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

PRESENT:

Dr Lisa Brownell	BSMHFT
Dr Paul Dudley	Birmingham and Solihull CCG
Prof Mark DasGupta	Birmingham and Solihull CCG
Nilima Rahman-Lais	Birmingham and Solihull CCG
Dr Nashat Qamar	Birmingham and Solihull CCG
Liz Thomas	Birmingham and Solihull CCG
Dr Sonul Bathla	Sandwell & West Birmingham CCG
Dr Angus Mackenzie	Sandwell & West Birmingham Hospitals NHS FT
Gurjit Kudhail	UHB NHS FT
Katy Davies	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
Ravinder Kalkat	Midlands & Lancashire CSU
Kuldip Soora	Midlands & Lancashire CSU
Daya Singh	Midlands & Lancashire CSU

IN ATTENDANCE:

Dr Ashley Liew for item 1118/05	Forward Thinking Birmingham Partnership
Dr Paritosh Sharma for item 1118/05	BSMHFT

No.	Item	Action

1118/01 Apologies for absence were received from:

Jonathan Boyd, Sandwell & West Birmingham CCG
Inderjit Singh, UHB NHS FT, deputy attended
Prof Jamie Coleman, UHB NHS FT
Dr John Wilkinson, Birmingham and Solihull CCG
Kate Arnold, Birmingham and Solihull CCG
Carol Evans, UHB NHS FT

It was confirmed that the meeting was quorate.

1118/02 Items of business not on agenda (to be discussed under AOB)

- Capsaicin 8% patch
- Acute NHS trust APC representation
- BSOL Universal Patient Offer and Shared Care
- Identified issues with some shared care documents (Sodium clodronate, denosumab, degarelix, apormorphine)
- Primary care issues with NOAC RICADs

1118/03 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.

1118/04 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.

1118/05 Lisdexamfetamine – new drug application – Shire Pharmaceuticals Ltd.

It was established one of the applicants, Dr Ashley Liew has declared interests in Shire Pharmaceuticals Ltd. Dr Liew has stated that for 2013-2017 details of benefit include speaker fees and travel support.

The Chair welcomed Dr Paritosh Sharma, Consultant Psychiatrist, BSMHFT, and Dr Ashley Liew, Consultant Paediatric and Adolescent Psychiatrist, Forward Thinking Birmingham to the meeting and invited them to present the application for lisdexamfetamine.

Dr Liew began by informing APC members that he will be discussing the paediatric aspects of lisdexamfetamine whilst Dr Sharma will consider the adult aspects of lisdexamfetamine. Dr Liew stated lisdexamfetamine is licensed as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in children aged 6 years and over. He explained that from a paediatric perspective there was a lot of interest when it came onto the market. Dexamfetamine is also licensed for ADHD in children aged 6 years and over. Lisdexamfetamine has a unique characteristic which may reduce the risk of substance abuse. Lisdexamfetamine is a pharmacologically inactive prodrug. After oral administration, lisdexamfetamine is rapidly absorbed from the

gastrointestinal tract and hydrolysed primarily by red blood cells to dexamfetamine, which is responsible for the drug's activity. Dr Liew stated lisdexamfetamine is recommended in children and young adults as second line treatment where first line treatment with methylphenidate is ineffective or has shown adverse effects.

Dr Sharma considered lisdexamfetamine from an adult's perspective and referred to *NICE guideline NG87 Attention deficit hyperactivity disorder: diagnosis and management* where it is recommended first line alongside methylphenidate. Dr Sharma added lisdexamfetamine is accepted for use in Scotland and Wales. He discussed a recent meta-analysis conducted in 2018. It was noted the meta-analysis is not included with the application circulated to members prior to the meeting. The meta-analysis '*Comparative efficacy and tolerability of medications for attention-deficit hyperactivity disorder in children, adolescents, and adults: a systematic review and network meta-analysis*' by Cortese et al. included 133 double-blind randomised controlled trials (81 in children and adolescents, 51 in adults, and one in both). Dr Sharma explained that the outcome was that the effect size was 0.8 for amphetamines compared to 0.5 for methylphenidate and 0.45 for atomoxetine. Lisdexamfetamine was found to be more effective than the other preparations and more acceptable to participants. He continued lisdexamfetamine is a controlled drug and it is important from an adult's perspective in terms of a reduction in substance abuse given it requires hydrolysis to the active component. He further explained that from a diversion point of view, it is very effective regardless of where it is prescribed in secondary or primary care.

Dr Sharma noted lisdexamfetamine has a longer efficacy with a half-life of 11 hours which is beneficial. Dr Sharma stated from experience lisdexamfetamine is more acceptable to patients due to it being effective for a longer period of time and patients are not required to take another dose in the afternoon.

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

- A member asked if lisdexamfetamine is considered to have a lower abuse potential then at what scale is dexamfetamine abused and what would stop occurring if lisdexamfetamine is used instead?
  Dr Sharma stated other stimulants such as methylphenidate have the potential to be abused. Dexamfetamine is shorter acting and therefore has a greater potential to be abused. In contrast, lisdexamfetamine is a pharmacologically inactive prodrug and has a longer half-life. It is less likely to be abused due to its mechanism of action, which is unique characteristic compared to other stimulant preparations. In addition, it is good choice for patients who have history of substance abuse.
- A member asked what the scale of the substance abuse problem is with the ADHD stimulant drugs. Dr Liew explained from a child and young adults' perspective, he is unaware of evidence for abuse with dexamfetamine in the UK, however there are a few cases in America. He further explained that there is some evidence for abuse with methylphenidate as this is more widely used for ADHD. The abuse potential for dexamfetamine is theoretically more attractive as it has a quicker onset of action and replicates a 'buzz' feeling whereas methylphenidate provides a more 'cognitive enhancing' feeling. Dr Liew explained that he has not come across literature around the

potential for serious outcomes such as death or organ failure in substance abuse but there have been a few case reports in America showing if taken in large quantities or injected there are serious cardiovascular risks. Dr Sharma explained there is potential for stimulant drugs being abused particularly the shorter acting stimulants, however he cannot quote statistics. Amphetamines are more likely to be abused than methylphenidate. Dr Sharma further explained that lisdexamfetamine which is a longer acting pro drug has the potential to divert substance abuse. In prison settings, lisdexamfetamine is preferred choice along with atomoxetine which is a non-stimulant.

- A member asked, beyond the ability to avoid abuse potential, is there anything else for lisdexamfetamine to be preferred over dexamfetamine? Dr Sharma replied that lisdexamfetamine has a longer duration of effect whereas dexamfetamine would be active for approximately 4 hours.
- A member added that the meta-analysis quoted showed lisdexamfetamine had a higher effect size than dexamfetamine.
- Dr Liew added the dosing schedule for paediatrics means giving one dose in the morning and not having to give a second dose in the afternoon at school which can be disruptive.
- It was clarified the application was for a change in RAG status for lixdexamfetamine from RED to AMBER with an effective shared care agreement (ESCA).
- It was clarified that monitoring requirements for lisdexamfetamine include blood pressure and weight.
- With regards to the shared care arrangement a member raised for adults, it may be difficult to arrange monitoring as this group of patients are not always seen within a comprehensive service within primary care. What is the risk if patients are not followed up. Dr Sharma responded that in his view secondary care initiate lisdexamfetamine, stabilise the patients and then arrange follow ups with the specialist. Dr Sharma does not expect primary care to undertake the monitoring but will want primary care to take on the prescribing of lisdexamfetamine. NICE guidelines recommend follow up reviews with a specialist are undertaken.
- A member asked how many patients are expected to be on lisdexamfetamine per 10,000 patients. Dr Liew responded that about 4-5 of 100 children will have ADHD and about 2-3 of 100 adults will have ADHD. This would translate into big numbers but not all will be on lisdexamfetamine. Dr Liew stated from a paediatric perspective they have a range of second line medication to use from, but he does not have data on clinician preference.
- A member raised that if there will be only 3-4 patients on lisdexamfetamine per GP practice then it will be difficult to train and familiarise GPs with lisdexamfetamine due to the small number of patients. In addition, if patients are going to be monitored under secondary care and issued prescriptions within primary care then this should be reflected in the ESCA.A member noted the ESCAs for the other ADHD drugs do mention that monitoring will take place under secondary care and an ESCA for lisdexamfetamine would be in line with this existing arrangement.
- A member asked if there is specific guidance for blood pressure or for weight monitoring which GPs should be aware of. Dr Sharma explained in his clinical practice this is not a huge concern however he has seen patients who are around 40-50 years of age with history of cardiac

issues. Cardiology opinion is sought for these patients however the evidence is quite positive for the use of stimulants in adults who have cardiovascular problems. Dr Liew explained that weight, height and blood pressure charts can be used to indicate deviation from the patients baseline and when thresholds limits have been reached in order to alert secondary care.

- A member was concerned that there seems to be an increase in adverse effects with lisdexamfetamine compared to methylphenidate and whether this is correct. The member referred to the application, '*In the longer-term study (NRP104.304) when all patients received lisdexamfetamine, 88% of patients experienced an adverse effects*.' Dr Sharma responded that from the meta-analysis by Cortese et al, it states that lisdexamfetamine is at par with methylphenidate or any other preparation in terms of tolerability but has a much better acceptability amongst patients which means patient are adhering more to lisdexamfetamine than other preparations.
- A member raised it would be helpful for GPs to have sight of a full blood count (FBC) to help with monitoring. Dr Sharma stated undertaking a full history is common practice and secondary care would be expected to undertake baseline monitoring in line with NICE guidelines including FBC, liver function tests, lipid profile, Hb1Ac and thyroid function.
- There was a discussion surrounding other methods of arranging monitoring of ADHD agents with the GP such as a clinic letter. One member stated there is a commissioning group looking at ADHD agents and they can explore this further in the forum.
- A member enquired how likely clinicians were to prescribe lisdexamfetamine for patients who have history of substance abuse. Dr Sharma stated stimulant drugs are used for drug abuse and that there is good evidence that a proportion of abusers have ADHD. Therefore, the clinician undertakes a holistic review of the patient with NICE guidance to support and if they history of substance misuse lisdexamfetamine may be the preferred agent. Dr Liew mentioned that there are also alternatives such as non-stimulant drugs for ADHD.
- A member commented from experience of working within substance misuse service, many of these patients have ADHD. Treating the ADHD has a massive impact on substance misuse and helps to reduce it. The stimulant agents are advantageous in this population as they are quicker acting.

The Chair thanked Dr Sharma and Dr Liew 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 asked as lisdexamfetamine and methylphenidate are both equal first line in NICE guidance, how does the clinician choose between them. A member responded the ADHD agents have different drug profiles and different pharmacological properties, therefore it depends on the individual patient need.
- It was clarified there is currently no ESCA in place for lisdexamfetamine, however there are ESCAs for the other ADHD drugs which indicate monitoring may take place in secondary care and prescribing in primary care.
- A member highlighted that there is currently at least an 18-month

waiting list for adult ADHD service therefore patients transitioning from paediatric to adult ADHD services and any new adult referrals have a long waiting time. An aspect of this may be due to the sole responsibility of ongoing prescribing being carried out in secondary care.

- There was a discussion around if secondary care should continue to carry out full sets of blood counts/screening. A member is aware of instances where GPs have refused to investigate any identified abnormal results as they have been highlighted by the Trust and therefore deemed secondary care responsibility. APC committee members agreed that this requires further discussion and should be raised as a separate issue at a future APC meeting.
- APC members clarified in future, evidence which has not been submitted with the original application will not be accepted for discussion. It is noted that the meta-analysis quoted by applicants was not pivotal in the final decision making.

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

Patient Safety: Theoretically less abusable than other ADHD drugs

Clinical effectiveness: Equal to or superior other agents

Strength of evidence: Consistent evidence across all studies

Patient Factors: Once daily dosing schedule

Cost-effectiveness or resource impact: Cost neutral

Place of therapy relative to available treatments: As per NICE guideline 72: lisdexamfetamine or methylphenidate 1st line in adults. lisdexamfetamine 2nd line in children over 5 years

National guidance and priorities: NICE guideline 72: Diagnosis and management of ADHD in children, young people and adults

Local health priorities: As per other ADHD agents

Equity of access: As per other ADHD agents

Stakeholder views: N/A

Implementation requirements: ESCA

Decision Summary: AMBER with ESCA. Please note that commissioning discussion is underway and arrangements currently vary across BSSE area.

ACTIONS:

- **Relay decision to Dr Liew and Dr Sharma by Thursday 15th November 2018** — **APC sec**
- **Add lisdexamfetamine to formulary as AMBER with ESCA and as per noted commissioning arrangements** — **APC sec**
- **Lisdexamfetamine ESCA to be produced in collaboration with applicants** — **BSMHFT/CSU**

1118/06 BSSE APC Dietetic group product evaluation Keyo®

The Chair presented the cost evaluation for Keyo® which had been produced by the dietetic group further to feedback received from the APC.

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

- A member commented there appears to be an increase in cost but lack of evidence for showing improvement in compliance.
- The cost evaluation shows BWCH NHS FT are currently using a combination of Calogen® and Fruitivits® costing £1 less than Keyo®. BSMHFT are using KetoCal 4:1 LQ they assessed as costing 4p less than Keyo®. The cost of Keyo® was calculated based on the 100 pot presentation.
- A member was concerned that there is potential for creep as if it is approved then it may be used much more widely than anticipated.
- There was a question as to why products used currently differ between the trusts and why BWCH NHS FT are using Ketocal currently when it is less cost effective than Frutivits® and Calogen®. Trust representative to follow up with their lead dietician.
- It was highlighted that £4.60 is based on 100 pots of Keyo whereas a pack size of 4 pots is £6.24 per pot. It is highly unlikely a GP would prescribe 100 or 48 pots at a time therefore if prescribing smaller quantities the cost of Keyo® will be much higher than indicated.

Decision Summary: Not approved Rationale: Keyo® does not provide the most cost-effective way of providing a ketogenic diet.

Actions:

- **Relay decision to Dietetic group** — **APC sec**

1118/07 BSSE APC Feraccru® RICaD – for ratification

The Feraccru® RICaD was updated in light of the discussion at September APC.

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

- A member highlighted the RICaD does not mention what should happen if the patient presents with a flare up.
- There were questions whether the APC considered this drug for sequential use after the initial 3 month course. A fellow member confirmed Feraccru® was originally approved on the basis that it was for one course only.
- It was agreed amongst APC members the RICaD should reflect that if a patient has a flare up when presenting then Feraccru® should be discontinued and referred back to secondary care.

ACTIONS:

- **Amend Feraccru RICaD as per discussion** — **APC Sec/ UHB NHS FT**

1118/08 BSSE APC Dermatology ESCAs

BSSE APC Azathioprine ESCA

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

- A member raised that a new condition, 'pemphigus vulgaris' had been added to the ESCA. Members discussed this and agreed that for any new indication to be added onto an existing ESCA approved during harmonisation, a new full application is required.
- The APC chair stated that a cross reference against any existing azathioprine ESCAs is needed to ensure there is consistency between the azathioprine ESCAs.

BSSE APC Ciclosporin ESCA

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

- It was noted that for the pre-treatment section should be amended to state blood pressure <140/90mmHg.
- There was discussion amongst members on why blood pressure measurements are required two weeks apart. It was noted that this may be due to the requirement for dermatologists to check the creatinine levels two weeks apart.
- A CCG representative member noted that primary care clinicians have expressed that they are reluctant to take on shared care agreements for ciclosporin.
- A member expressed this same concern and stated there are several drug interactions that need to be considered for ciclosporin. The member wondered whether dermatologists take into consideration the patient's medication history when prescribing on initiation, otherwise GPs would have to check interactions when care has been transferred to them.
- It was mentioned that if primary care is not prescribing ciclosporin then it should still appear on the clinical system for GPs as this would allow any interactions to be flagged up with existing medication.

BSSE APC Methotrexate ESCA

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

- The Chair noted there should be strong overlap between the existing Methotrexate ESCAs for other conditions and this ESCA for methotrexate use in dermatology.
- A member raised that celecoxib appears twice on the interaction list. It was agreed that once this has been amended, it can be approved.

BSSE APC Doxepin RICaD

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

- Doxepin cream (Xepin®) currently costs £11.70 for a 30g tube with a dose of 3g four times daily. It was noted that it is for short term use. A member questioned why a RICaD was required for a product that is to be used short-term.

- It was clarified formulary currently states AMBER with RICaD (in development).

ACTIONS: Amend the Dermatology documents as per discussion and bring to a future APC meeting **APC Sec**

1118/09 **BSSE APC away day documents** – for ratification

The first away day for the formulary chapter review process was held on Thursday 18th October.

Proposed formulary Chapter 3 - Respiratory

The Chair directed members to the proposed respiratory formulary chapter enclosure. The proposed changes presented by the APC secretariat are:

- Tiotropium Respimat RAG rating amended from Amber to Green in line with NICE guidance – add on maintenance bronchodilator.
- ICS/LABA inhalers were rationalised – Duoresp and Sirdupla proposed as non-formulary. Fostair, Flutiform, Seretide (paediatrics only), Relvar, Symbicort (MART regime) to remain.
- Ciclesonide – proposed as AMBER respiratory specialist initiation, maintenance within primary care with RICaD. RICaD to be developed by Col Wilson and UHB NHS FT.
- Zafirlukast – Agreed to change from Green to non-formulary. The manufacturer has discontinued the branded zafirlukast tablets, Accolate® and there are no other generics available within UK.
- OTC/self-care advice to be added on number of products – antihistamines, cough preparations sections.
- NICE TAs missing – Ivacaftor comes under NHSE specialised commissioning (RED) and ivacaftor/lumacaftor NICE TA to be added to formulary. RED status agreed.

The current Grazax RICaD is due for review in November 2018. The immunology specialist has noted that it is a useful RICaD and supports its ongoing use.

The ILD ESCAs for Methotrexate in ILD and azathioprine with prednisolone in ILD were reviewed by respiratory specialists and they are happy for the ESCAs to be continued for a further 2 years. The documents will therefore be updated with new approval and review dates and uploaded onto the formulary website.

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

- A member noted that Seretide® currently not for initiation with new adult patients is likely to be switched over to a bioequivalent in the next 12-18 months due to cost.
- A member asked that the methotrexate and azathioprine in ILD ESCAs are cross-referenced with existing approved methotrexate and azathioprine ESCAs in other conditions. E.g. are the interactions and side-effects generally the same within the ESCAs. If there are large differences these should be amended and reviewed by APC.

Proposed formulary Chapter 13 – Skin

The Chair directed members to the proposed skin formulary chapter enclosure.

The proposed changes presented by the APC secretariat are:

- Dermatology specialists had suggested Epimax® to become non-formulary as it is not used by them.
- References should be made to self-care/OTC policy within the formulary sections for emollients, acne and sunscreen, shampoos, head lice, minor cuts and abrasions and antiperspirants.
- A CCG representative member stated the Birmingham Antibiotic Advisory Group (BAAG) will be reviewing the topical antibacterial/fungal section of the Skin chapter within the Infections chapter review.
- Mometasone cream to be listed as a generic on the formulary.

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

- There was discussion amongst members regarding the comments from dermatologists regarding Zerorange® products. It was felt that even though dermatologists did not support use of these products, there were no real concerns being shown by the number of patients who receive Zerorange® in primary care.
- A CCG representative suggested the data on Zerorange® use in primary care could be collated. Members agreed to retain Zerorange® on formulary.
- Members expressed that there was no input from primary care at the away day on the usage of emollients.
- It was agreed to keep Epimax® RAG rating as Green despite feedback from secondary care dermatologists stating it is not used. Primary care representative members highlighted Epimax® is currently being offered as the most cost-effective option by the primary care prescribing support software. Epimax® is generally well received by patients within primary care.

Proposed formulary Chapter 11 - Eye

The Eye chapter will be revisited next year; date to be confirmed. Comments were received from SWB NHSFT ophthalmologists only (the corneal and external disease consultants). No amendments to the formulary were made as result of the comments. Comments made by APC members at the away day have been fed back and ophthalmologists thanked for their input. Ophthalmologists have been asked to work with neighbouring trusts to develop a collective view.

Chapter review work programme – for ratification

The changes to the chapter review work programme were relayed to APC members. There is a Midlands and East RMOC meeting on Thursday 4th April 2019 therefore the away day has been rescheduled for the morning of Thursday 11th April 2019. The standard APC meeting will remain in the afternoon.

Minutes of the away day held on Thursday 18th October 2018

The minutes of the away day held on Thursday 18th October 2018 were discussed for accuracy. No amendments were required. It was confirmed that the minutes are approved and can be uploaded to the APC sharepoint for

members information.

ACTIONS:

- **Update Respiratory and Skin chapters of the formulary as discussed** — **APC sec**
- **Update Grazax RICaD as discussed** — **APC sec**
- **Update Methotrexate in ILD and Azathioprine in conjunction with presdnisolone ILD ESCAs as discussed** — **APC sec**
- **Ciclesonide RICaD to be produced in conjunction with Col Wilson** — **UHB NHSFT/APC sec**

1118/10 RMOC recommendations – for information

The Chair directed members to the RMOC recommendations for October 2018. RMOC briefing on adalimumab October 2018, adalimumab press release, adalimumab toolkit for commissioners and providers, adalimumab barriers to uptake: result of national survey. No comments were made.

1118/11 Minutes of the meeting held on Thursday 11th October 2018 – for ratification

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

No amendments were required. It was confirmed that the minutes are approved and can be uploaded to the APC website and the recording deleted

The DST for Aymes® Crème and Neocate Syneo® was also approved for publication.

1118/12 Matters Arising

The Chair moved onto the action table for comments and updates:

APC secretariat informed members that actions can be considered closed if not discussed.

The outstanding actions include:

- 1018/13 - Contact CQC regarding concerns about inspections impact on shared care agreements operating within the area. Update: CQC have been contacted by a neighbouring CCG and have responded. Close action.
- 1117/07 – Task the CCG's digital team to develop/investigate an IT solution to deliver DMARD ESCAs in a concise and simple way. Update: Digital team are not currently available to deliver this. Close action.
- 1117/AOB – Formulary for patients in transition from paediatric to adult services. Pharmacists from CCGs and Trusts to meet outside of APC. Update: The meeting is yet to take place as there is a wider discussion in place between commissioners and the provider Trust's senior contracts team. Update: This has not occurred and not permitted to convene the meeting therefore being led by UHB NHS FT. Close action.

1118/13 NICE Technological Appraisals (TAs)

In October 2018, there were 3 TAs published; 2 are NHSE commissioned, 1 is CCG commissioned.

The CCG commissioned NICE TA is:

- NICE TA 543: Tofacitinib for treating active psoriatic arthritis after inadequate response to DMARDs. Tofacitinib is commissioned by clinical commissioning groups. Providers are secondary care and community care.

Red RAG status was agreed.

ACTION:

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

Any other business:

Capsaicin 8% patch:

- The Royal Orthopaedic Hospital NHS Foundation Trust have informed the APC secretariat that they will be considering Quetenza® (Capsaicin 8% patch) at their internal DTC on 26th November for peripheral neuropathic pain. They have requested it to be added onto the BSSE APC formulary for hospital use only with a RAG status of RED.
- Members agreed a full application would be required.

Representation from acute NHS trusts

- It was highlighted there is lack of representation from the member acute NHS trust clinicians and suggested for this to be flagged up at the internal drug and therapeutic committees. A member for UHB NHS FT responded that there will be representation attending from January 2019 onwards.

Primary care issues with novel oral anticoagulant agent (NOAC) RICADs

- A CCG representative member discussed a recent patient safety issue around the novel oral anticoagulants (NOACs). This has highlighted an inconsistency throughout the NOAC RICaDs; it is not clear clinicians should be using creatinine clearance as a measure of renal function and not electronic glomerular filtration rate (eGFR). The CCG safety team is currently looking at updating the RICaDs and will be proposing recommendations to the APC in future.

BSOL Universal Patient Offer and Shared Care

- A CCG representative informed members there are several primary care local improvement schemes which are being combined into one universal patient offer. One module of this patient offer includes shared care arrangements. This involves asking primary care clinicians to review every patient on clinical grounds if an ESCA request is made. It was noted that there have been cases where ESCAs have been refused which are not based on clinical grounds, therefore this module is designed to help tackle this.

Identified issues with some shared care documents (Sodium Clodronate, denosumab, degarelix, apormorphine)

- CCG representative raised that the feedback received from primary care clinicians is that they are becoming more uncomfortable prescribing high-risk medications such as ciclosporin or medicines for use in very uncommon conditions.
- There are four ESCAs that have been highlighted as problematic for primary care; denosumab, sodium clodronate, degarelix and apormorphine.
- Apomorphine was noted as having a wide range of considerations perhaps unsuitable for shared care.
- The sodium clodronate ESCA is deemed to be unclear with regards to monitoring requirements.
- Degarelix requires reconstitution which is impractical and there are parts of the ESCA which are regarded as incorrect.
- Denosumab involves the level of monitoring which is impractical within primary care setting particularly with monitoring of calcium levels. In addition, it was noted there are very rare adverse effects such as “danger of death” noted within the ESCA which are unsuitable.
- These four ESCAs should be sent to secondary care clinicians to review to ensure that the content is still appropriate and up to date.
- There have been concerns raised about the manner in which consultants approach general practitioners (GPs) regarding shared care issues. A member wished to remind secondary care colleagues that an ESCA is an invitation and GPs are under no obligation to participate. However, GPs should consider the invitation and respond clinically as part of their clinical duties. Members agreed there should be a mutual understanding between secondary and primary care colleagues and the patient’s care should be the paramount consideration.
- There was discussion amongst APC members regarding extending an invitation to clinicians to observe APC meetings therefore providing an insight into how formulary decisions are made. It was suggested this could be offered to clinicians who refuse participating in shared care agreements. It was suggested to have a single observer post each month.

ACTION: **Secondary care to review sodium clodronate, denosumbab, degarelix and apormorpine ESCAs** — **NHS Trusts/APC sec**

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

Date of next meeting: Thursday 13th December 2018 14:00 – 16:45
Birmingham Research Park