AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 11th June 2015
Birmingham Medical Institute, 36 Harborne Rd, Birmingham, West Midlands B15 3AF

PRESENT:

Dr Paul Dudley	PD	Birmingham CrossCity CCG (Chair)
Dr Lisa Brownell	LB	BSMHFT
Alan Pollard	AP	Birmingham Women's NHS FT
Dr John Wilkinson	JW	Solihull CCG
Prof Robin Ferner	RF	Sandwell & West Birmingham Hospitals NHST
Elizabeth Walker	EW	Sandwell & West Birmingham CCG
Inderjit Singh	IS	UHB NHSFT
Isabelle Hipkiss	IH	Midlands & Lancashire CSU
Kate Arnold	KA	Solihull CCG
Mandy Matthews	MM	NHS England
Mark DasGupta	MD	Birmingham CrossCity CCG
Nigel Barnes	NB	BSMHFT
Satnaam Singh Nandra	SSN	Birmingham CrossCity CCG
Tania Carruthers	TC	HEFT NHS FT
Dr Timothy Priest	TP	HEFT NHS FT
Tony Green	TG	Patient Representative
Brian Smith	BS	The ROH NHS FT
Louise Whitticase (For Dr Latthe)	LW	Birmingham Women's NHS FT

IN ATTENDANCE:

Kalvinder Bansal	KB	Minute taker, Midlands & Lancashire CSU
Carol Evans	CE	HEFT NHS FT
Miss Lynne Robinson	LR	Birmingham Women's Hospital For item 0615/11
Dr D McCorry	DMC	UHB NHS FT For item 0615/12
Col Duncan Wilson	DW	UHB NHS FT For item 0615/16

No.	Item	Action
0615/01	**Apologies for absence were received from:** • Alima Batchelor • David Harris • Prof Jamie Coleman • Dr Pallavi Latthe • Dr William Rea • Jonathan Horgan • Maureen Milligan • Patricia James • Peter Cooke	
0615/02	**Items of business not on agenda (to be discussed under AOB)** • IH- ESCAs and RICaDs • IH/ NB-Framework for antipsychotic prescribing • IH- Mycophenolate for rheumatology • TC- ganciclovir eye ointment	
0615/03	**Declaration of Interest (DoI)** The Chair reminded the members to submit their annual declarations to the APC Secretariat. IH thanked those members that had already submitted their DoI. **Action: all members to submit annual declaration** No new declarations were raised against any item on the agenda.	**ALL**
0615/04	**Welcome and Introductions** The Chair welcomed those present to the Area Prescribing Committee. Introductions were not deemed necessary on this occasion.	
0615/05	**Minutes of the Meeting held on Thursday 14th May 2015** The minutes of the meeting of 14th May 2015 were discussed for accuracy. TC- page 3: Not a matter of accuracy, but HEFT Immunologist, Dr Huissoon, is interested in seeing the draft RICaD for Grazax from Dr North, when available. MD- page 7: under PDE-5 Inhibitors, 3rd paragraph. Amend sentence to read "but MD remarked that the HSC guidance on number of tablets had not changed for <u>any of the</u> PDE-5 inhibitors" IH- page 10: under NICE approved drugs for non-NICE indications, amend sentence to read "TC asked if the members supported the use of certolizumab for psoriatic arthritis <u>and ankylosing spondylitis."</u> The minutes were approved subject to these amendments.	
0615/06	**Matters arising – Action Table** **0515/07 NICE TAs: Rifaximin RiCaD** To be discussed on the agenda **0515/10 Insulin degludec (Tresiba®) – draft RiCaD** This has been revised and is on the agenda	**Closed** **Closed**

0515/12 Tapentadol SR – Drug application

IH has advised Dr Hanu-Cernat and Dr Blaney of the decision. Dr Hanu-Cernat has raised a number of questions about transfer of prescribing from her clinic which have been referred to IS to discuss further. **Closed**

0415/07 NICE Technology Appraisals (TAs)

- RICaD for rivaroxaban in ACS.

IH confirmed that KA had forwarded a draft on the 15th May. KA confirmed it was a first draft and needs further review. IH to consult with specialists on the draft prior to presentation at the APC. **Closed**

Action: Circulate draft RICaD for rivaroxaban in ACS to specialists for comments before bringing back to APC **IH**

0415/09 Updated BNF Chapters

IH confirmed that BNF Chapters 1, 2, 4 and 10 have been circulated. These Chapters were all fully approved.

IH has also circulated BNF Chapters 3, 6 and 7 which have been partially approved at this stage.
IH thanked SSN for his support in updating these documents

TC made a comment that it is important to ensure that formulary decisions are sent to formulary leads and members before being disseminated to specialists within individual trusts.

Section 6.4.1.1.
AP asked about progress on Section 6.4.1.1.IH confirmed that the CSU has completed the usage analysis of HRT and Oral Contraceptives. She advised it was based on usage across two CCGs. IH asked how this was to be taken forward. Agreed that IH would circulate on email for review and decision to be brought back to future meeting.

Action: Circulate by email CSU's review of HRT and OC to members **IH**

0415/10 Feedback Respiratory Network

- IH to contact Jonathan North, Consultant Immunologist at City Hospital re Grazax and the need for supplementary documentation (RICaD) **Closed**

Dr North has agreed to draft RICaD. So this action is now closed. Col D. Wilson (UHB) and Dr Aarnoud Huissoon (HEFT) have asked to see draft version of this RICaD once drafted by Dr North.

Action: Once received from Dr North, send copy of draft Grazax RICaD to Col Wilson (UHB) and Dr Huissoon, Immunology (HEFT) **IH**

1214/03 Declaration of Interest

Concerns were expressed by the Chair again in relation to lack of attendance from BCH, especially in view of the stiripentol item on the agenda. It was proposed that Chairs need to meet to discuss with BCH. It was confirmed that JH and AB had been in conversations with BCH. LB to contact JH and AB and discuss next steps. **Open**

0615/07 NICE Technology Appraisal (TAs)

IH advised that at the time of producing the APC committee papers there were no new NICE TAs. However in the last week there have been 5 new TAs of which the following 3 are relevant for the APC;

- Vedolizumab for treating moderately to severely active ulcerative colitis (TA342)
- Apixaban for treatment and secondary prevention of DVT and /or PE (TA341)
- Ustekinumab for treating active psoriatic arthritis (TA 340)

It was confirmed these would be allocated as formulary status grey to show that the APC is aware of these, they would be considered further at the next meeting.
Action: IH to list these on APC formulary as GREY status **IH**

Revised RICaD for rifaximin following APC comments (for information)
The draft includes comments from the last meeting. Andrew Holt has been involved in the review.

It was agreed that a comment would be added to emphasise the use of concomitant lactulose as this was applied in a large percentage of the trials.

TC raised a comment from the specialists at HEFT that it would be difficult for them to see the patient for review after one month, and again after the second month if treatment was to be continued. A discussion ensued and the members concluded that the initiating consultant Hepatologist would only need to review the patient after the first month, and if the patient is deriving benefit, a further month's supply can be issued. This would allow time for the GP to be informed and the transfer of prescribing responsibility to be passed to Primary Care with the supporting information in the RICaD.

A number of further changes were proposed by the members;
KA: Change continuation criteria to satisfactory clinical response one month after treatment initiation (instead of two months)

MD proposed an amendment which was accepted by the members: *These patients should be under some form of secondary care follow up – at the minimum this will probably comprise 6 monthly reviews in clinic for Hepatoma surveillance*.

To change to
These patients should be under secondary care follow up – at the minimum this will comprise 6 monthly reviews in clinic for Hepatoma surveillance.

MM politely requested that she would like to share this document with Trusts in Worcester and there was also a request to share in Staffordshire. This was supported and it was advised that they may need appropriate advice on what a RICaD is to avoid any confusion.

The RICaD was approved subject to these amendments.

Actions:

- **IH to make amendments to draft document, send final version to Dr Holt, and publish on website.** **IH**
- **IH to send final version to MM to share with Worcester Trusts and CCGs** **IH**

0615/08 Trust Chairs non-formulary approvals

None were received from UHB NHSFT.

TC advised that HEFT has had two this month, relating to PAS schemes, pre-NICE approval. She would forward details to IH.

One was for omalizumab for chronic spontaneous urticaria. MM confirmed that NHSE was the responsible commissioner, but waiting for a circular to confirm NHSE would pick up the funding from day 90. NICE TA 339 states that the drug is to be given by a secondary care specialist in dermatology, immunology or allergy.
RB enquired if General Practitioners with Special Interest (GPwSI) were included in this category. MM confirmed that NHSE did not commission services from GPwSI, only from Trusts. It would be down to CCGs to make the decision with regards to GPwSI.

0615/09 Feedback from Lancashire Medicines Management Group
Deferred in the absence of JH.

0615/10 Insulin Degludec RICaD
MD raised concerns that the RICaD is not focused clearly enough on the agreed patient cohort who would otherwise progress to insulin pumps. Revision is required to make this clearer.

KA recommended that the document should be approved for nocturnal/severe hypoglycaemia in patients who would otherwise require insulin pump treatment. But recommended that the sections on recurrent DKA are removed whilst there is further review.

It was agreed that the indication for recurrent DKA episodes due to non-compliance and who would otherwise be suitable for pump therapy would be removed, as the NICE TA for insulin pumps did not include this criteria. IH to review the recording of the March away day and liaise with MD on subsequent amendments to the wording if needed.

RF proposed a change in the title to focus the use of the RICaD more clearly; *To avoid the use of an insulin pump in patients with severe/nocturnal hypoglycaemia (with or without hypoglycaemic unawareness)*

The RICaD was approved subject to these amendments

Actions:

- **Proposed amendments to be made to document** **MD/IH**
  Publish the revised document on the website. **IH**

The Chair advised that the order of agenda items would be adjusted to accommodate the applicants presenting.

0615/14 Stiripentol – transfer from BCH to UHBFT

IS advised that he thought there was a funding arrangement in place between the Children's Hospital and the previous PCT for the use of stiripentol in children with epilepsy. He was concerned that the arrangement was not in place for continued funding through to adult services.

The APC was of the view that the transfer of specialist high cost drugs from paediatric services to adult services should not occur until arrangements are in place for funding. Discussion is required with leads at BCH and Commissioners.

MM confirmed that this drug is in the payment by results tariff, and is not funded under specialist commissioning by NHS England (as far as NHS England were aware with the data they have currently).

It was agreed that this would be followed up further with BCH.

Action: to be followed up in discussions with BCH **Chairs/ AB/JH**

0615/11 New Drug Application: Utrogestan caps 100mg (progesterone)

The Chair welcomed Miss Lynne Robinson, Consultant Obstetrician and Gynaecologist, Birmingham Women's Hospital and invited her to present the drug application.

BWH currently recommends utrogestan as part of the HRT protocol for some women. It is referred and prescribed through GPs on recommendation by BWH and it has been found to be well tolerated by some women. LR highlighted that this product is useful for women who are intolerant of progestogenic side effects such as bloating, and androgenic side effects. It also allows flexibility with the ability to alter the oestrogen dose and use separate progesterone, as opposed to fixed-dose HRT combinations. There is some evidence that is may be better in terms of breast cancer risk and cardiovascular risk. In addition, a lot of women tolerate it well, would prefer to have this agent and can use it vaginally or orally.

The Chair invited questions for Miss Robinson from the members.

AP asked for clarification on the duration of treatment in the application as this differs from the Summary of Product Characteristics (SmPC). The application is 200mg daily for the last 14 days of the menstrual cycle, whereas the SmPC is for the last 12 days. LR confirmed she prescribes ranges of 12-14 days. This was partly to support adherence as patients can manage 2 weeks of oestrogen and 2 weeks of progesterone more easily. Continuous combined regime involving 100mg daily is also used and prevents breakthrough bleeding.

KA asked what was the place of Mirena® or similar intra-uterine delivery products. LR stated that Mirena® is commonly used but some women prefer not to have a coil device fitted, especially if menopausal. Patient preference is a key factor here.

KA also enquired what the number of women on this agent would be as it may initially look relatively cheap, but in terms of cost-effectiveness, it was far less cost- effective than the alternatives.

It was estimated 5-10% of LR's patients would be prescribed utrogestan, acknowledging the fact that these patients had already tried a number of other treatment options.

MD asked which oestrogen preparation would be used in combination with utrogestan. LR stated it would be an oral preparation (e.g. Elleste Solo®) or a transdermal patch (e.g.Evorel® patch).

RF highlighted that the Scottish Medicines Consortium did not approve this and asked why this preparation would be used over other products such as dydrogesterone.
LR advised that this preparation allows more flexibility in dosing for example for patients who need more oestrogen as it can be used separately. Patients that don't tolerate norethisterone or medroxyprogesterone, tend to tolerate utrogestan much better. Also patients not suitable for an oral oestrogen such as women with migraine or epilepsy that require a transdermal oestrogen preparation would need separate oral progesterone; this is where utrogestan is very useful.

PD asked about GP referrals. LR advised that they get a variety of referrals. Most commonly the referrals are for more complex patients who may need adjusted doses of HRT for example patients who have had DVTs, or who have migraine or epilepsy.

The Chair thanked Miss Robinson for attending, and she left the meeting.

RF suggested there may be a limited role for patients who require transdermal oestrogens, and who are not happy with transvaginal progestogens, and can't tolerate medroxyprogesterone acetate. RF noted that LR had outlined how transdermal oestrogens are less likely to cause seizures, strokes and migraines. In these patients this could be a niche requirement.

It was noted that oestrogens can increase the risk of stroke in patients with migraine.

If one is using a transdermal oestrogen then there has to be another method of giving progestogen.
TP advised that the studies were observational not randomised controlled trials so the strength of evidence was limited.

AP noted that cost difference per patient was low however it was agreed that the decision for cost effectiveness should be based on cost per QALY or a comparable method not on individual costs.

It was noted that a number of patients are prescribed the drug already.

The application recommends formulary status Green. Currently it is prescribed in primary care on recommendation by the specialists.

The Chair guided the members through the decision support tool:
Patient safety: No concerns on safety
Clinical effectiveness: No differential between peer group
Strength of evidence: Weak evidence

Cost effectiveness: Small impact per patient but moderate impact at population level.
Place of therapy relative to available treatments: third or fourth line.
National guidance: SMC has declined this.
Local health priorities: Likely to be low priority
Equity of access: There are other options if this product was not available. No impact if applied to all groups equally. Current patients would continue as the formulary is for new patients.
Stakeholder views: No groups identified.
Implementation requirements: No RICaD or ESCA would be required.

Decision Summary
The APC were of the view that Green was not appropriate given the cost and the potential for creating wider use of a product that has a smaller place. It may be more appropriate as Amber with a defined place for the therapy. It was agreed that AP would contact LR to review the application and develop a clearer protocol. The APC decision was deferred.

Action: AP to liaise with Miss L Robinson regarding the utrogestan application and develop a decision tree. **AP**

0615/12 Eslicarbazepine

The Chair welcomed Dr Dougall McCorry (UHBFT) and invited him to present his application. Dr McCorry consented to the digital recording for the purpose of the minutes.

Eslicarbazepine has been available in the UK for around 5 years for epilepsy. It is similar to some other antiepileptic drugs (AEDs). It is a related to carbamazepine and oxcarbazepine. DMC advised that oxcarbazepine has not been popular in Birmingham for the last 15 years, but this another option. This drug causes less hyponatraemia.

Usage: It would be considered for patients whose epilepsy is difficult to control. We would expect this to apply to around 1-3 patients per 1000 in a GP practice.

The UHBFT model of care for prescribing in neurology is joint care with the GP. This is a safe drug which doesn't require a blood test. It would be commenced by the specialist with the intention of transfer to the GP with agreement.

It doesn't require blood tests, and it is relatively safe to use.

Place in therapy:
It may be best used for patients that have not been controlled with other AEDs or those who do not tolerate other AEDs. It may be used for those that don't tolerate carbamazepine but require this type of treatment.
It may be used for patients that require once daily treatment only - but this is relatively rare.

As a comparison oxcarbazepine has not been widely used and this would be expected to be similar for last line use.

The Chair invited questions for Dr McCorry from the members

TP highlighted that the drug is expensive and advised that NICE have estimated this to be an incremental cost per QALY of over £54,000. At this cost it would not be widely recommended. It was confirmed that the usual dose would be 800mg per day, which costs £136 per month.

MD asked why not oxcarbazepine. Dr McCorry advised that oxcarbazepine would be a more appropriate first choice before this drug, unless there was a specific reason e.g. hyponatraemia.

RF asked if there were comparative trials. Dr McCorry confirmed that there were only trials against placebo. He confirmed that drug choice in epilepsy was largely based on clinician preference and experience as there was limited evidence base for choice of AED.

RF referred DMC to a graph and noted that the truncated axis in Figure 1 overemphasises its benefits. It was also noted that the trials show little benefit over placebo.

RF asked about the monitoring in the ESCA. The drug application doesn't define the monitoring that is required. DMC advised that on reflection, routine monitoring is not required unless there are specific symptoms and the ESCA could be modified. These drugs are generally safe, and this type of monitoring is not required unless there are specific reasons for an individual. This fits with clinical practice, and current advice to GPs.

RF summarised his understanding and requested confirmation as follows; In the most refractory patients who experience around 13 partial seizures in 4 weeks before using a drug; these could be reduced to 11 with placebo, or 9 with active treatment. In the add on trials which are often carried out in countries with less refractory patients, there was a slightly better response in both placebo, and active groups. The conclusion here is this is not hugely effective and at a considerable cost and the advantages in terms of safety (adverse drug reactions) are limited compared to oxcarbazepine.

DMC confirmed that this drug would not be a replacement for oxcarbazepine, but another drug to be used in a very modest group of patients. He also reiterated that as an advocate for patient with epilepsy he would argue for all drugs.

The Chair thanked Dr McCorry for presenting, and he left the meeting.

NB advised that this drug has not been used often over the last 5 years in his Trust's psychiatry units.

JW asked how long these patients remain on the drug before it is stopped if no benefits are demonstrated. IS suggested this could be clarified in the ESCA.

NB confirmed to the members that the use of oxcarbazepine was low. He outlined that the neurologists do review and stop or adjust drugs closely with patients and carry out clinical audits frequently. There wasn't a concern about prescribing moving to inappropriate levels through these specialists.

KA advised that NICE guidance defines the steps for use of AEDs and if

adjunctive treatment is not effective, consider referral to tertiary specialist who may consider use of eslicarbazepine and other preparations.

LB wanted to understand the term tertiary specialist in the guidance. MM confirmed that NHS England commissions specialised services for complex or intractable epilepsy, and in the derogations lists UHB, UHCW and UHNM in the West Midlands as the specialist centres. NICE has recommended tertiary specialists.
EW advised that NICE defines a tertiary care specialist in epilepsy as an adult or paediatric neurologist who devotes the majority of their working time to epilepsy, is working in a multidisciplinary tertiary referral centre with appropriate diagnostic and therapeutic resources, and is subject to regular peer review.

In Lancashire the CCGs have restricted its use to following referral to a tertiary care specialist.

RF advised that City and Sandwell DTC did not support the inclusion of this drug on the APC formulary, and would consider it through DTC Chairs actions

The Chair guided the members through the decision support tool:

Patient safety: Potential, but reduced risk of hyponatraemia. There are drug interactions (enhances metabolism of oral contraceptives). Warning about suicidal ideation in SPC.
Clinical effectiveness: Established licensed product. Some evidence demonstrated against placebo similar to other AEDs
Strength of evidence: Weak. No head to head comparative studies presented. Placebo controlled trials were short duration (12 weeks)
Cost effectiveness: NICE states: the addition of eslicarbazepine was associated with increased costs and better health outcomes (higher QALYs) than continuation of existing therapy alone (placebo), but with an expected incremental cost effectiveness ratio (ICER) of £53,585 per QALY which exceeds the NICE willingness to pay threshold.
Place of therapy relative to available treatments: Last line (up to 8th tier)
National guidance: An option for tertiary centres in NICE guidance.
Local health priorities: MD expressed concerns that this sets precedence for any other AEDs. MD reminded the members that this is one drug of eight AED choices with limited evidence above other similar drugs. This effectively means all AEDs are put on the formulary. This is not a typical approach to formulary. In addition neurologists do use more than one AED to achieve the control required.
Equity of access: There are other options if this product was not available on the formulary.
Stakeholder views: N/A
Implementation requirements: ESCA has been submitted, but needs to be revised if approved onto formulary.

Decision Summary
Amber with an ESCA is currently the proposed position. Concerns were expressed by several members that this drug was not appropriate for amber with an ESCA given the limited evidence for benefit and high cost. The members felt additional controls were required to ensure that the use of this drug was as outlined by Dr McCorry as last line. It was agreed given the low number of patients that the Trust could manage the use of this internally, and the formulary would need to support this.

It was agreed that this drug would be amber with an ESCA plus additional steps for approval. The ESCA needs to be revised to reflect that approval is required by the Trust's decision making body (e.g.DTC), and it should reflect the place in therapy as tertiary recommended in line with NICE guidance.
This is similar to the restriction process at B&SMHT.

Action:

- **Inform Dr McCorry of APC decision** **IH**
- **Liaise with Dr McCorry to revise ESCA as discussed** (remove monitoring requirements, include statement re eslicarbazepine should only be considered following referral to a tertiary care specialist and after oxcarbazepine has been tried, additional step for approval i.e. approval by Trust's DTC or equivalent decision making body) **IS**
- **Circulate revised ESCA to APC members for ratification** **IH**

0615/16 Ciclesonide evidence review

The Chair welcomed Col Duncan Wilson, respiratory physician from UHBFT and invited him to present on behalf of the respiratory network.

Ciclesonide is an inhaled corticosteroid for management of mild to moderate asthma. It doesn't offer any efficacy advantage over other inhaled corticosteroids. So the discussion today is around niche use of this drug.
There are 2 potential advantages with this product;

1. It is delivered as a fine particle from the inhaler
2. It is delivered as a prodrug and is converted to steroid in the lung which reduces systemic absorption and the potential for local and systemic side effects.

The guidelines under development propose;

- To use this product for those who cannot tolerate conventional inhaled steroids due to side effects such as dysphonia or oral candidiasis. This is a particular problem for a small but defined group of patients such as professional voice users (e.g. actors, singers, and teachers) and these may benefit.
- To use the product to reduce total steroid burden for patients with endocrinology diseases. These patients may be taking oral steroids or have other steroid loads and have a clinical aim to keep the total steroid levels as low as possible to minimise the long term side effects from suppression of the HPA axis.
- To use the product in those with severe difficult to treat asthma. These patients will already be on high dose inhaled steroids (mainly combination inhalers) and will have uncontrolled symptoms. In the clinic we can improve diagnosis and airway inflammation assessment with exhaled nitric oxide testing. Additional steroid treatment to other inhaled steroid/combination inhalers would be ciclesonide at high dose may be used up to 320 micrograms twice daily. This would be preferable to adding in oral steroids. Studies are underway and there is emerging evidence to support this.

Col Wilson concluded that he would find it difficult to run a specialist asthma service without it, and would ideally have it placed on the formulary such that it is available for prescribing on specialist advice with continuation in Primary Care.

The Chair invited questions for Col Wilson from the members.

JW enquired if ciclesonide would replace high doses Seretide® or be added to it. It was confirmed that for patients with severe asthma in most cases this would be additional to current inhaled steroids.

RF highlighted that the HPA suppression in adults is largely due to oral steroids as opposed to inhaled steroid load. RF asked if there was outcome evidence for the reduction in dysphonia and other side effects. Col Wilson confirmed that this is based on anecdotal experience not outcome evidence. RF also asked whether this was of appropriate value for the additional NHS Cost. Col Wilson personally felt it was worth the cost to reduce the steroid burden & number of exacerbations for these patients.

RF summarised his conclusion that this is a relatively expensive drug compared to other inhaled steroids without outcome evidence to support the benefits for patients. Col Wilson highlighted that it was valuable in the small niche group of patients who are at the severe end of the spectrum and very high user of healthcare resource. He did not see this agent as first line treatment.

KA asked about the licensing in combination with other steroid inhalers & the dose he quoted. It was confirmed that this dose was outside licensed dosing. Use with other inhalers is probably unlicensed use too.

The Chair thanked Col Wilson for attending, and he left the meeting.

It was confirmed that this presentation was to support the harmonisation process as more information had been requested.

The members felt that the case for this medication was not strong.
TP confirmed that it cost twice as much as the other drugs, but BS highlighted that it was cheaper than the biologicals.

The members felt that there was limited evidence to demonstrate benefit of this drug over other drugs. Outcome evidence for the reduction in steroid burden is limited.

MD was concerned as this appeared to introduce a new step in the management of asthma, between steps 3 and 4.
PD felt more data was required and proposed that a retrospective audit was needed to show if total oral steroids are reduced in practice.

JW was concerned about the use of this drug off license and its use when two steroid inhalers were prescribed together. He also highlighted that GP's should be concerned about the high dosages.
KA noted that the information was observational and a robust review of evidence has not been presented.

The members agreed to defer decision and request an audit.

Action: IH to request further evaluation from the Respiratory Network/Col Wilson. **IH**

0615/13 Generic sildenafil for digital ulceration

The Chair advised this was enclosed for information.

IH received a notification from Heart of England NHS FT regarding the addition to their formulary of generic sildenafil for digital ulceration following NHSE's new interim clinical commissioning policy. Standard medical treatment and sildenafil will not be charged to NHSE as payment by results (PbR) excluded drugs. Therefore in order to comply with the NHSE Commissioning policy, when sildenafil is indicated it will be initiated and maintained by HEFT. To this end, generic sildenafil for off label use in digital ulceration by Rheumatology Directorate will be added to the red section of the formulary. This will be reflected on the APC formulary

There were no comments from the members

Action: add generic sildenafil for digital ulceration to APC formulary as RED status. **IH**

0615/15 Any other business

CE raised a number of items

- Aciclovir eye ointment has a manufacturers delay. Ganciclovir will be used as an alternative in the meantime. This was agreed by members
- PDE-5 inhibitors. Confirmed this was as per minutes.
- Prof Hackett has requested clarification on the agents available on the formulary for impotence due to severe distress. It was confirmed the formulary applies to all patients including those with severe distress.

Antipsychotic prescribing framework

IH had circulated a revised framework on the prescribing of antipsychotics. NB advised that there had been concerns raised about the framework and GP prescribing. It was confirmed that at the away day in November it was agreed that an ESCA is not required, and a RICaD is not needed for antipsychotics. It was agreed that a framework would be the most appropriate tool to support best prescribing practice for antipsychotics. This recognises that the advice is not required at an individual patient level. However the document does look like an ESCA/RICaD and so may cause confusion.

It was noted that there are practices that have commenced antipsychotics without specialist support and this framework would support this group of clinicians to improve best practice as much as other specialists and GPs.

It was agreed that the framework should be revised to be clearer as guidance. The drugs can be amber with a supporting framework or guidance.

It was noted that a GP can refuse to prescribe any drug in primary care but they should explain their rationale for this decision.

PD confirmed that a number of GPs in Birmingham CrossCity CCG were supportive of the framework following recent discussion.

ESCAS and RICaDs

CE had requested clarification on progress with these on the formulary.

IH advised that there was a backlog of ESCAs largely with chapters 2 and 4. SN and IH had reviewed these and in some cases these had changed significantly

and may need to be approved by the APC.

KA offered support for urgent ones for example NOACs and recommended these were prioritised. PD requested tracked changes to help with review.

Mycophenolate use in connective tissue disease

UHB FT Rheumatologists requested the addition of mycophenolate to the list of drugs supported by an ESCA and had drafted such a document and prescriber checklist.

IH advised that clarity was required on the position and use of mycophenolate in SLE. This use hasn't been reviewed in the harmonisation process so far. It was agreed that an application was required.

Action: IH to request a drug application from UHB FT. **IH**

PD thanked the members for their input today, especially in view of the extended meeting. The meeting closed at 17:10.

Date of next meeting

Thursday 9th July 2015 14:00-16:00
Birmingham Medical Institute,
36, Harborne Road, Edgbaston, Birmingham B15 3AF
Solomon Wand Room, 1st Floor