within BSSE would be less problematic.
- It is recognised that many GPs are willing to participate in shared care agreements. However, the rarity of the conditions listed, the off-license indication of these agents and the blood testing issue that is the applicants main concern will not urge GPs to participate in these ESCAs.
- It was added there are pressures of phlebotomy targets within GP practices.
- A member raised that the ESCAs have asked GPs to monitor patient's response to treatment rather than monitor blood results and feedback.
- Members recognised there is a logistics issue with getting the blood test results from primary care to secondary care particularly if the patient is outside of the region. However, the proposed monitoring arrangement may cause patients more concern and distress, which is the opposite of what shared care agreements intend to do.
- It was clarified that the applicant expressed that he would be content with prescribing the immunosuppressant agents but would like support from GPs to undergo the long term blood testing and monitoring. Members questioned whether this is to be considered a shared care agreement or whether it is a request to facilitate blood monitoring. Members agreed that the latter was pertinent to the applicant and this was not considered a shared care agreement and therefore not considered to be within the APCs remit.

Decision Summary: RED status agreed Rationale: Unlicensed treatments for rare conditions which GPs have little to no experience, small patient numbers.

ACTIONS:

- **Relay decision to Dr Jacob by Thursday 18th October 2018** **APC sec**
- **Update APC formulary to reflect a RED status for the use of immunosuppressants for neurology** **APC sec**

1018/06 BSSE APC Dietetic formulary group documents

BSSE APC Harmonised joint formulary section 9.4 Enteral feeds

The Chair welcomed the Dietetic sub group members Marie Orford, Chair of Dietetic sub group and Prescribing Support Dietitian, Birmingham Community Healthcare NHS Trust, Carolyn Patchell, Head of Nutrition and Dietetics and Specialist Dietitian, Steve Kitchen, Team lead for Metabolic Disorders Dietetics and Professor Anita Macdonald, Consultant Paediatric Dietitian (PKU & metabolic disease), BWCH NHS FT to the meeting and invited them to present the Dietetic Group's recommendations.

Marie delivered a short presentation on the updated recommendations. She explained that the first draft of the formulary was bought to APC in 2016 Dietitians, representing dietetic services across Birmingham, Solihull and Sandwell produced this document at the request of the APC. The sub group members were asked throughout the process to liaise with colleagues and specialists within their organisations to provide expertise in relevant areas. Each section and product reviewed considered cost, using the BNF and Drug Tariff, with rationale provided for each product. Personal preference was not on option for inclusion. Where no clinical benefit between two alike products, the most cost-effective was included.

The first submission was approved as a draft by APC. The dietetic sub group were requested to reduce the number of products in each category, state why any products are excluded or why they are needed, outline use and state cost. The group reduced the number of products as far as possible but these products cover not just malnourished people but a range of clinical conditions. The explanatory section has been expanded, the use of dietary measures included, and first line powder supplements were emphasised as they were found to be the most cost effective for underweight patients. All products reviewed by the Dietetic group had recommendations on monitoring and reference to guidance added where possible.

When considering Gluten free products advice from NHS England's consultation on gluten free prescribing was followed.

The market for nutritional products is constantly evolving. Where clinically effective and cost effective new products were identified and the sub group felt they would be useful to patients they were evaluated by at least two organisations. These products are being put forward for replacement or addition where the evaluation was found to be positive.

Aymes Creme® is a dessert style low volume oral nutritional supplement and is currently priced at £1.17 compared to its comparator Forticreme® which is priced at £1.96. The sub group evaluated Aymes Creme® to have the same clinical benefits and more cost effective than its comparator.

Marie explained that Keyo® is a unique highly specialised semi solid, for conditions requiring a ketogenic diet, e.g. GLUT-1 deficiency syndrome or in epilepsy and this can cost between £4.67 to £6.24. It is not anticipated to be widely used as it is for highly specialised diets. It is a unique product and proposed as an addition to the formulary.

The final product for evaluation was Neocate Syneo® which is an infant formula powder and is amino acid-based. Marie explained the product contains a probiotic to combat dysbiosis, shown by infants with allergies, which may delay oral tolerance and affect development of immune related conditions such as in food allergy and atopic dermatitis.

Other products were not put forward as formulary recommendations due to not evaluating positively.

Expert specialist input was required for recommendations to produce the separate guidance Guidelines for Prescribing Specialist Infant Formula in Primary Care, Metabolic products, section on PKU. Clinicians spend

considerable time explaining to their GP colleagues the requirement for these products as they are costly however they are essential for the very few patients with PKU.

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

- A member asked whether the prices quoted within the formulary document are the prices within community setting or are they prices based on for example a rebate scheme available only to secondary care? An example given was Fortisip® where there was considerable cost difference between the two settings. Marie responded that these are community prices.
- The member asked whether any cost saving schemes available to secondary care could impact on what secondary care prefer to prescribe. For example, hospital might prefer Forticreme® to the recommended Aymes® creme that would be used in primary care when the patient is discharged. It was acknowledged that some acute units may still prescribe products at a discounted price whilst it is available to them. Marie explained the formulary aims to rationalise products to the most clinically cost effective products available to both primary and secondary care. The powdered shakes are recommended as first line in many cases as cost effective, patients find them more palatable and they have been implemented in care homes successfully.
- A member noted that it would be useful if in cases where a more cost effective product is used within secondary care and the patient is discharged to primary care, it should be noted on the discharge letter and communicated to patients that the product may change when prescribed by their GP. Marie emphasised that powders products are being recommended as first line within the proposed formulary for use in secondary and primary care.
- Prof Macdonald added that from a paediatric perspective palatability and compliance is the driving force when recommending a supplement as a supplement given and not taken is worthless.
- A member mentioned that the Wound care sub group implemented a system where hospitals can use dressings available to them, however on discharge, dressings are changed to adhere to the formulary and perhaps the dietetic group follow the same system. A dietetic group member added that the formulary includes a range of options so most patients would be discharged to community on a formulary product. The aim is to provide products that are appropriate to patient need and can achieve compliance.
- With the powdered supplements it was clarified that the cost does not include the cost of milk.
- It was also clarified powdered shakes would not be suitable for lactose intolerant individuals as they contain milk solids. They are also unsuitable for patients with renal failure because they contain high levels of phosphate.
- It was clarified that within the proposed formulary the RAG rating stating *AMBER (Proposal is RED with correct commissioning and resource allocation).* The dietetic group would like these products to remain as AMBER currently, however asking the committee members for their thoughts on whether they would support making these products to become RED, specialist use only, in future. The dietetic team spend a lot of time answering queries from primary care regarding these products and would like to restrict prescribing to specialist only subject

to the correct resource allocation. If agreed the sub group would pursue this by engaging with their trust colleagues. Members welcomed this proposal as PKU and the very specialist areas of nutrition do cause many queries.

- A member asked how do dietetics get involved with the specialist home ordering services? Dietetics are reliant on home delivery services especially for specialist products such as the metabolic products. A controlled trial has been conducted looking into the delivery via pharmacy services versus home services. In speciality areas the home delivery services were found to be safer and fewer errors are made possibly because the products tend to look the same with similar sounding names.
- A member asked why generic sodium chloride ampoules cannot be used to make up some of the products as advised by these home ordering services; the companies recommend certain brands of sodium chloride ampoules which are costly. This is not challenged because patient need is put above cost. A dietetic subgroup member explained that it may be due to the different additives within the different products which may not be suitable. However, the dietetic group will question this as there may be certain products that can be made up using generic sodium chloride ampoules.

Decision Summary: The harmonised formulary section 9.4 enteral feeds and the Guidelines for Prescribing Specialist Infant Formula in Primary Care were approved.

The Chair directed members to the product evaluation for Aymes® creme. The Chair invited questions or comments from members. Discussion points/concerns raised included:

- A member asked whether Aymes® creme and Forticreme Complete® are nutritionally similar? They are similar, there is 12 calories and 1 gram of protein between them.
- There were no further questions.

The Chair directed members to the product evaluation for Neocate Syneo® The Chair invited questions or comments from members. Discussion points/concerns raised included:

- A member raised that there is no indication of cost and the number of patients to be treated using Neocate Syneo®. The group responded that they do not have the data for the potential number of patients to be treated using this product, but it will be used for the dietary management of cow's milk allergy for those who don't tolerate a extensively hydrolysed formula.. The dietetic group anticipate the same number of patients using Neocate LCP would use Neocare Syneo®. Evidence is it reduces the duration of cow's milk allergy. A member asked whether the group agreed with the evidence that this is a superior product. The dietetic group directed members to the company trial data submitted with the application.
- The cost for both Neocate® LCP and Neocate® Syneo is £29.56 for 400 grams.

The Chair directed members to the product evaluation for Neocate Syneo® The Chair invited questions or comments from members. Discussion points/concerns raised included:

- A member asked Keyo® is a unique product and what were the group using before this product? They responded a ketogenic diet is by requires a high fat and a low carbohydrate diet therefore the children on this diet consume a lot of natural high fat food with supplementary high fat food which lack vitamin and minerals. Patients take separate vitamin and mineral supplementation which can be unpalatable. Keyo® is fortified with vitamins and minerals which reduces the need for additional supplementation.
- A member asked how much the additional vitamin supplementation costs. Prof Macdonald replied that the product used is FruityVits® which is currently on the formulary and costs approximately £2 a day.
- It was clarified there is a current treatment which is nutritionally similar however unfortified. A member asked whether Keyo® was more cost effective than the current treatment. Prof Macdonald responded that compliance with vitamins and minerals is generally poor. Adherence is expected to be better with Keyo®.
- It was confirmed that the cost of Keyo® is approximately £6 a day which gives calories in addition to vitamins and minerals. The current treatment FruityVits® costs £2 a day providing vitamin supplements and a non-fortified product to give calories which could be for example Calogen®, Liquigen or cream.
- The numbers of patients on this diet is small. The trust has capacity for 75 patients currently.

The Chair thanked the dietetic group for attending the meeting, for answering all the questions from the APC members. They were advised a decision would be relayed within 5 working days, in line with APC policy

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

Aymes Creme®

Patient Safety: No issues

Clinical effectiveness: Equivalent to comparison product

Strength of evidence: Local evaluation

Patient factors: N/A

Cost-effectiveness or resource impact: Cost saving of 80p per serving

Place of therapy relative to available treatments: 2nd tier

National guidance and priorities: NICE clinical guidelines on nutritional supplementation

Local health priorities: CCGs supportive

Equity of access: No concerns

Stakeholder views: N/A

Implementation requirements: N/A

Decision Summary: AYMES® creme to be added to the formulary as AMBER to replace Forticreme complete® as per recommendation

Neocate Syneo™

Patient Safety: No issues

Clinical effectiveness: Local evaluation

Strength of evidence: Non-inferior

Patient factors: N/A

Cost-effectiveness or resource impact: Cost neutral

Place of therapy relative to available treatments: 2nd tier if unable to tolerate extensively hydrolysed formula

National guidance and priorities: NICE clinical guidelines on nutrition supplementation

Local health priorities: CCGs supportive

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: N/A

Decision Summary: Neocate Syneo™ to be added to the formulary as AMBER as per recommendation

Keyo®

Patient Safety: No issues

Clinical effectiveness: Local evaluation

Strength of evidence:

Patient factors: Aids compliance

Cost-effectiveness or resource impact: No cost effectiveness or resource impact data given

Place of therapy relative to available treatments: 2nd tier

National guidance and priorities: N/A

Local health priorities: Awaiting costing information

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: N/A

Decision Summary.Decision deferred until further information available
Rationale: Cost evaluation between Keyo® and alternative required

ACTIONS:

- **Relay decisions to the Dietetic group by Thursday 18th October 2018.** **APC sec**
- **Update the APC formulary with the harmonised formulary section 9.4 enteral feeds and the Guidelines for Prescribing Specialist Infant Formula in Primary Care.** **APC sec**
- **Add Aymes® creme to formulary as AMBER to replace Forticreme® Complete.** **APC sec**
- **Add Neocate Syneo® to formulary as AMBER** **APC sec**
- **Request resubmission of Keyo® recommendation with more information on cost comparison between Keyo® and currently available treatments.** **APC sec/Dietetic sub group**

1018/07 BSSE APC Feraccru® RICaD – for ratification

The Feraccru RICaD was deferred to the next APC meeting.

1018/08 BSSE APC Decision to Decline Prescribing form

The Decision to Decline (DtP) form has been updated to reflect the merged organisations. Contact details have been updated. The document has been updated to include an additional column to specify when the request to prescribe was received from secondary care. This was a suggestion from a secondary care member as it would help secondary care to trace timelines on the systems and make sure that the practice isn't inadvertently acting on any old communication.

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

- APC members agreed to remove fax numbers from the form and that only the email should be made available on the from
- A member raised that the 'other' section on the reason to decline should be audited in order to understand the reasons why GPs are refusing to prescribe
- Members agreed with the additional column which indicates when the request to prescribe was received from secondary care
- A member raised that it would be beneficial if the relevant consultants read the decline to prescribe forms. A fellow colleague mentioned that for her Trust, the decline to prescribe forms are read by the relevant clinician.

ACTION: **Finalise and publish DtP form** **APC sec**

1018/09 BSSE formulary chapter review – update

APC secretary reminded members that the first away day for the formulary

chapter review is being held next week Thursday 18th October from 10am until 5pm. Tea and coffee is available from 9.30am. Lunch will be provided.

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

- No responses have been received from Trusts to the APC secretariat.
- A member raised that they have struggled to engage the relevant specialists at the Trust to attend the away day.
- Members clarified that the purpose of the away day is to review the individual chapters and any supporting documents such as ESCAs/RICaDs.

ACTION: APC members to provide details of which APC member/specialist representative will be attending to present each chapter review via APC inbox — **APC members**

1018/10 RMOC recommendations – for information

The Chair directed members to the RMOC recommendations for September 2018.
It was noted that there is a Midlands and East RMOC Update – Sep 18, Adalimumab resources to use with patients, Adalimumab commissioning intentions.

1018/11 Minutes of the meeting held on 13th September 2018 – for ratification

The minutes of the meeting held on Thursday 13th September 2018 were discussed for accuracy.

- Page 7: item 0918/10 add further detail to this section
- Page 10: second paragraph: spelling error

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 DST for Urgoclean® was also approved for publication.

1018/12 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:

- 0918/12- RMOC recommendations - Highlight differences between BSSE APC Position Statement on Use of Manufacturers' Free of Charge Medicines Schemes and the RMOC advice on Free of Charge Medicines and feedback to APC Update: scheduled for a future APC meeting

- 0518/05- BSSE APC NOACs on formulary - preferred agent feedback. Wording on the formulary to be amended. APC members to discuss outside of the meeting and come back to APC with proposed wording. Update: A secondary care representative has suggested the wording "The APC prefers the use of apixaban and rivaroxaban for reasons of education

and familiarity" APC members agreed that the current wording on the formulary for preferred agents is sufficient and no further additions or alterations should be made.

1018/13 NICE Technological Appraisals (TAs)

In September 2018, there were 2 TAs published; both are NHSE commissioned. Red RAG status was agreed.

- Pembrolizumab for treating relapsed or refractory classical Hodgkin lymphoma [TA540]

- Inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia [TA541]

ACTION:

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

Any other business:

- **GP CQC Inspections and shared care agreements**

  A member raised that they received a letter at their Trust from a GP surgery expressing that they will no longer enter into shared care agreements for existing or future patients for the following high-risk medications: Methotrexate, leflunomide, azathioprine, sulfasalazine, mycophenolate, hydroxycarbamide, ciclosporin and mercaptopurine.
  This is a result of a CQC inspection that took place in a neighbouring GP surgery. This has impacted on other GP surgeries nearby. The GP surgery is not located within the BSSE area however could impact wider level. There is concern this might have a big impact on the APC regarding an increase in the decline to prescribe forms from GPs.
  CQC have identified concerns about the safety with regards to concern GPs not having up to date monitoring to prescribe safely.

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

- Members agreed that the APC should continue to support ESCAs and a statement should be issued to the CQC to inform them that their inspections are having an impact on existing ESCAs issued by the APC
- A member has mentioned their Trust is also aware of this issue as they have had a GP surgery decline shared care agreements for DMARDs and there is currently an ongoing process within the Trust to resolve this issue.
- A member raised that the health economy is at risk as secondary care would not cope with the influx of patients back into their care as GPs declining shared care agreements.

ACTION: Contact CQC regarding concerns about inspections impact on shared care agreements operating within the area. **APC chairs/CCGs**

- **Trimovate® cream**

  The APC secretariat informed members that Trimovate® cream is currently

only available as an unlicensed import. Views were collected from dermatology specialists on alternatives to Trimovate®. They responded there is no alternative and would like it to remain on formulary.

A primary care member informed they have been unable to obtain Trimovate® due to supply issues for quite some time. Hospital pharmacy departments have been able procure Trimovate® but these supplies may be limited.

A member commented one of the suggestions from the dermatologists was if Trimovate® became part of restricted prescribing due to costs they would support physician prescribing only as they felt there is potential overuse in district nurse prescribing.

A member asked what the issue was with prescribing two different creams that contain similar ingredients to Trimovate® cream. It was felt that due to compliance issues with using multiple creams that it can be difficult for patients.

Members discussed issues with hospitals discharging patients on Trimovate® cream as GPs are unable to carry on the prescribing due to supply issues.

ACTION: Annotate APC formulary to inform there is a temporary change from Green to Red due to supply issues. **APC sec**

- **Loperamide melts**

There was a question as to whether loperamide melts were ever available on the APC formulary. The formulary harmonisation documents show only the capsules and syrup were approved as Green. However, there a link on the formulary entry for loperamide to a UKMI Q&A document on High dose loperamide to reduce stoma output. A member stated that loperamide melts are available on their Trust formulary.

It was noted for this indication the liquid must be used in large quantities and the tablets are costly.

ACTION: Amend current formulary annotation to reflect that loperamide melts can be used in high risk stoma output patients only **APC sec**

- **Selegilline oral lyophisilate**

A member brought it to the APC's attention that there is a selegilline oral melt version available and requested for clarification on the formulary website whether it is formulary or not. Selegiline lyophisilate costs approximately £12 more than the standard tablets.

Members agreed that the oral melt version should be approved for patients with swallowing difficulties in advanced Parkinson's disease.

A member raised there is a selegilline ESCA which will require updating if

the oral lyophisilate is available. It was agreed to review this as part of the away day process for its relevant chapter.

ACTION: Add annotation to formulary entry to reflect that the dispersible tablets are restricted for use in patients with swallowing difficulties. **APC sec**

The Chair thanked the members for their input today. The meeting closed at 17:05.

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