AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 14th January 2016
Venue – Birmingham Research Park, Vincent Drive,
Birmingham B15 2SQ – Conference Room A

PRESENT:

Dr Lisa Brownell	LB	BSMHFT (chair)
Dr Paul Dudley	PD	Birmingham CrossCity CCG
Alan Pollard	AP	Birmingham Womens NHS FT
Alima Batchelor	AB	Birmingham South Central CCG
Dr Neil Bugg	NBu	Birmingham Children's Hospitals NHSFT
Dr Timothy Priest	TP	HEFT NHS FT
Inderjit Singh	IS	UHB NHST FT
Isabelle Hipkiss	IH	Midlands & Lancashire CSU
Jonathan Horgan	JH	Midlands & Lancashire CSU
Kate Arnold	KA	Solihull CCG
Mark DasGupta	MD	Birmingham CrossCity CCG
Nigel Barnes	NBa	BSMHFT
Prof Robin Ferner	RF	Sandwell & West Birmingham Hospitals NHST
Sangeeta Ambegaokar	SA	Birmingham Children's Hospital NHS FT
Satnaam Singh Nandra	SSN	Birmingham CrossCity CCG
Christine Gunner	CG	HEFT NHS FT
Tony Green	TG	Patient representative
Prof Jamie Coleman	JC	UHB NHS FT
Kalpesh Patel	KP	Midlands & Lancashire CSU
Carol Evans	CE	HEFT NHS FT/ Solihull CCG
Elizabeth Walker	EW	Sandwell & West Birmingham CCG
Mandy Matthews	MM	NHS England

IN ATTENDANCE:

Patricia James	PJ	Minute taker, Midlands & Lancashire CSU
Dr Andrea Richards	AR	Birmingham Community Healthcare NHST, Dental services
Dr Clara Day	CD	Consultant Nephrologist, UHB NHS FT, for item 0116/12
Dr Marcus Mottershead	MMo	Consultant Gastroenterologist, HEFT NHS FT, for item 0116/13
Clare Horrobin	CH	Colorectal CNS, HEFT, for item 0116/14
Kelly Stackhouse	KS	Clinical manager FINCH service, SWBH, for item 0116/14

No.	Item	Action

0116/01 **Apologies for absence were received from:**

- Maureen Milligan, The ROH NHS FT
- David Harris, Birmingham Community Healthcare NHST
- Tania Carruthers, HEFT NHS FT
- Dr Pallavi Latthe, Birmingham Women's NHS FT
- Dr John Wilkinson, Solihull CCG

0116/02 **Items of business not on agenda** (to be discussed under AOB)

- COPD guidelines - IH
- Palliative Care - IH
- Vitamin D guidelines - SSN
- Collagenase clostridium histolyticum (Xiapex®) – TP (on behalf of TC)
- Apremilast – impact on NICE TA/CCG – TP (on behalf of TC)

0116/03 **Declaration of Interest (DoI)**

MM – Celgene Ltd for apremilast discussion under AOB.

It was confirmed that all declarations of interest were received from the clinicians presenting the drug applications and only Dr Day (Renavit®) had declared Medical Advisory Board - no fees taken.

0116/04 **Welcome and Introductions**

The chair reminded members, that the meeting is digitally recorded for the purpose of accurate minute taking and once the minutes were approved, the recording is deleted by the APC secretary.

The chair welcomed Dr Andrea Richards, Dental Services specialist from Birmingham Community Healthcare NHST. Introductions were undertaken.

0116/05 **Minutes of the meeting held on Thursday 10th December 2015**

The minutes of the meeting held on 10th December 2015 were discussed for accuracy. The following amendments are required:

- Page 7: 1215/11 – **Mycophenolate draft ESCA**
  Add a question mark after Can you clarify monitoring requirements after 12 months -
  The CSU confirmed they have been in contact with Dr Rhodes and this would be brought up under the action table.
- Page 8: 1215/13 - **Avamys® (fluticasone furoate nasal spray) – DST and updated drug review**
  It was confirmed that Avamys® was approved for both adults and children.
  Second paragraph; to be amended to read: *It was therefore agreed to bring back to the meeting to establish whether the members wish to review the decision of the APC.*

  Third paragraph, first sentence to be amended to read: "Budesonide

(Rhinocort Aqua®) was removed from the formulary at the September Away day as not much use across the Trusts and BCH specialists do not recommend it."

- Page 11: 1215/16 - **Sirdupla® and other respiratory products– summary of issues**
  Paragraph starting with "There is an advantage" to be amended to read "the incentive offered poses a financial concern."
- Page 14: Any other business; lisdexamphetamine (HEFT)
  An error of fact was outlined and the last sentence should be amended to read" except lisdexamphetamine which was approved and RAG rated RED by the then Formulary Working Group.

The chair confirmed that subject to the above amendments, the minutes were approved as a true and accurate record.

Eye-formulary (UHB) would be discussed under the action table as it appears some members have received letters from Alcon about Travatan®/ travoprost.

0116/06 Matters arising – Action Table

The chair turned to the action table for discussion. See appendix 1 for updated action table.
Discussions around action points are detailed below:

1215/06 Matters arising – action table

- 1510/08 Letter to chair of NICE re naloxegol
  CSU confirmed NICE acknowledged receipt of letter on 18th December 2015, with an aim to respond within 18 working days. ***Closed***
- Need to make decision around RAG rating ***Closed***

  On agenda, to be discussed under NICE TA.

1215/07 Operations Issues

- Governance sub group: draft ToR for ratification – on the agenda ***Closed***
- APC ToR – revised re quoracy; digital recording- on the agenda ***Closed***
- Share audit of members' attendance over last 6 months with Committee. ***Closed***

1215/08 NICE Technology Appraisals

- Liaise with MM for further clarification on NHSE's requirements around TAs. ***Closed***

Update: IH/MM have liaised by email to clarify the position. There was a general concern that patients may expect to be able to access a specific treatment if it is included as available via secondary care on the formulary; this may be further complicated when only available via selected trusts. MM can advise when NHSE will commission a specific drug from; the majority of the time this will be from day 91. The dates are confirmed in a circular from NHSE, which is then passed onto the Trusts. However there are cases where NHSE

agree to fund from day 1 (e.g. pembrolizumab for advanced melanoma TA366) or within 30 days of publication when available via EAMS. There was some discussion whether it would be deemed negligent to wait 90 days to fund a treatment, but on a few occasions where clinicians have approached MM with very good clinical reasons to access a drug earlier than 90 days this had been approved in individual cases.

It was suggested that the default formulary entry for NHSE commissioned drugs would be "in line with NICE and available from day 91 following publication of TA", unless informed otherwise by MM, or 30 days if under EAMS. MM already updates the NICE TA adherence checklist sent by IH with dates once available.

1215/10 Decline to prescribe forms – summary from Trusts for information

- Drug application to be presented unless Trust can demonstrate that cinacalcet was on their formulary, and which RAG status it was.

Update: UHB and HEFT confirmed cinacalcet was rated as RED for dialysis patients only. HEFT will be submitting a new drug application form to the Committee for other indications. MM confirmed that cinacalcet is only excluded from tariff when used for dialysis and NHSE only fund in line with NICE TA currently. An NHSE commissioning policy is being developed for complex primary hyperparathyroidism unsuitable for surgery. ***Closed***

1215/11 Mycophenolate draft ESCA

- Amend monitoring and side effects sections on page 2 as agreed. ***Closed***
- Add "Off label use" to document. ***Closed***
- Incorporate 4 points made by Dr Rhodes to point 5 of the specialist responsibilities. ***Closed***
- Contact Dr Rhodes to establish the definition of the "more relaxed" monitoring after 12 months. ***Closed***

Update: Dr Rhodes (Consultant Rheumatologist, UHB NHS FT) suggested that monitoring could move to two monthly for the second year of treatment and three monthly from the third year onwards, provided there have been no drug related monitoring abnormalities and unless advised differently by the supporting secondary care team. The recent MHRA warnings with regards to teratogenicity have also been added.

ACTION: Recirculate the revised ESCA to members (with draft minutes) for members to approve. **CSU**

1215/12 Utrogestan® – Draft RICaD – Review of evidence

- Amend document in line with comments made. Approved subject to minor amendments ***Open***

Update: Take back to BWH DTC as further amendments were not minor, and bring back to the APC for approval.

1215/14 - Avamys® (fluticasone furoate nasal spray) – DST and updated drug review

- Issue new DST to state we note all the comments around cost effectiveness/pricing and ease of use, indication in children. ***Open***

- Update formulary (add Avamys®, remove Flixonase® and Nasofan®) ***Open***

1215/15 - New drug application – Anthelios XL® melt-in cream

- Add Anthelios XL® melt-in cream to the formulary as GREEN. ***Closed***
- Remove most expensive alternate after cost analysis. ***Open***

Update: Uvistat® will be removed from formulary once Chapter 13 is ratified. Sunsense Ultra®'s cost per gram reduces as the pack size increases and is more cosmetically acceptable (Dr Shah's view). BSMHFT support this decision.

1215/16 - Sirdupla® and other respiratory products

- Add DuoResp® to the formulary on the basis that it is, to all intents and purposes, an equivalent to Symbicort®. Patients should not be changed from one to another without being consulted. DuoResp® represents a considerable cost saving opportunity if used in appropriate patients.
- Update the entry for Symbicort® and DuoResp® in the formulary to indicate that these inhalers should be prescribed by the intended brand to ensure that patients receive the device that they are used to.
- Add Sirdupla® to formulary as GREEN as a more cost effective alternative to Seretide® in patients not suitable for a review and switch to a different chemical agent.
- Add a comment to Sirdupla® entry that patients who object to alcohol may not be suitable for the medication and that it should not be switched without consultation.
- Update the entry for Seretide® MDIs and Sirdupla® in the formulary to indicate that these inhalers should be prescribed by the intended brand to ensure that patients are maintained on the formulation that they are used to.
- Add AirFluSal® to the formulary as a cost effective alternative to Seretide Accuhaler®.
- Update the entry for Seretide® and AirFluSal® in the formulary to indicate that these inhalers should be prescribed by the intended brand to ensure that patients receive the device that they are used to.
- As new inhalers / devices come on the market, the APC will recommend prescribing by brand to avoid situations where license / formulation /device differ

Update: All the above action points are still ***Open***

1215/17 - Vacuum pumps for erectile dysfunction

- Add statement to the formulary:
  Green – if in line with SLS, Red - not in line with SLS,
  Use device with lowest acquisition cost ***Closed***

1215/18 - Cost of DOACs (from November Meeting)

- Contact Dr Will Lester and invite to the February meeting with clear remit of what members aim to achieve. ***Closed***
- Add list price to the formulary. ***Open***

Any other business

Tapentadol

- Advise UHB of the outcome. ***Closed***

COPD guidelines

- Circulate final COPD guidelines for endorsement ***Closed***

ESCAs process

- Add to future agenda for further discussion/ thoughts ***Open***

Update: defer to the February meeting

Lisdexamphetamine

- Add to January agenda for further discussion
  On agenda ***Closed***

Seretide®

- Extend the formulary to cover paediatric use up to 18 years of age.

Eye formulary

- UHB ophthalmologists to submit application for travoprost eye drops.

Update: IH advised she had been in correspondence with Lucy Titcomb (Lead Ophthalmic Pharmacist, Birmingham & Midlands Eye Centre (BMEC)) who made some observations on the October 2015 APC minutes which have now been published:

- Regarding the comment that NICE guidelines (CG85) for glaucoma recommend prostaglandin analogues, but do not specifically mention prostamides: the NICE guidance published in 2009 followed the style of the BNF in 2009 in which no distinction was made between prostaglandin analogues and prostamides. The current edition does differentiate between these agents.
- Regarding the sentence "Travoprost is due to come off patent in November 2016, bimatoprost in March 2017", Lucy provided an update: travoprost was due to come off patent in November 2016 but it has a 6 month extension due to the paediatric licence and the revised patent expiry is May 2017. Bimatoprost was due to come off patent in March 2017 but this referred to the 0.03% strength and now only applies to the unit dose eye drops. The patent expiry for the 0.01% strength is 2026. This makes travoprost the lowest cost out of the two.
- The ophthalmologists want a first line agent (latanoprost) and a second line prostaglandin analogue (travoprost) and the prostamide (bimatoprost) on the formulary.

It was suggested that, in line with the approach taken with tapentadol and the 4 COPD agents not approved, the Committee agree to review these in 12 months' time.

The following was agreed as a way forward:

a. There is no point in submitting a drug application for travoprost as it has already been considered alongside bimatoprost. The Committee made a decision as it had no guidance from the clinicians when asked to make a choice between the 2 drugs.
b. Review these agents in 1 year.
c. The Committee would understand if the clinicians wish to appeal

and would draw their attention to the appeal process.

CSU

ACTION: Inform Lucy Titcomb and colleagues of the proposed way forward.

1115/06 - Matters arising- Action table

- SharePoint access to be arranged for members ***Open***

1115/08 - NICE Technology Appraisals

- Trust leads to seek views from respective nephrologists on requirements for implementation of tolvaptan TA and feedback to APC. ***Open***

Update: UHB confirmed they would not expect GPs to prescribe due to monitoring requirements. SWB would be guided by UHB nephrologists. Propose RED RAG status. HEFT will chase up their specialists and confirm at the February meeting.

1115/10 - Lidocaine 5% plasters RICaD

- Joint chairs to request drug application for lidocaine patches from pain specialists. ***Open***

Update**:** TC has emailed the clinical director at HEFT, but it was confirmed that this is a pan- Birmingham issue and the letter should go to all pain specialists from all local trusts.

Trust Leads.

ACTION: Forward pain specialists' names to APC secretary.

1115/12 – BNF Chapter 9 – for ratification

- Applications to be submitted for various in-tariff preparations used in IMD patients. ***Closed***
- Liaise with renal team on iron dextran injection (CosmoFer®) to clarify RAG status and need for supplementary documentation. ***Open***

Update: To be considered at UHB's next MMAG meeting. Deferred until reviewed internally.

1115/13 - **BNF Chapter 12- for ratification**

- Submit application for Dymista® for paediatric use. Defer to March 2016 ***Closed***
- Seek clarification on section 12.3.5 (dry mouth) from palliative care teams.

Update: Email correspondence from Dr John Speakman, Consultant in Palliative Medicine at UHB with regards to choice of agent to be made available on the formulary, ideally one gel, one lozenge and one spray. His comments were relayed to the members.

The members also turned to Dr A Richards for her expertise in oral/ dental medicine. She confirmed that the Dental hospital prescribe a variety of products, and advised that patients prefer to use a spray formulation during the day and a gel at night as gels tend to be longer lasting due to their thicker formulation. It was also pointed out that Saliva Orthana® contains porcine derived gastric mucin, and may therefore not be suitable for certain patients on religious grounds. Saliveze® is a cost-effective alternative. Biotene Oral balance® gel is a useful formulary choice. Pilocarpine tablets can be included but side effects tend to limit their use. Glandosane® which is a popular preparation should not be prescribed to patients with their own teeth due to acidic pH. It was also noted that lozenges and pilocarpine tablets need patients

to have residual salivary gland function for them to be effective.
With regards to the indications to be covered by the formulary, it was confirmed that saliva substitutes are included in the Dental Practitioners Formulary (DPF) and also allowed on FP10 for specified conditions approved by Advisory Committee on Borderline Substances (ACBS) which are xerostomia (dry mouth) as a result of having or having undergone radiotherapy or sicca syndrome.
In conclusion, having taken advice from palliative care and oral medicine specialists, the Committee agreed the following agents as GREEN on the formulary for ACBS approved conditions/palliative care and Dental practitioners :

- Saliveze® spray
- Biotene Oralbalance® gel
- Salivix® lozenges
- Pilocarpine tablets

ACTION: Update section 12.3.5. (Dry mouth) of Chapter 12 with decisions outlined above. **CSU**

1115/17 Any other business

- Send doodle poll to identify a suitable date for March 2016 Away Day.

Update: Wednesday 30th March is the agreed date for the next APC away day ***Closed***

ACTION: Email confirmation of date time and venue to all members **CSU**

0915/07 - Operational Issues

- Draft ToR management/development subgroup to be drawn up and circulated to members for comments. These will be circulated with draft minutes. ***Closed***

0116/07 Operational Issues

- Revised APC ToR

Just a couple of minor changes were made:

- Page 6 : Quorum
  It was agreed this should now read: “The meeting will be quorate if there is at least one member present from each of six organisations, two organisations from each of the following groups:"
  The bullet points should be changed to Group 1, 2 and 3.

- Revised Governance sub group ToR
  Page 3: Accountability
  These have been amended as agreed at the December meeting.

The members agreed to ratify both these documents subject to the amendments outlined, and to be published on the website.

ToR for the development sub group are still outstanding. JH confirmed these will be emailed out with the draft minutes for comments.

ACTIONS:

- **Email ToR for development sub group with draft minutes** **CSU**
- **Finalise and publish APC and governance subgroup ToR** **CSU**

0116/08 NICE Technology Appraisals (TAs)

IH went through the formulary adherence checklist.

It was established that 6 new NICE TA's had been published in December 2015:

1. Erlotinib and gefitinib for non-small-cell lung cancer (TA374). Erlotinib is recommended, gefitinib is not recommended. Secondary care prescribing. NHSE is the responsible commissioner and will commission this treatment from the specified date (date to be confirmed by MM when known). RED status.
2. Abatacept, adalimumab, etanercept and tocilizumab for juvenile idiopathic arthritis (TA373). NHSE is the responsible commissioner. MM commented that this is standard practice and believes NHSE is already funding this treatment. RED status.
3. Apremilast for treating active psoriatic arthritis (TA372). Not recommended.
4. Trastuzumab emtansine for breast cancer (TA371). - Not recommended.
5. Bortezomib for mantle cell lymphoma (TA370). Secondary care prescribing. NHSE is the responsible commissioner and will commission this treatment from 15th March 2016. RED status.
6. Ciclosporin eye drops for dry eye disease (TA369).
   Primary Care commissioned treatment. Currently published as GREY status. SPC states specialist initiation – AMBER RAG status was agreed.

Update on past NICE TAs (dates provided by MM):
TA366 - commissioned from day 1 – 26th November 2015
TA359 - commissioned from 26th January 2016
TA357 - commissioned from 6th November 2015 (EAMS)
TA347 – commissioned from 28th October 2015
All the Hep C TAs published in November 2015 (TA365, TA364, TA363 - commissioned from 23rd February 2016.

ACTION: Update formulary adherence checklist with dates and agreed RAG status and recirculate to all members. **CSU**

The Committee went on to discuss the appropriate RAG status for naloxegol in treating opioid-induced constipation (TA345) which is GREY status currently. It was determined that this should only be used in a particular group of patients when all other drugs had been exhausted (i.e. try for 3-4 days then stop). The Trusts' representatives stated that their pain specialists would like access to this drug. The question was raised around whether pain specialist input may be required before GPs would prescribe, but it was agreed that it was not appropriate to refer patients to secondary care for opioid-induced constipation. It was therefore agreed to be rated as GREEN £££. It was also agreed that guidance was required to support this.

ACTION: **Draft guidance to be brought back for discussion at the next meeting.** **CSU**

0116/09 Trust chairs non formulary approvals- for information

Item deferred to the next meeting.

0116/10 Decline to prescribe forms – summary from Trusts – for information

Item deferred to the next meeting.

0116/11 Feedback from December Away day

- **Draft notes from December Away day**
- **Chapter 13 – for ratification**
- **Treatment algorithm for actinic keratosis**
- **Chapter 7 – OC section – for ratification**

Item deferred to the next meeting.

ACTION: **Defer to February meeting** **CSU**

0116/12 New drug application – Renavit® – Dr Clara Day (UHB NHSFT)

The chair welcomed Dr Clara Day. Dr Day gave a power point presentation to support the application for Renavit®, a water soluble multivitamin tablet for dialysis patients.

Dialysis patients are often deficient in water soluble vitamins due to dietary restriction of fresh fruit and vegetables (due to high potassium levels), significant loss during dialysis (high flux dialysis and haemodiafiltration) and impaired vitamin metabolism.
There are no RCTs, but the evidence of clinical relevance came from the Dialysis Outcomes and Practice Patterns Study (DOPPS), which was a prospective, multicentre observational study (n=16,345).

Patient use of water-soluble vitamins was associated with a substantially and significantly lower risk for mortality (RR, 0.84; P<0.001).
With regards to national guidelines, the UK Renal Association guideline on nutrition in CKD recommends that haemodialysis patients should be prescribed a supplement of water soluble vitamins.

The current available options for water soluble vitamin replacement are Ketovite® and Dialyvit®. Ketovite® requires refrigeration and the patient to take one tablet three times a day at a cost of £7.73 a month. Dialyvit® requires import from the USA at a cost of at least £15 per month.
Renavit® requires one tablet daily at a cost of £3.50 per month, and no refrigeration.

The chair thanked Dr Day for her presentation and confirmed that the outcome

will be relayed to her within 7 days.

The chair directed the members to the decision support tool for completion:

Patient safety: water soluble vitamin supplement. Low risk.

Clinical effectiveness: Moderate effect as evidenced by DOPPS study.

Strength of evidence: No randomised controlled trials but a large observational study (DOPPS) which demonstrated a significant lower mortality risk despite methodological difficulties (potential for confounding factors).

Cost-effectiveness or resource impact: Cost effective compared to alternative preparations such as Ketovite®. It also offers a lower tablet burden and does not require refrigeration.

Place of therapy relative to available treatments: 1st line and replace current treatment options.

National guidance and priorities: No NICE or MTRAC guidelines. Renal association guidelines on nutrition in CKD recommend that haemodialysis patients should be prescribed a supplement of water soluble vitamins.

Local health priorities: None

Equity of access: None

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Stakeholder views: None

Implementation requirements: None

Formulary status (RAG) and rationale: Add Renavit® to APC formulary as GREEN, remove Ketovite® from APC formulary. Despite the lack of robust evidence, guidance acknowledges vitamin provision as a low cost, low risk practice which may reduce morbidity and mortality.

ACTION:

- **Inform Dr Day of outcome of application for Renavit®.** **CSU**
- **Add Renavit® to APC formulary as GREEN** **CSU**
- **Remove Ketovite® from APC formulary** **CSU**

0116/13 New drug application –linaclotide - Dr Marcus Mottershead - HEFT

The chair welcomed Dr Marcus Mottershead (MMo), Consultant Gastroenterologist from HEFT. MMo presented the new drug application for linaclotide (Constella®▼) for moderate to severe Irritable Bowel Syndrome with constipation (IBS-C) in adults to the committee.

MMo highlighted the following points:-

- No NICE TA for linaclotide however use recommended in NICE Clinical Guidelines 61 for IBS.
- Linaclotide has a unique mechanism of action compared to other

laxatives.

- Linaclotide is cost effective at £37 per month.
- Competitive products like prucalopride cost £59 per month and. lubiprostone costs £53 per month.
- Patients treated in his clinic complaining of bloating as well as constipation.
- Clinical data at 26 weeks and 52 weeks available.
- Safety profile: diarrhoea is most commonly reported side effect and dose can be adjusted to every other day to suit patients.

30% patients in MMo's clinic are patients with IBS- C and these could be treated in primary care.

- A pan-Birmingham IBS/IBD pathway is being worked on with local Trusts. The suggestion to treat this cohort of patients in primary care for a month is based on this pathway.

The chair invited questions from the members.

A committee member asked whether the saving of £500 per year (linaclotide £37 per month) was a true saving. Patients would have had to be treated with bisacodyl 14 pence per month. It is unclear what % of patients would require linaclotide to attribute a true saving.

MMo stated that there 2 groups of patients being treated as part of the pathway:

- Patients who have IBS symptoms but not labelled as having IBS.
- Patients who have had a trial of bisacodyl, Buscopan®, Movicol® and senna in secondary care with problematic constipation.

MMo stated that linaclotide be considered as second or third line therapy for problematic patients in whom 1st/2nd treatments had been tried. The number of patients treated would be small.

A committee member stated that a decision has to be made whether linaclotide to be made Green or Amber as an alternative to prucalopride or lubiprostone in light of the above discussions.

MMo further stated that prucalopride doesn't work well and out of the 40 patients he has tried it in only 50% responded. A committee member pointed out that NICE TA only approved use of prucalopride in women, although it is now licensed in adults.

MMo stated that linaclotide has GREEN status in Scotland, Coventry and Norwich.
MMo suggested that treating these patients in primary care would save a consultation referral cost for IBS of £108.

A committee member raised concerns whether small cohort of patients would reduce referral costs. IBS is where there is pressure to refer due perception of symptoms like cancer and the need for referral for a second opinion.
At what point does a patient seek a second opinion in conditions such as IBS?

MMo stated that a patient may not seek a second opinion if medications are working well.
Another committee member asked whether there is any evidence of reduced

bloating with linaclotide. MMo stated in the trials an IBS designed questionnaire was used to include bloating symptoms and there is evidence of reduced bloating with linaclotide.

A member asked if GP were to prescribe what % would remain in primary care versus those that are referred. MMo stated it is unclear what proportion/% of patients prescribed linaclotide in primary care who stay in primary care.
MMo stated that any IBS treatment has 40% placebo effect and this presents an issue for IBS trials

The chair thanked Dr Mottershead for his presentation. The outcome/decision will be relayed to Dr Motterhead within 7 days.

The chair directed the members to the decision support tool for completion, however it was felt that due to the complexity of the medication a general discussion would be required before a decision could be made.

The chair stated that both prucalopride and lubiprostone are NICE approved and the formulary status is Amber with RiCaD and expensive compared to linaclotide.

The discussion included the following points:

- no head to head trials of linaclotide.
- 3 trials has shown evidence of reduced abdominal bloating, discomfort, pain and cramps at weeks 4 and 12 IBS treatments and placebo effect and clarity required around GP treating this cohort of patients and reduced referrals back to hospital.

It was agreed that there wasn't enough evidence to support reduced referrals in secondary care with the evidence presented.

- There are concerns around making linaclotide GREEN and GPs initiating treatment.
- There is a place in therapy as all agents linaclotide, prucalopride or lubiprostone have novel mechanisms of action.
- Consider linaclotide for specialist initiation as AMBER status with RiCaD similar to prucalopride or lubiprostone and review this decision at a later stage.
- Evidence from MTRAC states that linaclotide is suitable for prescribing in primary care in those patients for whom all other treatment alternatives have proved ineffective or are contraindicated.
- NICE states optimal or maximum tolerated doses of previous laxatives from different classes have not helped and they have had constipation for at least 12 months.
- The diagnosis for IBS is by exclusion.

Patient safety: Most common side effect is diarrhoea (occurs in less than 20% of patients). In rare and more severe cases, this may lead to hypokalaemia, dehydration, dizziness and hypostatic hypotension. Risk of delayed diagnosis.

Clinical effectiveness: Large placebo response was noted: 55% of treatment group vs. 42% of placebo group.

Strength of evidence: Short randomised control trials. No head to head trials.

Cost-effectiveness or resource impact: Cost effective, lower cost than prucalopride and lubiprostone – but more expensive than all the other alternative agents.

Place of therapy relative to available treatments: For patients who have not responded adequately to or cannot tolerate all other suitable treatment options but before other agents with higher costs.

National guidance and priorities: NICE Clinical Guideline 61 but no NICE TA. MTRAC has considered it suitable for prescribing in Primary Care, but evidence was considered relatively weak and place in therapy to be low.

CCG views: Alternative to the more expensive options such prucalopride and lubiprostone. Patients should be followed up 3 months after taking linaclotide.

Stakeholder views: None

Implementation: requires RICaD

Formulary status (RAG) and rationale: Approved as AMBER with a RICaD. Similar RAG rating to other agents with novel mechanism of action.

ACTION:

- **Inform Dr Mottershead of decision and invite him to draft RICaD for linaclotide.** **CSU**
- **Add linaclotide to formulary as AMBER with RICaD.** **CSU**

0116/14 New drug application – anal irrigations – Clare Horrobin (HEFT) and Kelly Stackhouse (SWBH)

The chair welcomed Clare Horrobin and Kelly Stackhouse. They went through a power point presentation to support the applications for 3 transanal irrigations systems to the committee: Peristeen®; Qufora®; IRY pump®

The packs tabled for the committee consist of patient experience information and patient pathway algorithm for use of anal irrigations.

The presentation was structured as follows: objectives, who is anal irrigation used for, product range, assessment, cost benefit and proposal.

The presenters highlighted the following points:

- Anal irrigation is a method to empty the rectum using warm tap water. The irrigation device will stimulate evacuation of the rectum. It is used for up to 3 days.
- Anal irrigations provide patients with the flexibility to manage their treatment independently in their own home without further intervention from professionals.
- Patients using anal irrigation will have predictable bowel function
- Anal irrigations are used at stage 4 in the anal treatment pathway.
- An assessment is carried out to determine the choice of anal irrigation.

- Not all patients are suitable for anal irrigation.
- Irrigation investigation tool determines the choice of anal irrigation; the patient and environment will determine the choice of system used.
- Benefits of anal irrigation include improved quality of life.
- There are overall reductions in health costs such as reduction in hospital admissions and colorectal surgery (e.g. 61% reduction in stoma surgery).

The chair invited questions from the members. The following points were clarified as a result.

- Patients will be on anal irrigation long term.
- The choice of device will depend on patient's dexterity. Can acquire loan equipment.

Used primarily in patients with constipation and those with red flag symptoms and also complex diverticulitis disease.

The chair thanked the two presenters and the outcome will be relayed to them within 7 days.

The chair asked the committee if there was adequate information presented on the new drug application for anal irrigation systems to make a formulary decision. It was agreed to defer such decision as it was felt this was a commissioning decision and needs to be responded to as such.

ACTION: Draft a response on anal irrigation applications (on behalf of the chair) **MD**

0116/15 Lisdexamphetamine (HEFT)

Deferred to the next meeting.

Any Other Business :

Due to limited time before end of meeting, the following was agreed:

- COPD guidelines – Agreed to be posted on the website
- Palliative Care – IH – deferred to the next meeting
- Vitamin D guidelines – SSN - deferred to the next meeting
- Xiapex® – TP (on behalf of TC) - deferred to the next meeting
- Apremilast – impact of NICE TAs/CCG's views - deferred to the next meeting

The chair thanked the members for their input today. The meeting closed at 16:52pm

Date of nex11th February 2016 14:00 – 16:45
Conference Room A
Birmingham Research Park
Vincent Drive
Birmingham B15 2SQ

Appendix 1: ACTION TABLE

Minute number	Description	Action by	Date due	Status at 20/01/16
0116/06	**Matters arising – action table**			
	• 1215/11 Mycophenolate draft ESCA; recirculate the revised ESCA to members with draft minutes	**CSU**	**21/01/16**	**Open**
	• 1115/10 Lidocaine 5% plasters RICaD; forward specialists names to APC secretary so letter can be drafted	**Trust Leads**		**Open**
	• Any other business; email confirmation of date, time and venue for the next APC away day	**CSU**	**21/01/16**	**Open**
	• Inform Lucy Titcomb and colleagues of the proposed way forward.	**CSU**	**21/01/16**	**Open**
	• Update section 12.3.5. (Dry mouth) of Chapter 12 with decisions agreed at meeting.	**CSU**	**28/01/16**	**Open**
0116/07	**Operational issues;**			
	• Email ToR for development sub group with draft minutes	**CSU**	**21/01/16**	**Open**
	• Finalise and publish APC and Governance subgroup ToR	**CSU**	**21/01/16**	**Open**
0116/08	**NICE Technology appraisals (TAs)**			
	• Update formulary adherence checklist with dates and agreed RAG status and recirculate to all members	**CSU**	**21/06/16**	**Open**
	• Naloxegol: draft guidance to be brought back for discussion at the next meeting (February)	**CSU**	**11/02/16**	**Open**
0116/12	**New Drug Application- Renavit®**			
	• Inform Dr Day of outcome of application for Renavit®.	**CSU**	**21/01/16**	**Open**
	• Add Renavit® to APC formulary as GREEN	**CSU**	**28/01/16**	**Open**
	• Remove Ketovite® from APC formulary	**CSU**	**28/01/16**	**Open**
0116/13	**New Drug Application- linaclotide**			
	• **I**nform Dr Mottershead of decision and invite him to draft RICaD for linaclotide.	**CSU**	**21/01/16**	**Open**
	• Add linaclotide to formulary as AMBER with RICaD	**CSU**	**28/01/16**	**Open**
0116/14	**New Drug application – anal irrigations**			
	• Draft a response to presenters for anal irrigations	**MD**	**21/01/16**	**Open**
	Any other business			
	• Publish COPD guidelines on APC website	**CSU**	**28/01/16**	**Open**
	• Add all deferred items to February agenda	**CSU**	**04/02/16**	

Minute number	Description	Action by	Date due	Status at 20/01/16
	UPDATED ACTION TABLE FROM PREVIOUS MEETING			
1215/06	**Matters arising- Action table** **1015/08** Letter to chair of NICE re naloxegol • Send out letter as missed opportunity to appeal decision • Need to make decision around RAG rating	 CSU ALL	 17/12//15 14/01/16	 Closed Closed
1215/07	**Operational Issues** Governance sub group: draft ToR for ratification • Amend the ToR as agreed (Accountability Page 3) APC ToR – revised re quoracy; digital recording • Amend the ToR as agreed (Page 1, 3 and 6) • Share audit of members' attendance over last 6 months with Committee.	 CSU CSU CSU	 17/12/15 17/12/15 07/01/16	 Closed Closed Closed
1215/08	**NICE Technology Appraisals (TAs)** • Liaise with MM for further clarification on NHSE's requirements around TAs	CSU	07/01/16	Closed
1215/10	**Decline to Prescribe forms – summary from Trusts for information** • Add specialist initiation to testosterone gel entry in formulary. • Drug application to be presented unless Trust can demonstrate that cinacalcet was on their formulary, and which RAG status it was.	CSU Trusts	18/12/15 TBC	Closed Closed
1215/11	**Mycophenolate draft ESCA** • Amend monitoring and side effects sections on page 2 as agreed. • Add "Off label use" to document. • Incorporate 4 points made by Dr Rhodes to point 5 of the specialist responsibilities. • Contact Dr Rhodes to establish the definition of the "more relaxed" status after 12 months. Ratify with chair by email.	CSU CSU CSU CSU	07/01/16 07/01/16 07/01/16 07/01/16	Closed Closed Closed Closed
1215/12	**Utrogestan® – Draft RICaD – Review of evidence** • Amend document in line with comments made. Approved subject to minor amendments	**CSU/AP/SSN**	**07/01/16**	**Open**
1215/13	**Avamys® (fluticasone furoate nasal spray) – DST and updated drug review** • Issue new DST to state we note all the comments around cost effectiveness/pricing and ease of use, indication in children. • Update formulary (add Avamys®, remove Flixonase® and Nasofan®)	 CSU CSU	 07/01/16 07/01/16	 Open Open
1215/15	**New drug application – Anthelios XL® melt in cream**			

Minute number	Description	Action by	Date due	Status at 20/01/16
	• Add Anthelios XL® melt in cream to the formulary as GREEN	CSU	07/01/16	Closed
	• Remove most expensive alternate after cost analysis.	CSU	07/01/16	Open
1215/16	**Sirdupla and other respiratory products**			
	• Add DuoResp® to the formulary on the basis that it is, to all intents and purposes, an equivalent to Symbicort®. Patients should not be changed from one to another without being consulted. DuoResp® represents a considerable cost saving opportunity if used in appropriate patients.	CSU	07/01/16	Open
	• Update the entry for Symbicort® and DuoResp ®in the formulary to indicate that these inhalers should be prescribed by the intended brand to ensure that patients receive the device that they are used to.	CSU	07/01/16	Open
	• Add Sirdupla® to formulary as GREEN as a more cost effective alternative to Seretide® in patients not suitable for a review and switch to a different chemical agent.	CSU	07/01/16	Open
	• Add a comment to Sirdupla® entry that patients who object to alcohol may not be suitable for the medication and that it should not be switched without consultation.	CSU	07/01/16	Open
	• Update the entry for Seretide® MDIs and Sirdupla® in the formulary to indicate that these inhalers should be prescribed by the intended brand to ensure that patients are maintained on the formulation that they are used to.	CSU	07/01/16	Open
	• Add AirFluSal® to the formulary as a cost effective alternative to Seretide Accuhaler®.	CSU	07/01/16	Open
	• Update the entry for Seretide® and AirFluSal® in the formulary to indicate that these inhalers should be prescribed by the intended brand to ensure that patients receive the device that they are used to.			
	• As new inhalers / devices come on the market, the APC will recommend prescribing by brand to avoid situations where license / formulation /device differ.	CSU	07/01/16	Open
1215/17	**Vacuum pumps for erectile dysfunction** Add statement to the formulary: • Green – if in line with SLS, Red - not in line with SLS, Use device with lowest acquisition cost	CSU	17/12/15	Closed
1215/18	**Cost of DOACs (from November Meeting)**			
	• Contact Dr Will Lester and invite to the February meeting with clear remit of what members aim to achieve.	CSU	07/01/16	Closed
	• Add list price to the formulary.	CSU	07/01/16	Open

Minute number	Description	Action by	Date due	Status at 20/01/16
	Any other business			
	Tapentadol			
	• Advise UHB of the outcome	**CSU**	**07/01/16**	**Closed**
	COPD guidelines			
	• Circulate final COPD guidelines for endorsement	**CSU**	**07/01/16**	**Closed**
	ESCAs process			
	• Add to future agenda for further discussion/ thoughts – **Defer to February Meeting**	**CSU/All**	**TBC**	**Open**
	Lisdexamphetamine			
	• Add to January agenda for further discussion	**CSU/All**	**07/01/16**	**Closed**
	Eye formulary			
	• UHB ophthalmologists to submit application for travoprost eye drops.	**UHB**	**TBC**	**Open**
1115/06	**Matters arising- Action table**			
	• SharePoint access to be arranged for members	**CSU**	**3/12/15**	**Open**
1115/08	**NICE Technology Appraisals**			
	• Trust leads to seek views from respective nephrologists on requirements for implementation of tolvaptan TA and feedback to APC. **Confirm at February Meeting**	**Trust Leads**	**10/12/15**	**Open**
1115/10	**Lidocaine 5% plasters RICaD**	**Joint chairs**		
	• Joint chairs to request drug application for lidocaine patches from pain specialists		**26/11/15**	**Open**
1115/12	**BNF Chapter 9- for ratification**			
	• Applications to be submitted for various in-tariff preparations used in IMD patients.	**UHB**	**TBC**	**Closed**
	• Liaise with renal team on iron dextran injection (CosmoFer®) to clarify RAG status and need for supplementary documentation.	**JC**	**10/12/15**	**Open**
1115/13	**BNF Chapter 12- for ratification**			
	• Submit application for Dymista® for paediatric use in January 2016. Update: Defer to Feb/ March 2016	**BCH**	**Feb 2016**	**Closed**
	• Seek clarification on section 12.3.5 (dry mouth) from palliative care teams.	**UHB**	**3/12/15**	**Closed**
1115/17	**DOAC review**			
	• Revise format and correct error. Defer to December meeting. Update: defer to 2016	**CSU**	**2016 TBC**	**Open**
0915/07	**Operational Issues**			
	Draft minutes from management/ development meeting			
	• Draft TOR to be drawn up and circulated to members for comments	**JH/CSU**	**01/10/15**	**Closed**