AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs

Minutes of the meeting held on
Thursday 11th December 2014
Birmingham Medical Institute, 36 Harborne Rd, Birmingham, West Midlands B15 3AF.

PRESENT:

Dr Paul Dudley	PD	Chair, Birmingham CrossCity CCG
Dr Lisa Brownell	LB	BSMHFT
Sumaira Tabassum	ST	Sandwell & West Birmingham CCG
Kate Arnold	KA	Solihull CCG
Nigel Barnes	NB	BSMHFT
Satnaam Nandra	SN	Birmingham CrossCity CCG
Liz Thomas	LT	Birmingham CrossCity CCG
Tony Green	TG	Patient Representative
David Harris	DH	Birmingham Community Healthcare Trust
Professor Robin Ferner	RF	Sandwell & West Birmingham Hospitals Trust
Jonathan Horgan	JH	Midlands & Lancashire CSU
Isabelle Hipkiss	IH	Midlands & Lancashire CSU
Alan Pollard	AP	Birmingham Womens NHSFT
Tim Priest	TP	Heart of England Foundation Trust
Tania Carruthers	TC	Heart of England Foundation Trust
Inderjit Singh	IS	UHB NHSFT
Maureen Milligan	MM	The Royal Orthopaedic Hospital NHSFT
Alima Batchelor	AB	Birmingham South Central CCG

IN ATTENDANCE:

Patricia James	PJ	APC Secretary, Midlands & Lancashire CSU (minute taker)
Baljit Ahitan	BA	HEFT Principal Pharmacist Respiratory Medicine representing Clinical Respiratory Network for agenda item 1214/11

No	Item	Action
1214/01	**Apologies** Mandy Matthews, NHS England Mahesh Mistry. South East Staffs and Seisdon Peninsula CCG Dr Jamie Coleman, University Hospitals Birmingham NHS FT Dr Waris Ahmad, Birmingham South Central CCG Elizabeth Walker, Sandwell and West Birmingham CCG	
1214/02	**Items of business not on the agenda (for AOB)** • APC Branding - IH	
1214/03	**Declaration of Interest** The Chair advised that members who had not attended for the last 6 months and had not returned a declaration of interest form would be removed from the circulation. These members are: Dr Adnan Masood, Birmingham CrossCity CCG Professor Anthony Sinclair, Birmingham Children's Hospital NHSFT Dr Gwyn Harris, Sandwell and West Birmingham CCG James Ward, South East Staffs and Seisdon CCG Neil Bugg, Birmingham Children's Hospital NHSFT **Action:** APC Secretary to amend circulation	**PJ**
1214/04	**Welcome and introductions** The Chair welcomed those present to the Area Prescribing Committee and members introduced themselves.	
1214/05	**Minutes of the meeting (13th November 2014)** The minutes of the meeting held on Thursday 13th November, 2014 were discussed for accuracy. The draft minutes were approved with no amendments.	
1214/06	**Matters arising – Action Table** **1114/05 Minutes of meeting held on 09/10/14** Make amendments as noted: ***Closed*** Acute Trusts to notify the APC Secretary of any specialist representatives and availability on the day by Wednesday 19th November 2014: ***Closed*** **1114/06 Matters arising- Action table** Update as per minutes: ***Closed*** Revise format and circulate with draft minutes: ***Closed*** **1114/08 Decision to decline prescribing of medicines recommended by hospital specialist**	

Amendments on “Unable to contact consultant”: Done ***Closed***

Trust members to share with APC secretary contact details (email and safe haven fax numbers if available) to be incorporated into the form: Awaiting responses from SWB, ROH and BSMHT. APC Secretary to email reminder to leads at Trusts. Item closed for minutes to be brought back by exception if not completed. ***Closed***

Email revised form to all CCG members for dissemination within own organisation and implementation: ***Open***

1114/09 ESCAs- azathioprine for IBD, oral methotrexate in adult patients (gastroenterology)

APC branding and formatting to be finalised and brought back to December meeting: to be discussed later on this agenda and carried forward to January.

SN clarified that comments back from the group were still required. ***Open***

(LB joined the meeting)

1114/11 New drug application: Brimonidine 3mg/g topical gel (Mirvaso ®)

Complete DST and circulate to members for comments by 17.11.14: ***Closed***

Members to feedback comments to APC Secretary by 20.11.14: ***Closed***

Inform Dr Kaur of APC decision: ***Closed***

Dr Kaur has emailed advising that she believes the decision should have been amber to allow transfer to primary care. There was discussion about the role of members in relaying decisions to their own trusts and the appeal process.

An initial response has been given to Dr Kaur to advise why the committee has decided not to recommend an amber formulary status to ensure that the prescribing was focused on those patients most likely to benefit defined by the clinical trials. TP advised that Dr Kaur remains unhappy and wishes to explore the appeal process. It was noted that some other APCs had adopted a non-formulary status in contrast to our decision of formulary approved as ‘red’ status.

It was noted that the APC Secretary had agreed the time and date for the APC application presentation with Dr Kaur but she was not able to attend on the day. It was agreed that attendance is important and would be facilitated as much as possible to ensure that the applicant is properly engaged with the process. This may reduce appeals.

JH outlined the appeal process from the Policy:

An appeal can be raised if it is felt that the APC had not followed due process, or with the same evidence a reasonable committee could not have reached the same decision.

An appeal must be raised within 4 weeks. This has been done by Dr Kaur on email. A template form will be provided to support the appellant.

The first stage is screening by the Chairs to consider if the process has been breached or if the decision was unreasonable when considering the appeal questions.

The appeal is then screened by the Chairs to confirm if it can be resolved and then it is raised with another APC under a reciprocal arrangement.

This process is untested but has been developed in line with NICE Good Practice Guidance.

JH expressed concern that other APCs may not want to engage on a reciprocal arrangement if we get appeals on lots of applications. If this is the case, the appeal process will need to be reviewed.

It was highlighted that a senior member of the APC would need to present the APC's decision making as part of the appeal process.

There was discussion about who can raise an appeal and it was confirmed that this was anyone involved in the application process. RF confirmed this is equivalent to NICE processes that allow those organisations engaged in the application to appeal. The Policy wording should be revised to make this clearer. JH to review this during the current appeal process and bring back to the committee.

Actions:

- **Develop appeal template form** **IH**
- **Review the appeals section of the Policy** **JH**

It was confirmed that appeals need to be signed off by the medicines committee within the organisation as part of the template form to ensure that these have been discussed locally with the APC member to avoid unnecessary appeals due to misunderstanding of formulary status. This will be defined in the template form.

It was noted that the appeal is on the decision made by the committee and whether this was reasonable based on the evidence presented. The appeal in this case would not be a reapplication to request amber status. It was also noted that the evidence presented needs to be the same for the appeal committee. New evidence for submission would not be an appeal.

ACTION: Email Dr Kaur the Appeal process form and a copy of the Policy to ensure she is aware of the process. **IH**

Update formulary website*:* it was agreed that publication of the decision would be delayed until the appeal period has been completed. ***Open***

Review APC policy to clarify process around drugs approved as RED status by Trusts DTC/ Formulary groups.
JH confirmed that a draft revised APC policy would be circulated with draft minutes of this meeting for members' comments. To be ratified at January meeting. ***Open***

1114/12 Formulary harmonisation: Chapter 2 CVS (brand rationalisation) and Chapter 3 Respiratory

To be finalised on APC Away day on 24/11/14: ***Closed***

1114/13 Any other business
Antibiotic harmonisation by regional group:
Invite Chair of this regional group to come to APC ***Open***
Share our RAG rating information with regional group ***Open***

Vitamin D guidelines: BCC CCG to complete an application form for new licensed high strength preparations and submit to APC:
Closed

0914/06 Matters arising- Action log
CCG Medicines Leads to be contacted and to confirm support in relation to transfer of suitable hospital D&T Chairs non-formulary approvals to GPs: ***Closed***

Letter to CCG Medicines Lead to go out week commencing 17/11/14
Closed

KA asked how a GP will know if the request to prescribe a non-formulary drug has been approved by the Trust Chair and whether a form will be provided from the Trust to show its approval. IS confirmed that NHS trust leads would contact the CCG medicines leads if any of the Trust Chairs actions would go to a GP for longer term prescribing. The majority remain prescribed by the Trust.

If GPs receive a request to prescribe a non-formulary drug without an appropriate patient rationale they can complete the "decision to decline prescribing " form and advise their CCG Medicines lead.

1214/07 **NICE Technology Appraisals (TAs)**

There were two new TAs this month:

Imatinib: NHSE is the responsible commissioner and so this TA is not under the remit of this committee.

Nalmefene: This is a treatment for alcohol dependence in accordance with defined criteria. It was noted that the provision of services under the 'Crime Reduction Initiative' relates to commissioning arrangements in

Birmingham only. Table to be amended to reflect this.

To be added to the formulary as grey whilst local commissioning arrangements are discussed.

ACTION: **IH to amend NICE TA table as noted and add nalmefene to the APC formulary as grey** **IH**

1214/08 **Trust Chairs non Formulary approvals**

Rifaximin: IH has been advised that this drug was referred out of UHBFT to South Worcester CCG. IS confirmed that this should not have happened and had been addressed. UHBFT is not referring this out to primary care whilst awaiting NICE guidance.

DH raised a query on prescribing and costs of these drugs for inpatients in the community trusts. Similar issues occur for specialist trusts. In most cases it was agreed that this should be similar to the approach for the GP, which is that the Trust would be expected to prescribe or fund.

TC provided a verbal report that colesevelam was approved by Medical Director for off-label use to treat lenalidomide toxicity

1214/09 **Feedback and actions from November Away Day**

Draft notes from Away Day:

Members reviewed the draft notes from Away day (November). No amendments were proposed to the notes.

Chapter 2 Brand rationalisation for ratification:

Option 2 was ratified with amendment to the wording as follows;

“Leave existing patients on the current treatment; only switch to recommended cost effective brands if the condition is not controlled on existing treatment or if a patient requires treatment as an inpatient and does not have any of their own drugs available, then the Trust can consider the preferred formulary choice with the patient.”

It was confirmed that the order of agents does not reflect a preferred order of use.

Chapter 2 was approved.

Chapter 4 (Neurology and Mental Health) for ratification:

IS highlighted that eslicarbazepine (section 4.8 antiepileptic drugs) was discussed on the away day as approved at UHB awaiting an ESCA to be finalised. The members present had agreed that it would go onto the APC formulary as an amber status as soon as the ESCA had been considered by the committee.

Tapentadol M/R: KA highlighted that tapentadol M/R was not discussed and agreed for formulary at the away day. It was agreed that these would be discussed at the January Away Day and to be removed from the ESCA table.

Melatonin M/R: KA proposed that a comment should be added to show that the formulary status applies only to licensed use. There was discussion about this proposal and it was confirmed that if any formulary decision needs to specify licensed use only then this would be added for the individual drug. An overall statement for the whole formulary was not felt appropriate as it is recognised that a number of drugs need to be appropriately prescribed 'off label' and the formulary advice within drug groups may give guidance on choice for clinicians.

There was discussion around melatonin used in the treatment of ADHD outside license. The members were unable to reach agreement so it was requested that this is reviewed and brought back for discussion with the evidence. The aim being to reflect the place of melatonin for its variety of uses in the formulary. DH offer to forward evidence from UKMI to support the discussions.

4.9 Drugs used in parkinsonism and related disorders:
KA highlighted that RICaDs were not listed for rotigotine patches and selegiline liquid. The committee agreed this should be amended.

Ropinirole:
TC enquired on the formulary status for this drug. Ropinirole is proposed as amber with a RICaD for Parkinson's disease.
This category may not be suitable for this drug for restless legs syndrome (RLS). PD confirmed that you need a specialist to diagnosis Parkinson's disease which means amber status is required.

Following some discussion it was agreed that patients with severe RLS who may be considered for ropinirole would be managed by a specialist but then if prescribed long term could be transferred to a GP. However initiation would be the specialist for RLS.

In conclusion it was confirmed that amber status was suitable for the drug however a RICaD is required for Parkinson's disease and an ESCA with specialist initiation is required for RLS.

'Restricted medicines':
This appears in the notes for some drugs in e.g. sections 4.2 or 4.3. LB advised that this was an internal Trust measure to control the transfer of prescribing to primary care for appropriate drugs and patients. These medicines would only be discharged with a restricted medicines form to GPs from the Trust. The form provides a rationale to show why it is being used. It was highlighted that this is not part of the APC formulary status. LB to review the RICaD form to assess if this would be suitable or consider how to incorporate. Report back in the January away day.

ACTION: LB to review restricted form terminology and report back in January away day. **LB**

BNF Section descriptors:
AP highlighted that drugs used in tics and antimuscarinics are not labelled correctly in the corresponding BNF section. It was confirmed that the publication of the formulary is by BNF section and will be correct.

Zolpidem:
LB proposed a change to put zopiclone tablets as tier 1 as opposed to zolpidem due to cost effectiveness and current use. **SN**

Aripiprazole in Tourette's syndrome:
LB advised that aripiprazole is off-label use but is recognised internationally as the appropriate treatment. LB has highlighted difficulties in transferring this to GP prescribing by the lead specialist. It was confirmed that the formulary covers licensed indications and would support the use off- label where appropriate based on MHRA advice on using licensed drug choices first where available.

ACTION: **Update chapter 4 harmonised table as described above** **SN/IH**

Clarification was requested for how the committee manages the publication of formulary status when it differs from the current commissioning arrangements.
It was confirmed that the APC needs to make clear the decision that it reaches is based on the clinical evidence, as well as issues of cost-effectiveness (for example taking into account the cost to the NHS as a whole of having patients attending regular reviews in secondary care just in order to receive a prescription) and what is best for patients.
Where this decision is at odds with current commissioning arrangements, APC should:-

1. Indicate on the APC formulary that the decision of the APC is X, but as yet this is not implemented due to commissioning decisions, so the current position of this drug is Y. It seems at the moment the easiest thing is to have the drug listed as per Y, but annotate it to make it clear that the APC view is that this should change to X. So for example, APC decision is that drugs in dementia should be amber. Commissioning decisions currently are red. So we will list them as red, but annotate to indicate that APC view is that these should be amber, and we are awaiting commissioning to catch up with this.
2. Take action to ensure that these discrepancies are addressed in a timely manner. At the last APC, it was suggested that the joint chairs send a letter to CCG Chairs and to provider Trust CEOs, to request action be taken in the light of APC decision. It was suggested that we ask for a response within 3 months.

Chapter 10 Musculoskeletal for ratification

BNF 10.3.1:
Collagenase Clostridium (Xiapex®) - KA confirmed that the Procedures

of limited clinical value policy state that this is on hold and awaiting outcome of a trial at ROH.

Hyaluronidase injection – this is to be reviewed in January away day once Trust information is available.

Committee agreed to approve Chapter 10 with exception of the two drugs named in 10.3.1 under review, and the NSAIDs (to be reviewed at January Away day)

1214/10 **Confirmation of chapters for review on January Away day**

The Chair confirmed Chapters for discussion at the January Away Day as**:**

- Chapter 4 Analgesics and Antimigraine drugs
- Chapter 10 NSAIDs
- Chapter 6 Endocrine (minus Diabetes 6.1)
- Chapter 7 Obstetrics, gynaecology, and urinary-tract disorders

IS confirmed that this could go ahead as long as appropriate representation was present on behalf of University Hospital Birmingham.

1214/11 **Chapter 3: Feedback from Respiratory network- Baljit Ahitan (HEFT Principal Pharmacist Respiratory Medicine on behalf of Clinician from Respiratory Network who was unable to attend) for ratification.**

Baljit Ahitan presented feedback from the Respiratory Network in relation to questions that had been raised by the committee.

She commenced by advising that the Network is preparing a COPD guideline which will align to the APC formulary products. The guideline will be shared shortly once it has been ratified in January.

LAMA review:

- The Network requests all three LAMA bronchodilators on formulary as green; glycopyrronium, aclidinium and tiotropium. They highlight that these work by a class effect. They are different inhaler devices benefiting different groups of patients.

- The Network recommends: glycopyrronium first line, aclidinium second line and tiotropium third line due to cost effectiveness. They do not recommend switching patients from tiotropium due to difficulty for patients with device changes.

Rationalisation of single ICS inhalers:

- Ciclesonide – this is a once daily inhaler steroid. The Network advise that it is effective in severe and brittle asthmatics and used as ‘add on’ for patients at high dose of another steroid. As an ‘add on’ it may have a steroid sparing effect due to its mode of action compared to increasing the doses of a steroid. Ciclesonide is a prodrug that is activated locally in the lungs. It would be

initiated by specialist for the severe patients, and would be amber in the formulary.

- Consider removing fluticasone.

- The committee members were mindful of safety concerns that have been raised in relation steroid doses of other products such as fluticasone in the past and had some concern that the evidence for a steroid sparing effect was not well established. The committee requested that the evidence from trials is forwarded for review. Decision deferred.

Rationalisation of ICS/LABA combinations:

- Flutiform, Fostair, Symbicort and Seretide '500' accuhaler. Network recommends these are kept on the formulary as green.

- They recommended that Seretide '125' and '250' are removed, but that Seretide 500 Accuhaler remains for licensed COPD use and asthma.

- The Network would support switching of patients from Seretide 125 or 250 to Flutiform or Fostair who are on metered dose inhalers. They felt it would not be appropriate to switch patient prescribed accuhalers due to device change.

- RF highlighted a recent paper from the New England Journal of Medicine (NEJM) that showed steroid inhalers have no benefit from point of view of COPD exacerbations. He offered to share this with Baljit Ahitan for the consultants to consider further.

LABA review:

- Formoterol and salmeterol – the respiratory network recommended that these are both retained on the formulary. The network highlighted that indacaterol was being considered for the new guideline. The APC committee requested a new drug application for this drug to be submitted before the guideline is published.

Other discussions on this chapter:

- Dornase alpha, tobramycin and colomycin – IH advised that Mandy Matthews has highlighted that these drugs are planned for repatriation to NHSE for cystic fibrosis only. It was confirmed no change to the formulary until discussions with NHS England are concluded. The ESCAs will remain in place to support GPs with existing patients. Any new initiations will be retained by the hospital trusts. Other indications such as bronchiectasis are CCG commissioned. MM enquired if CCGs had considered developing ESCAs for this indication. KA confirmed that issues around on-going prescribing for this condition have not yet been resolved. The formulary will therefore reflect the use for cystic fibrosis only.

- Acetyl cysteine- IH advised that Mandy Matthews questioned the

evidence for benefit. Baljit Ahitan supported the discussions in favour of keeping this drug on formulary. Agreed that the evidence for benefit would need to be evaluated.

Due to outstanding issues to be resolved, Chapter 3 has not been ratified.

1214/12 **ESCAs and RICaDs templates for ratification**

SN advised that these were templates to use for the documents, and would be populated with the clinical content once approved. SN confirmed that examples of populated ESCAs and RICaDs had previously been circulated with APC papers on numerous occasions but, as they were embedded documents, some members had difficulty in extracting these.
Members requested time to review these further for sign off in the January meeting. Comments to SN.

ACTION: Email templates and examples of populated documents as separate attachments to all members rather than embedded. **IH/ SN**

1214/13 **Draft ESCA for Lubiprostone**

TC confirmed that as this product does not require any on-going monitoring a RICaD would be more appropriate. KA advised this was meant to be a short term shared arrangement for GP review at 2 weeks. It was agreed the main safety and licensing issue is to ensure that there is a review at 2 weeks however it was felt that a RICaD would cover this. Apologies were given to SN as he had developed an ESCA.

Action: RICaD to be developed. **SN**

1214/14 **Any Other Business**

Branding for APC:
IH advised that this APC is not a statutory body so cannot use a logo as part of the NHS. However banners can be used. IH proposed a footer banner and tabled examples. The committee approved this.

Local CCG branded generic decisions:
LT sought clarification from the APC as to whether notification to the APC is required when making individual organisational decisions about branded products on cost effectiveness grounds. These may be shared with GP via Scriptswitch. JH confirmed that this would not be expected as the formulary is at drug level by generic name. The only exceptions are those drugs with bioavailability differences or similar leading to clinical differences between brands. If the CCG is promoting a particular brand on formulary for cost effective reasons then this doesn't affect the use of the formulary across the area.

The Chair thanked everyone for attending and the meeting closed at 16:35 pm.

Date of Next Meeting:
Thursday 8th January 2015 - Birmingham Medical Institute,
36 Harborne Road, Edgbaston, Birmingham B15 3AF
Solomon Wand Room, 1st Floor